METHYCAP LA

SCHEDULING STATUS S6

1. NAME OF THE MEDICINE

METHYCAP 10 mg LA modified release hard capsules
METHYCAP 20 mg LA modified release hard capsules
METHYCAP 30 mg LA modified release hard capsules
METHYCAP 40 mg LA modified release hard capsules

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

METHYCAP 10 mg LA: Each capsule contains 10 mg methylphenidate hydrochloride. Contains sugar: 59,7 mg sucrose.
METHYCAP 20 mg LA: Each capsule contains 20 mg methylphenidate hydrochloride. Contains sugar:119,5 mg sucrose.
METHYCAP 30 mg LA: Each capsule contains 30 mg methylphenidate hydrochloride. Contains sugar: 179,2 mg sucrose.
METHYCAP 40 mg LA: Each capsule contains 40 mg methylphenidate hydrochloride. Contains sugar: 238,9 mg sucrose.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Modified release hard capsules
METHYCAP 10 mg LA: Hard gelatin capsule size 2, with a dark yellow opaque cap and a white opaque body, imprinted with "RUB" in red ink on the cap and "M10" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.
METHYCAP 20 mg LA: Hard gelatin capsule size 2, white opaque capsule, imprinted with "RUB" in red ink on the cap and "M20" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.
METHYCAP 30 mg LA: Hard gelatin capsule size 2, ivory opaque capsule, imprinted with "RUB" in red ink on the cap and "M30" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.
METHYCAP 40 mg LA: Hard gelatin capsule size 1, dark yellow opaque, imprinted with "RUB" in red ink on the cap and "M40" in red ink on the body, containing white and whitish pellets. Capsule length: 20 mm.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

METHYCAP LA is indicated for attention deficit hyperactivity disorder (ADHD) in children aged 6 years or older, and in adults with ADHD onset in childhood.

ADHD diagnosis should be made according to current Diagnostic and Statistical Manual of Mental Disorders (DSM) criteria or the guidance from International Classification of Diseases (ICD).

4.2 Posology and method of administration

Posology
The dosage of METHYCAP LA should be individualised according to the patient's clinical needs and responses.
METHYCAP LA should be started at a low dose, with increments at weekly intervals.
Daily doses above 60 mg are not recommended for the treatment of ADHD in children. Effective doses in adults may vary, and range from 40 - 80 mg per day.
Daily doses above 80 mg are not recommended for the treatment of ADHD in adults.

METHYCAP LA should be discontinued if improvement is not observed after appropriate dosage adjustment over a one-month period.
METHYCAP LA should be discontinued if paradoxical aggravation of symptoms or other adverse effects occur.

Pre-treatment screening
Patients should be assessed for pre-existing cardiovascular and psychiatric disorders and a family history of sudden death, ventricular dysrhythmia and psychiatric disorders prior to treatment initiation of METHYCAP LA (see sections 4.3 and 4.4).

Periodic assessment of the treatment in ADHD
METHYCAP LA treatment should not and need not be indefinite and should be periodically discontinued to assess the patient's condition. Improvement may be sustained when the medicine is either temporarily or permanently discontinued.
When used in children with ADHD, METHYCAP LA can usually be discontinued after puberty.

Paediatric population
Children and adolescents (6 years and older)
METHYCAP LA is for oral administration once daily, in the morning. The recommended starting dose is 20 mg. When, in the judgement of the clinician, a lower initial dose is appropriate, patients may begin treatment with METHYCAP 10 mg LA.
Daily dosage above 60 mg is not recommended.

Adults
The individualised dose of METHYCAP LA is administered once daily in the morning.
The recommended starting dose of METHYCAP LA in patients who are new to, or not currently taking methylphenidate, is 20 mg once daily.

In patients currently taking methylphenidate, treatment may be continued with the same daily dose. If the patient was previously treated with an immediate release formulation, a conversion to an appropriate recommended dose of METHYCAP LA should be made (see below subsection, Switching patients to METHYCAP LA).
A maximum dose of 80 mg should not be exceeded.

Switching patients to METHYCAP LA
The recommended dose of METHYCAP LA should be equal to the total daily dose of an immediate release formulation not exceeding a total of 60 mg in children and 80 mg in adults. An example in patients being switched from the immediate release formulation is provided below.

Recommended daily dose when switching patients to METHYCAP LA

Previous methylphenidate dose	Recommended METHYCAP LA dose
5 mg methylphenidate twice daily	10 mg once daily
10 mg methylphenidate twice daily	20 mg once daily
15 mg methylphenidate twice daily	30 mg once daily
20 mg methylphenidate twice daily	40 mg once daily

For other methylphenidate regimens, clinical judgment should be used when selecting the starting dose. METHYCAP LA dosage may be adjusted at weekly intervals in 10 mg increments for children and in 20 mg increments for adults.

Special populations
Renal impairment:
No studies have been performed in renally impaired patients.

Hepatic impairment
No studies have been performed in hepatically impaired patients.

Elderly patients
No studies have been performed in patients over the age of 60.

Method of administration
General recommendations
METHYCAP LA is for oral administration once daily, in the morning.
METHYCAP LA capsules may be taken/administered with or without food. They should be swallowed whole, or alternatively the contents of the capsule can be sprinkled over a small amount of food (refer to specific instructions below). The granules must be swallowed whole and not chewed or crushed.
METHYCAP LA capsules and/or their contents should not be crushed or chewed.

When METHYCAP LA is administered/taken by sprinkling capsule contents on food
The capsules may be carefully opened and the beads sprinkled over soft food.
The food should not be warm because this could affect the modified release properties of this formulation.
The mixture of medicine and food should be consumed immediately in its entirety. This soft food mixture should not be chewed but swallowed only. The medicine and food mixture should not be stored for future use.

METHYCAP LA, administered as a single dose, provides comparable overall exposure (area under the curve (AUC)) of methylphenidate compared to the same total dose of methylphenidate administered twice daily.

Missed dose
Doctors should advise patients who forget to take METHYCAP LA to take it as soon as they remember in the morning, failing which, the normal dose should be taken the next day. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications

METHYCAP LA is contrainidicated in the following:
- hypersensitivity to methylphenidate or to any of the excipients of METHYCAP LA (see section 6.1)
- anxiety, tension, agitation
- family history or diagnosis of Tourette's syndrome
- hyperthyroidism or thyrotoxicosis
- diagnosis or history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder
- diagnosis or history of severe and episodic (type 1) bipolar (affective) disorder (that is not well controlled)
- glaucoma
- phaeochromocytoma
- pre-existing cardiovascular disorders, including hypertension, angina, arterial occlusive disease; heart failure, haemodynamically significant congenital heart disease, cardiomyopathies, myocardial infarction, potentially life-threatening dysrhythmias, channelopathies (disorders caused by the dysfunction of ion channels) and QT prolongation either congenital, familial or caused by medication (see section 4.4)
- pre-existing cerebrovascular disorders, cerebral aneurysm, vascular abnormalities including vasculitis or stroke or known risk factors for cerebrovascular disorders
- during treatment with monoamine oxidase (MAO) inhibitors, or within a minimum of 2 weeks of discontinuing those medicines, due to risk of hypertensive crisis (see section 4.5)
- pregnancy and lactation (see section 4.6).

4.4 Special warnings and precautions for use

General
METHYCAP LA should not be used for the prevention or treatment of normal fatigue states.

METHYCAP LA is not indicated in all cases of attention-deficit/hyperactivity disorder and should be considered only after detailed history-taking and evaluation. The decision to prescribe METHYCAP LA should depend on a thorough assessment of the severity and chronicity of symptoms and, in paediatric patients, their appropriateness to the child's age and not simply on the presence of one or more abnormal behavioural characteristics.

METHYCAP LA should not be used for the treatment of attention-deficit or hyperactivity secondary to amenable causes, including acute stress reactions.

Chronic abuse of METHYCAP LA can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes may occur. Abuse of METHYCAP LA may prove a problem in predisposed patients e.g. in emotionally unstable individuals or those with a history of drug dependence or alcoholism.
METHYCAP LA should therefore be used only under medical supervision.
Clinical data indicate that children given methylphenidate are not more likely to abuse drugs than adolescents or adults.

Cardiovascular
Pre-existing Structural Cardiac Abnormalities or Other Serious Heart Problems
Sudden death has been reported in association with the use of methylphenidate at usual doses in patients with pre-existing structural cardiac abnormalities or other serious heart problems. No causal relationship with METHYCAP LA has been established since some of these conditions alone may carry an increased risk of sudden death.
METHYCAP LA generally should not be used in patients with known structural cardiac abnormalities or other serious cardiac disorders that may increase the risk of sudden death due to its sympathomimetic effects. Before initiating METHYCAP LA treatment, patients should be assessed for pre-existing cardiovascular disorders such as a congenital long QT syndrome, or a family history of sudden death and ventricular dysrhythmia (see section 4.2).

Misuse and Cardiovascular Events
Misuse of METHYCAP LA, may be associated with sudden death and other serious cardiovascular adverse events.

Cardiovascular conditions
METHYCAP LA is contraindicated in patients with hypertension. METHYCAP LA increases heart rate and systolic and diastolic blood pressure. Therefore, caution is indicated in treating patients whose underlying medical conditions might be compromised by increases in blood pressure or heart rate, e.g. those with pre-existing hypertension and severe cardiovascular disorders (see section 4.3).
Monitoring of blood pressure at appropriate intervals should be undertaken in all patients taking METHYCAP LA. A prompt cardiac evaluation should be undertaken should a patient develop symptoms suggestive of cardiac disease while taking METHYCAP LA.

Cerebrovascular conditions
Patients with pre-existing central nervous system (CNS) abnormalities, e.g. cerebral aneurysm and/or other vascular abnormalities such as vasculitis or pre-existing stroke should not be treated with METHYCAP LA.

Patients with additional risk factors (history of cardiovascular disease, concomitant medications that elevate blood pressure) should be assessed regularly for neurological/psychiatric signs and symptoms after initiating treatment with METHYCAP LA (see above, paragraph on Cardiovascular conditions and section 4.5).

Cerebral vasculitis appears to be very rare idiosyncratic reaction to methylphenidate exposure. There is little evidence to suggest that patients at higher risk can be identified and the initial onset of symptoms may be the first indication of an underlying clinical problem.
Early diagnosis, based on a high index of suspicion, may allow the prompt withdrawal of METHYCAP LA and early treatment. The diagnosis should therefore be considered in any patient who develops new neurological symptoms that are consistent with cerebral ischemia during METHYCAP LA therapy. These symptoms could include severe headaches, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory.

Treatment with METHYCAP LA is not contraindicated in patients with hemiplegic cerebral palsy.

Psychiatric disorders
Co-morbidity of psychiatric disorders in ADHD is common and should be taken into account when prescribing METHYCAP LA. Prior to initiating treatment with METHYCAP LA, patients should be assessed for pre-existing psychiatric disorders and a family history of psychiatric disorders (see section 4.2). Treatment of ADHD with METHYCAP LA should not be initiated in patients with acute psychosis, acute mania or acute suicidality. These acute conditions should be treated and controlled before ADHD treatment is considered.
In the case of emergent psychiatric symptoms or exacerbation of pre-existing psychiatric symptoms, METHYCAP LA should not be given to patients unless the benefit outweighs the potential risk.

Patients diagnosed with or have a history of severe depression, anorexia nervosa/anorexic disorders, suicidal tendencies, psychotic symptoms, severe mood disorders, mania, schizophrenia, psychopathic/borderline personality disorder should not be treated with METHYCAP LA.

Emergence of new psychotic or manic symptoms
Treatment-emergent psychotic symptoms (visual/tactile/auditory hallucinations and delusions) or mania in patients without prior history of psychotic illness or mania can be caused by METHYCAP LA at usual doses. If manic or psychotic symptoms occur, consideration should be given to a possible causal role for METHYCAP LA and discontinuation of treatment may be appropriate.

Aggressive behaviour
Emergent aggressive behaviour or an exacerbation of baseline aggressive behaviour or hostility may occur during METHYCAP LA therapy. However, patients with ADHD may experience aggression as part of their medical condition. Therefore, a causal association with treatment may be difficult to assess. Medical practitioners should evaluate the need for adjustment of treatment regimen in patients experiencing these behavioural changes, bearing in mind that upwards or downwards titration may be appropriate. Treatment interruption can be considered.

Suicidal tendency
Patients with emergent suicidal ideation and behaviour during treatment for ADHD should be evaluated immediately by their medical practitioner. The medical practitioner should initiate appropriate treatment of the underlying psychiatric condition and consider a possible change in the ADHD treatment regimen.

Tics
Methylphenidate is associated with the onset or exacerbation of motor and verbal tics. Worsening of Tourette's syndrome has also been reported (see section 4.8). Family history should be assessed and clinical evaluation for tics or Tourette's syndrome in patients should precede use of METHYCAP LA for ADHD treatment. METHYCAP LA is contraindicated in case of diagnosis or family history of Tourette's syndrome (see section 4.3).
Patients should be regularly monitored for the emergence or worsening of tics during treatment with methylphenidate. Monitoring should be at every adjustment of dose and then at least every 6 months or every visit.

Anxiety, agitation or tension
Methylphenidate is associated with the worsening of pre-existing anxiety, agitation or tension. Clinical evaluation for anxiety, agitation or tension should precede use of methylphenidate and patients should be regularly monitored for the emergence or worsening of these symptoms during treatment, at every adjustment of dose and then at least every 6 months or every visit.

Forms of bipolar disorder
Particular care should be taken in using METHYCAP LA to treat ADHD in patients with co-morbid bipolar disorder (including untreated type 1 bipolar disorder or other forms of bipolar disorder) because of concern for possible precipitation of a mixed/manic episode in such patients. Prior to initiating treatment with methylphenidate, patients with co-morbid depressive symptoms should be adequately screened to determine if they are at risk for bipolar disorder; such screening should include a detailed psychiatric history, including a family history of suicide, bipolar disorder, and depression. Close ongoing monitoring is essential in these patients (see above, Psychiatric disorders and section 4.2). Patients should be monitored for symptoms at every adjustment of dose, then at least every 6 months and at every visit.
If a patient is diagnosed or has a history of severe and episodic (type 1) bipolar (affective) disorder, that is not well controlled, treatment with METHYCAP LA is not recommended.

Serotonin syndrome
Serotonin syndrome has been reported following co-administration of methylphenidate with serotonergic medicines such as selective serotonin reuptake inhibitors (SSRIs) and serotonin-norepinephrine reuptake inhibitors (SNRIs). The concomitant use of METHYCAP LA and serotonergic medicines are not recommended as this may lead to the development of serotonin syndrome. The symptoms of serotonin syndrome may include mental status changes (e.g. agitation, hallucinations, delirium, and coma), autonomic instability (e.g. tachycardia, labile blood pressure, dizziness, diaphoresis, flushing, hyperthermia), neuromuscular symptoms (e.g. tremor, rigidity, myoclonus, hyperreflexia, incoordination), seizures, and/or gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea). Prompt recognition of these symptoms is important so that treatment with METHYCAP LA and serotonergic medicines can be immediately discontinued and appropriate treatment instituted (see section 4.5).

Priapism
Prolonged and painful erections, sometimes requiring surgical intervention, have been reported with methylphenidate products in both paediatric and adult patients. Priapism generally developed after some time on the medicine, often subsequent to an increase in dose. Priapism has also been reported during a period of medicine withdrawal (medicine holidays or during discontinuation). Patients who develop abnormally sustained or frequent and painful erections should seek immediate medical attention.

Growth retardation
Reduced weight gain and slight growth retardation have been reported with the long-term use of METHYCAP LA (see section 4.8). Growth, weight, and appetite should be monitored at least 6 monthly during treatment with METHYCAP LA with maintenance of a growth chart. Patients who are not gaining height or weight as expected or are losing weight may need to have their treatment interrupted and adjusted.

Haematological effects
The long-term safety and efficacy profiles of METHYCAP LA are not fully known. Patients requiring long-term therapy should therefore be carefully monitored and complete and differential blood counts and a platelet count performed periodically. In the event of haematological disorders appropriate medical intervention should be considered (see section 4.8).

Seizures
METHYCAP LA should be used with caution in patients with epilepsy as clinical experience has shown that it can cause an increase in seizure frequency. Methylphenidate may lower the convulsive threshold in patients with prior history of seizures, in patients with prior electroencephalogram (EEG) abnormalities in absence of seizures, and rarely in patients without a history of convulsions and no EEG abnormalities. If seizure frequency increases or new-onset seizures occur, METHYCAP LA should be discontinued.

Medicine abuse and dependence
METHYCAP LA should be used with caution in patients with known drug or alcohol dependency because of a potential for abuse, misuse or diversion. Chronic abuse of METHYCAP LA can lead to marked tolerance and psychological dependence with varying degrees of abnormal behaviour. Frank psychotic episodes may occur, especially with parenteral abuse.
Patient age, the presence of risk factors for substance use disorder (such as co-morbid oppositional-defiant or conduct disorder and bipolar disorder), previous or current substance abuse should be taken into account when deciding on a course of treatment for ADHD. Caution is called for in emotionally unstable patients, such as those with a history of drug dependence or alcoholism, because they may increase the dosage on their own initiative.
For some high-risk substance abuse patients, methylphenidate or other stimulants may not be suitable and non-stimulant treatment should be considered.

Withdrawal
Careful supervision is required during METHYCAP LA withdrawal since this may unmask depression as well as chronic over-activity. Some patients may require long-term follow-up.
Careful supervision is required during withdrawal from abusive use since severe depression may occur.

Excipients with known effect
METHYCAP LA capsules contain sucrose. Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take METHYCAP LA capsules.

Paediatric population
METHYCAP LA is not indicated in children younger than 6 years.

Treatment with METHYCAP LA is not indicated in all cases of attention-deficit/hyperactivity disorder and should be considered only after detailed history-taking and evaluation. The decision to prescribe METHYCAP LA should depend on the medical practitioner assessment of the chronicity and severity of the child's symptoms and, their appropriateness to the child's age. Prescription should not depend solely on the presence of one or more abnormal behavioural characteristics. Where these symptoms are associated with acute stress reactions, treatment with METHYCAP LA is not indicated.

4.5 Interaction with other medicines and other forms of interaction

Pharmacodynamic interactions:
Anti-hypertensive medicines
The effectiveness of medicines used to treat hypertension may be decreased with concomitant use of METHYCAP LA.

Use with medicines that elevate blood pressure
METHYCAP LA should be used with caution in patients being treated with medicines that elevate blood pressure (see paragraph on Cerebrovascular conditions under section 4.4). METHYCAP LA is contraindicated in patients being treated (currently or within the preceding 2 weeks) with MAO-inhibitors due to the risk of hypertensive crisis (see section 4.3).

Use with alcohol
Alcohol may exacerbate the central nervous system adverse reactions of METHYCAP LA. Alcohol can also affect the coating of the capsule contents causing accelerated release or dose dumping, potentially leading to toxicity. It is advisable for patients to abstain from alcohol during treatment.

Use with dopaminergic medicines
As an inhibitor of dopamine reuptake, METHYCAP LA may be associated with pharmacodynamic interactions when co-administered with direct and indirect dopamine agonists (including DOPA and tricyclic antidepressants) as well as dopamine antagonists (antipsychotics, e.g. haloperidol). The co-administration of METHYCAP LA with antipsychotics is not recommended because of the counteracting mechanism of action.

Use with anaesthetics
There is a risk of sudden blood pressure increase during surgery. If surgery is planned, METHYCAP LA should not be used on the day of surgery.

Use with centrally acting alpha-2 agonists (e.g. clonidine or dexmedetomidine)
Serious adverse events including sudden death may occur in concomitant use with clonidine or dexmedetomidine, although no causality for the combination has been established.

Use with serotonergic medicine
Concomitant use of METHYCAP LA and serotonergic medicine is not recommended as this may lead to the development of serotonin syndrome (see section 4.4).
Methylphenidate has been shown to increase extracellular serotonin and norepinephrine and appears to have weak potency in binding serotonin transporter.

Pharmacokinetic interactions
It is not known how methylphenidate may affect plasma concentrations of concomitantly administered medicine. Therefore, caution is recommended at combining methylphenidate with other medicine, especially those with a narrow therapeutic window.
Methylphenidate is not metabolised by cytochrome P450 (CYP450) to a clinically relevant extent. Inducers or inhibitors of cytochrome P450 are not expected to have any relevant impact on METHYCAP LA pharmacokinetics.

Conversely, the d- and l-enantiomers of methylphenidate as in METHYCAP LA did not relevantly inhibit cytochrome P450 1A2, 2C8, 2C9, 2C19, 2D6, 2E1 or 3A.

Methylphenidate co-administration did not increase plasma concentrations of the CYP2D6 substrate desipramine.

Case reports suggested a potential interaction of methylphenidate as in METHYCAP LA with warfarin, some anticonvulsants (e.g. phenobarbital, phenytoin, primidone) and tricyclic antidepressants, however pharmacokinetic interactions were not confirmed when explored at higher sample sizes. The dosage of these medicines might have to be reduced.

Other specific medicine-medicine interaction studies with methylphenidate have not been performed *in vivo*.

When starting and stopping treatment with METHYCAP LA, it may be necessary to adjust the dosage of these medicine already being taken and establish drug plasma concentrations (or for coumarin, coagulation times).

Medicine/laboratory test
METHYCAP LA may induce false positive laboratory tests for amphetamines, particularly with immunoassays screen test.

4.6 Fertility, pregnancy and lactation

Pregnancy
METHYCAP LA is contraindicated in pregnancy and lactation as safety has not been demonstrated (see section 4.3).

Breastfeeding
Mothers taking METHYCAP LA should not breastfeed their infants.

Fertility
No human data on the effect of methylphenidate on fertility are available.

4.7 Effects on ability to drive and use machines

METHYCAP LA may cause dizziness, drowsiness, blurred vision, hallucinations, or other central nervous system (CNS) side effects (see section 4.8). It may have a moderate influence on the ability to drive and use machines. Patients experiencing such side effects should refrain from driving, operating machines or engaging in other potentially hazardous activities.

4.8 Undesirable effects

a) Summary of the safety profile
Nervousness and insomnia are very common adverse reactions. These usually occur at the beginning of treatment and may be reduced by decreasing the dose and omitting the METHYCAP LA in the afternoon or evening.
Decreased appetite is very common.
Abdominal pain, nausea and vomiting are common to very common.
Reports of neuroleptic malignant syndrome (NMS) have been received. In most of these reports, patients were also receiving other medications. It is uncertain what role methylphenidate played in these cases.

b) Tabulated summary of adverse reactions

System Organ Class	Frequency	Side effects
Infections and infestations	*Frequent*	Nasopharyngitis
	Less frequent	Gastroenteritis
Blood and lymphatic system disorders	*Less frequent*	Leucopenia, thrombocytopenia, anaemia
	Frequency unknown	Pancytopenia, epistaxis
Immune system disorders	*Less frequent*	Hypersensitivity reactions, such as auricular swelling, including angioedema and anaphylaxis
Metabolism and nutrition disorders	*Frequent*	Decreased appetite
	Less frequent	Anorexia, reduced weight and height gain during prolonged use in children
Psychiatric disorders	*Frequent*	Nervousness, insomnia, affect lability, aggression, irritability, abnormal behaviour, libido decreased, panic attack, stress, bruxism, anxiety, restlessness, sleep disorder, agitation
	Less frequent	Hyperactivity, psychosis (sometimes with visual and tactile hallucinations), transient depressed mood, anger, tearfulness, mood altered, mood swings, hypervigilance, tension, mania, disorientation, abnormal thinking, apathy, repetitive behaviours, over-focusing, suicidal ideation or attempt (including completed suicide), libido disorder, apathy, confusional state, dependence, cases of abuse and dependence
	Frequency unknown	Delusions, thought disturbances, logorrhoea
Nervous system disorders	*Frequent*	Dyskinesia, tremor, headache, drowsiness, dizziness, psychomotor hyperactivity, somnolence
	Less frequent	Convulsions, choreo-athetoid movements, tics or exacerbation of existing tics and Tourette's syndrome, cerebrovascular disorders including vasculitis, cerebral haemorrhages and cerebrovascular accidents, sedation, akathisia, dysphemia, reversible ischaemic neurological deficit
	Frequency unknown	Migraine, cerebral arteritis, cerebral occlusion, grand mal convulsions
Eye disorders	*Less frequent*	Blurred vision, difficulties in visual accommodation, mydriasis, visual disturbances
	Frequency unknown	Diplopia
Cardiac disorders	*Frequent*	Dysrhythmia, tachycardia palpitations
	Less frequent	Chest pain, angina pectoris, cardiac arrest, myocardial infarction
	Frequency unknown	Supraventricular tachycardia, bradycardia, ventricular extrasystoles, extrasystoles
Vascular disorders	*Frequent*	Hypertension, peripheral coldness
	Less frequent	Cerebral arteritis and or occlusion, Raynaud's phenomenon
Respiratory, thoracic and mediastinal disorders	*Frequent*	Cough, pharyngolaryngeal pain, dyspnoea
Gastrointestinal disorders	*Frequent*	Nausea, dry mouth, abdominal pain, diarrhoea, stomach discomfort, vomiting, dyspepsia, toothache
	Less frequent	Constipation
Hepatobiliary disorders	*Less frequent*	Hepatic enzyme elevations, abnormal liver functions, including hepatic coma
Skin and subcutaneous tissue disorders	*Frequent*	Rash, pruritus, urticaria, fever, scalp hair loss (alopecia), hyperhidrosis
	Less frequent	Thrombocytopenic purpura, exfoliative dermatitis, erythema multiforme, angioneurotic oedema, bullous conditions, exfoliate conditions, macular rash, erythema fixed drug eruption
	Frequency unknown	Angioedema
Musculoskeletal, connective tissue and bone disorders	*Frequent*	Arthralgia
	Less frequent	Muscle cramps, muscle tightness, myalgia, muscle twitching
	Frequency unknown	Trismus
Renal and urinary disorders	*Less frequent*	Haematuria
	Frequency unknown	Incontinence
Reproductive system and breast disorders	*Less frequent*	Gynaecomastia
	Frequency unknown	Priapism, erectile dysfunction, erection increased and prolonged erection
General disorders and administrative site conditions	*Frequent*	Feeling jittery, pyrexia, thirst, growth retardation during prolonged use in children, fatigue
	Less frequent	Chest pain, sudden cardiac death
	Frequency unknown	Chest discomfort, hyperpyrexia
Investigations	*Frequent*	Weight decreased, changes in blood pressure and heart rate (usually an increase)
	Less frequent	Blood alkaline phosphatase increased, blood bilirubin increased, platelet count decreased, white blood count abnormal, cardiac murmur, hepatic enzyme increased

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are requested to report any suspected adverse drug reactions to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website. An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za to ensure safety of the product.

4.9 Overdose

Signs and symptoms
Vomiting, agitation, tremors, hyperreflexia, muscle twitching, convulsions (may be followed by coma), euphoria, confusion, hallucinations, delirium, sweating, flushing, headache, hyperpyrexia, tachycardia, palpitation, cardiac dysrhythmias, hypertension, mydriasis, dryness of mucous membranes and rhabdomyolysis.

Management of overdose
When treating overdose, the healthcare provider should bear in mind that a second release of methylphenidate from METHYCAP LA (methylphenidate hydrochloride modified release capsules) occurs approximately four hours after administration.

There is no specific antidote to methylphenidate overdosage.
Treatment consists of appropriate supportive measures and symptomatic treatment of life-threatening events e.g. hypertensive crisis, cardiac dysrhythmias, convulsions. For the most current guidance for treatment of symptoms of overdose, the healthcare provider should consult a certified Poison Control Centre or current toxicological publication.

Supportive measures include protection of the patient against self-injury and against external stimuli that would exacerbate the overstimulation already present. If the overdose is oral and the patient is conscious, administration of activated charcoal is recommended.

Intensive care must be provided to maintain adequate circulation and respiratory exchange; external cooling procedures may be required to reduce hyperpyrexia.

Efficacy of peritoneal dialysis or extracorporeal haemodialysis for overdosage of METHYCAP LA has not been established.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Psychostimulants
ATC code: N06BA04
Pharmacological classification: A 1.2 Psychoanaleptics (antidepressants)

Mechanism of action
Methylphenidate is a racemate, consisting of a 1:1 mixture of d-methylphenidate and l-methylphenidate.
Methylphenidate is a central nervous system stimulant with more prominent effects on mental than on motor activities. Its mode of action in man is not completely understood, but its stimulant effects are thought to be due to inhibition of dopamine reuptake in the striatum, without triggering the release of dopamine. The mechanism by which methylphenidate exerts its mental and behavioural effects in children is not clearly established, nor is there conclusive evidence showing how these effects relate to the condition of the central nervous system.

The effect of treatment with 40 mg dexmethylphenidate hydrochloride, the pharmacologically active d-enantiomer of methylphenidate, on QT/QTc interval was evaluated in a study in 75 healthy adult volunteers. The maximum mean prolongation of QTcF intervals was < 5 millisecond (ms), and the upper limit of the 90 % confidence interval was below 10 ms for all time matched comparisons versus placebo. This was below the threshold of clinical concern and no exposure response relationship was evident.

5.2 Pharmacokinetic properties

Absorption
Following oral administration of methylphenidate hydrochloride (modified release capsules) to children diagnosed with ADHD and adults, methylphenidate plasma concentration-time profiles show a bi-modal profile (i.e. two distinct peaks approximately four hours apart). The fluctuations between peak and trough plasma methylphenidate concentrations are smaller for methylphenidate modified release given once a day compared to methylphenidate tablets given twice a day. Methylphenidate hydrochloride may be administered with or without food. There were no differences in the bioavailability of methylphenidate modified release when administered with either a high fat breakfast or applesauce, compared to administration in the fasting condition. There is no evidence of dose dumping in the presence or absence of food.

For patients unable to swallow the capsule, the contents may be sprinkled on soft food and administered (see section 4.2).

Distribution
In the blood, methylphenidate and its metabolites are distributed in the plasma (57 %) and in the erythrocytes (43 %). Methylphenidate and its metabolites have a low plasma protein-binding (10 - 33 %).

The apparent distribution volume has been calculated as 13,1 L/kg after an oral dose; the volume of distribution after intravenous dose (Vss) is 2,23 L/kg for the racemate in healthy adult volunteers.
The volume of distribution was 2,65 ± 1,11 L/kg for dextromethylphenidate (d-MPH) and 1,80 ± 0,91 L/kg for levomethylphenidate (l-MPH).
Methylphenidate is excreted in breast milk.

Biotransformation
Peak plasma concentrations of PPAA (ritalinic acid) are attained approximately 2 hours after administration of methylphenidate and are 30 - 50 times higher than those of the unchanged substance. The half-life of PPAA is roughly twice as long as that of methylphenidate, and the mean systemic clearance is 0,17 L/h/kg.

Elimination
Methylphenidate is eliminated from the plasma with a mean half-life of 2 hours, and the systemic clearance is 0,40 ± 0,12 L/h/kg for d-MPH and 0,73 ± 0,28 L/h/kg for l-MPH. After oral administration 78 % to 97 % of the dose is excreted in the urine and 1 % - 3 % in the faeces in the form of metabolites within 48 - 96 hours. Unchanged methylphenidate appears in the urine only in small quantities (< 1 %). The bulk of the dose is excreted in the urine as α-phenyl-2-piperidine acetic acid (PPAA, 60 % to 86 %).

Pharmacokinetics in special patient groups
Paediatrics
There are no apparent differences in the pharmacokinetic behaviour of methylphenidate in hyperactive children and healthy adult volunteers.

Renal failure
Renal excretion of the unchanged methylphenidate is hardly diminished at all in the presence of impaired renal function; however, renal excretion of PPAA is reduced.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Capsule content:
Ammonio methacrylate copolymer
Methacrylic acid-methyl methacrylate copolymer
Povidone
Sugar spheres (sucrose and maize starch)
Talc
Triethyl citrate

Hard gelatin capsule size 2 (10 mg, 30 mg) and hard gelatin capsule size 1 (40 mg)
Gelatin
Titanium dioxide
Yellow iron oxide

Hard gelatin capsule size 2 (20 mg)
Gelatin
Titanium dioxide

Red printing ink
Potassium hydroxide
Propylene glycol
Red iron oxide
Shellac glaze
Strong ammonia solution

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

36 months

6.4 Special precautions for storage

Store at or below 30 °C and protect from moisture.
Keep blisters in outer carton until required for use.

6.5 Nature and contents of container

Peelable child-resistant blisters (Aclar/PVC/Al/PET) cross-perforated, packed inside an outer carton.
Each pack contains 30 capsules.

6.6 Special precautions for disposal

No special requirements.

7. HOLDER OF THE CERTIFICATE OF REGISTRATION

Pharma Dynamics (Pty) Ltd
1st Floor Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Cape Town, South Africa
Tel.: +27 21 707 7000
or 0860-PHARMA (742 762)

8. REGISTRATION NUMBERS

METHYCAP 10 mg LA: A57/1.2/0792
METHYCAP 20 mg LA: A57/1.2/0793
METHYCAP 30 mg LA: A57/1.2/0794
METHYCAP 40 mg LA: A57/1.2/0795

9. DATE OF FIRST AUTHORISATION

July 2025

pharma dynamics

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS S6

METHYCAP 10 mg LA modified release hard capsules
METHYCAP 20 mg LA modified release hard capsules
METHYCAP 30 mg LA modified release hard capsules
METHYCAP 40 mg LA modified release hard capsules
Methylphenidate hydrochloride
METHYCAP 10/20/30/40 mg LA contains sugar
(sucrose: 10 mg: 59,7 mg; 20 mg: 119,5 mg; 30 mg: 179,2 mg; and 40 mg: 238,9 mg respectively)

Read all of this leaflet carefully before you start taking METHYCAP LA
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- METHYCAP LA has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What METHYCAP LA is and what it is used for
2. What you need to know before you take METHYCAP LA
3. How to take METHYCAP LA
4. Possible side effects
5. How to store METHYCAP LA
6. Contents of the pack and other information

1. What METHYCAP LA is and what it is used for
METHYCAP LA improves the activity of certain parts of the brain which are under-active. The medicine can help improve attention (attention span), concentration and reduce impulsive behaviour. METHYCAP LA is used for attention deficit hyperactivity disorder (ADHD) in children aged 6 years and older and in adults with ADHD onset in childhood.

ADHD is a medical condition where the child or adult has difficulty in paying attention and staying focused on most tasks given to them. They also tend to move around a lot and are very fidgety (making unnecessary fuss).

METHYCAP LA is prescribed only by a specialist in behavioural disorders. This specialist will follow up your further treatment. A thorough examination is necessary. If you are an adult and have not been treated before, the specialist will carry out tests to confirm that you have had ADHD since childhood. Using treatment programmes as well as medicine helps to manage ADHD.

2. What you need to know before you take METHYCAP LA
Do not take METHYCAP LA:
- if you are hypersensitive (allergic) to methylphenidate, or to any of the ingredients of METHYCAP LA (see section 6)
- if you suffer from anxiety, tension or agitation
- if you have uncontrolled speech and body movements (Tourette's syndrome) or if any other family members suffer from Tourette's syndrome
- if you have a thyroid problem
- you have mental health problems such as:
  - ◆ a 'psychopathic' or 'borderline personality' problem
  - ◆ abnormal thoughts or visions or an illness called 'schizophrenia', signs of a severe mood problem like feeling like killing yourself, severe depression (where you feel very sad, worthless and hopeless), mania (where you feel excitable, over-active and uninhibited), anorexia
- if you have increased pressure in your eye (glaucoma)
- if you have a tumour of your adrenal gland (phaeochromocytoma)
- if you have ever had heart problems – such as a heart attack, uneven heartbeat, pain and discomfort in the chest, heart failure, heart disease or were born with a heart problem
- if you have very high blood pressure or narrowing of the blood vessels, which can cause pain in the arms and legs
- you have had a problem with the blood vessels in your brain – such as a stroke, swelling and weakening of part of a blood vessel (aneurysm), narrow or blocked blood vessels, or inflammation of the blood vessels (vasculitis)
- if you are taking a medicine called a 'monoamine oxidase inhibitor' (MAOI) used for depression or have taken a MAOI in the last 2 weeks
- if you are pregnant or breastfeeding your baby.

Do not take METHYCAP LA if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before you take METHYCAP LA. This is because METHYCAP LA may make these problems worse.

Warnings and precautions
Take special care with METHYCAP LA if you or your child:
- unexpectedly experience prolonged erections during treatment, in both children and adults. This may be painful and can occur at any time. It is important to contact your doctor straight away if your erection lasts for longer than 2 hours, particularly if this is painful.
- experience a combination of the following symptoms: mental status changes (e.g. agitation, hallucinations, delirium, and coma) a dysfunction of the nerves that regulate non-voluntary body functions, such as heart rate, blood pressure and sweating (irregular heartbeat, temporary high blood pressure, dizziness, excessive sweating, flushing, overheating), muscular problems (e.g. tremor, rigidity, muscle jerks, overactive or overresponsive bodily reflexes, incoordination), seizures/fits and gastrointestinal problems (e.g. nausea, vomiting, diarrhoea) while taking METHYCAP LA with medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression like sertraline and venlafaxine), stop treatment with METHYCAP LA and medicines that raise the level of serotonin in the body and tell your doctor immediately
- have a history of drug or alcohol abuse
- have had fits, epilepsy, convulsions, seizures
- have high blood pressure (hypertension)
- have any heart defects (e.g. structural cardiac abnormality) or any other current or previous heart problems
- have or have had any disorder of the blood vessels in the brain e.g. weakening of blood aneurysm, stroke, inflammation of blood vessels (vasculitis) – symptoms of vasculitis include severe headache, numbness, weakness, paralysis, and impairment of coordination, vision, speech, language or memory
- have acute mental disorders that cause abnormal thinking and perceptions, psychosis or feeling unusually excited, over-active and uninhibited acute mania – your doctor will have told you if you have this
- if you have depression, anorexia nervosa/anorexic disorders (an eating disorder causing people to obsess about weight and what they eat), suicidal tendencies, psychotic symptoms, severe mood disorders, mania (extremely elevated and excitable mood), schizophrenia (a disorder that affects a person's ability to think, feel and behave clearly), psychopathic/borderline personality disorder (a mental disorder characterised by unstable moods, behaviour and relationships)
- experience psychotic symptoms such as seeing or feeling things that are not really there (hallucinations)
- already have, or start to experience aggressive behaviour
- experience any suicidal thoughts or behaviour
- already have or start to experience hard-to-control, repeated twitching of any parts of the body or you repeat sounds and words, or if any other family members suffer from tics
- have been diagnosed with any form of bipolar disorder (see Do not take METHYCAP LA)
- experience slower weight gain and slightly slower growth when using METHYCAP LA for a long time.

There is evidence that patients with ADHD may become addicted to METHYCAP LA, especially in patients who have a history of drug or alcohol abuse. METHYCAP LA will be given to you or your child only under close medical supervision and after a proper diagnosis.

METHYCAP LA is not indicated for use in children under the age of 6 years.

Other medicines and METHYCAP LA
Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).

Do not take METHYCAP LA if you are taking:
- a medicine called a monoamine oxidase inhibitor (MAOI), used to treat depression or have taken an MAOI in the last 2 weeks. Taking an MAOI with METHYCAP LA may cause a sudden increase in your blood pressure.

It is particularly important that you tell your doctor or pharmacist if you or your child are taking any of the following medicines:
- medicine used to treat high blood pressure
- medicines that increase blood pressure
- tricyclic antidepressants and DOPA (used to treat depression)
- medicines that influence the level of dopamine in the body (dopaminergic medicines used to treat Parkinson's disease or psychosis e.g. haloperidol)
- warfarin (anticoagulant used to prevent blood clots)
- alpha-2 agonists e.g. clonidine and dexmedetomidine (used to treat high blood pressure)
- some anticonvulsants (used to treat seizures e.g. phenobarbital, phenytoin, primidone)
- medicines that raise the level of serotonin in the body (serotonergic medicines, for example those used to treat depression, like sertraline and venlafaxine).

If you are going to have an operation, tell the doctor that you are taking METHYCAP LA. You should not take METHYCAP LA on the day of your operation if a certain type of anaesthetic is used. This is because there is a chance of a sudden rise in blood pressure during the operation.

This medicine may give a positive result when testing for drug use. This includes testing used in sport.

METHYCAP LA with food and drink
METHYCAP LA can be taken with or without food.
Do not drink alcohol while taking this medicine. Alcohol may make the side effects of this medicine worse. Alcohol can also affect the coating of the capsule contents causing accelerated release, rather than slow release, of METHYCAP LA which could lead to toxicity.

Pregnancy, breastfeeding and fertility
If you are pregnant or breastfeeding your baby, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before using METHYCAP LA.

Do not take METHYCAP LA if you are pregnant or breastfeeding your baby (see Do not take METHYCAP LA).

Fertility
No human data on the effect of methylphenidate on fertility are available.

Driving and using machines
METHYCAP LA may cause dizziness, drowsiness, blurred vision, hallucination or other central nervous system side effects, which affect concentration. If you experience such symptoms, do not drive or use machines, or do other activities that need quick reactions.
It is not always possible to predict to what extent METHYCAP LA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which METHYCAP LA affects you.

METHYCAP LA contains sucrose
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take METHYCAP LA
Do not share medicines prescribed for you with any other person. Always use METHYCAP LA exactly as your doctor has told you. You should check with your doctor or pharmacist if you are unsure.

Adults
Your doctor will tell you how many capsules to take. The usual starting dose in patients taking METHYCAP LA for the first time is 20 mg daily.
If you have previously been treated with an immediate release medicine containing methylphenidate for ADHD, your doctor will inform you of the relevant dosage to take.
Your doctor will monitor your progress and may increase your dose at weekly intervals in 20 mg increments.

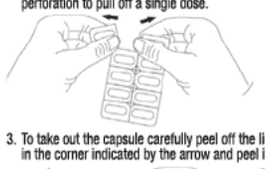
The highest recommended daily dose in adults is 80 mg.

Children and adolescents (6 years and older):
The doctor will tell you how many capsules of METHYCAP LA to give your child. The usual starting dose is 20 mg once daily, gradually increased until an improvement is noticed. A lower dose starting at 10 mg may be recommended by your doctor. The highest recommended total daily dose is 60 mg.

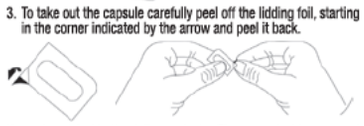
When and how to take METHYCAP LA
Take METHYCAP LA once daily in the morning, with or without food. Swallow the capsule as a whole with water. Do not crush, chew or divide the capsule or the contents.

If you or your child are unable to swallow a METHYCAP LA capsule, you can sprinkle the contents on a small amount of food, as follows:
- carefully open the capsule and sprinkle the beads over a small amount of soft food (e.g. applesauce)
- the food should not be warm because this could affect the special properties of the beads
- immediately swallow all of the medicine/food mixture.
- this soft food mixture should not be chewed; it must be swallowed only
- do not store any medicine/food mixture for future use.

Opening instruction for the blister
METHYCAP LA is available in peelable, child resistant blisters. Please observe the following opening instruction for the blister:
1. Do not push the capsule out of the blister, as this will crush it.
2. Take the blister with the printed foil up and bend it backwards along the perforated line, bend the blister in the opposite direction and repeat several times. Tear along the cross-perforation to pull off a single dose.



3. To take out the capsule carefully peel off the lidding foil, starting in the corner indicated by the arrow and peel it back.



If you do not feel better, tell your doctor. They may decide you need a different treatment.

Your doctor will tell you how long your treatment with METHYCAP LA will last. Do not stop treatment early because stopping treatment immediately can cause unwanted side effects. If used inappropriately, this medicine may become addictive. Treatment for ADHD varies in length from patient to patient. The doctor may discontinue METHYCAP LA periodically to see whether it is still needed.
If you have the impression that the effect of METHYCAP LA is too strong or too weak, tell your doctor or pharmacist.

If you take more METHYCAP LA than you should
In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

Symptoms of overdose may include:
- vomiting, agitation, tremors, hyperreflexia (overactive or overresponsive bodily reflexes), muscle twitching, convulsions (may be followed by coma), euphoria (a feeling or state of intense excitement and happiness), confusion, hallucinations, delirium (a serious change in mental abilities), sweating, flushing, headache, fever, irregular heartbeats, high blood pressure, mydriasis (dilated pupils), dryness of mucous membranes and red-brown urine which could be possible signs of abnormal breakdown of muscles (rhabdomyolysis).

If you forget to take METHYCAP LA
METHYCAP LA capsules should not be taken too late in the morning as it may cause disturbances in sleep. If you miss your morning dose, take your normal dose the next day. Do not take a double dose to make up for forgotten individual doses.

If you stop taking METHYCAP LA
If you suddenly stop taking this medicine, the ADHD symptoms may come back or unwanted effects such as depression may appear. Your doctor may want to gradually reduce the amount of medicine taken each day, before stopping it completely. Talk to your doctor before stopping METHYCAP LA.

4. Possible side effects
METHYCAP LA can have side effects.
Not all side effects reported for METHYCAP LA are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using METHYCAP LA, please consult your healthcare provider for advice.

If any of the following happens, stop using METHYCAP LA and tell your doctor immediately or go to the casualty department at your nearest hospital:
- swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing
- rash or itching
- fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to METHYCAP LA. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:
- uneven heartbeat (palpitations)
- changes in personality, anxiety, restlessness, depression, disorientation, abnormal thinking
- excessive teeth grinding (bruxism)
- thinking about or feeling like killing yourself
- feeling, or hearing things that are not real, these are signs of psychosis or hallucinations
- uncontrolled speech and body movements (Tourette's), fits (seizures, convulsions epilepsy), fast heartbeat, chest pain, uncontrollable twitching and jerking (sign of dyskinesia)
- mood changes/mood swings, feeling unusually excited, over-active and un-inhibited (mania), disorientation, hypervigilance, confusion, dependence, delusions, thought disturbances, excessive and often incoherent talkativeness or wordiness
- tightness or pain in the chest, neck, back or arms, as well as fatigue, light-headedness, abnormal heartbeat and anxiety (symptoms of a heart attack)
- severe headache or confusion, weakness or paralysis of limbs or face, difficulty speaking (signs of disorders of blood vessels in the brain)
- muscle spasms which you cannot control affecting your eyes, head, neck, body and nervous system -due to a temporary lack of blood supply to the brain
- skin peeling or purplish red patches (sign of erythema multiforme)
- skin blisters or itching (sign of exfoliative dermatitis)
- prolonged erection, causing discomfort of the penis (sign of priapism)
- decrease in number of blood cells (red cells, white cells and platelets) which can make you more likely to get infections, and make you bleed and bruise more easily (thrombocytopenia)
- fatigue, weakness, dizziness, trouble breathing, fast heartbeat, fever, pale skin, purple or red spots on the skin, rash, easy bruising, and abnormal bleeding (pancytopenia).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:
Frequent side effects:
- sore throat and runny nose
- decreased appetite
- nervousness, insomnia (sleeplessness), uncontrollable outburst of laughter or crying, aggression, irritability, abnormal behaviour, lower sex drive, panic attack, stress, anxiety, restlessness, sleep disorder, agitation
- uncontrolled, involuntary muscle movement. tremors, headache, drowsiness, dizziness, restlessness or an inability to sit still, sleepiness
- high blood pressure, coldness of hands and feet
- cough, pain in your throat, difficulty breathing
- nausea, dry mouth, stomach pain and discomfort, diarrhoea, vomiting, indigestion, toothache
- rash, itching, hives, fever, hair loss, excessive sweating
- joint pain, swelling and stiffness
- feeling jittery, fever, thirst, growth retardation, fatigue
- weight loss, blood pressure and heart rate changes (increased).

Less frequent side effects:
- stomach flu
- anaemia, easy bruising, bleeding and pinpoint-sized reddish-purple spots on the lower legs, abnormal blood test results, a problem with the blood-forming stem cells in the bone marrow (symptoms include fatigue, weakness, dizziness, trouble breathing, fast heartbeat, fever, pale skin, purple or red spots on the skin, rash, easy bruising, and abnormal bleeding) (leucopenia)
- anorexia (no appetite), reduced weight and height gain during prolonged use in children
- hyperactivity, anger, tearfulness, mood swings, apathy, tension, disorientation, repetitive behaviour, over-focusing, sex drive disorder, abuse, and dependence
- temporary muscle weakness, sedation, movement disorder, speech impediment, loss of skin sensation or other functions of the body due to a temporary lack of blood supply to the brain (reversible ischaemic neurological deficit)
- blurred vision, difficulties in visual accommodation, dilated pupils, visual disturbances
- chest pain
- inflammation and/or blocking of central nervous system arteries, cold hands and feet, fingers and toes feeling numb, tingling and changing colour (from white to blue, then red) when cold (Raynaud's phenomenon)
- constipation
- abnormal liver function including liver coma
- easy bruising, bleeding and pinpoint-sized reddish-purple spots on the lower legs, painless swelling under the skin, itchy, hive-like welts or fluid-filled blisters, peeling skin, skin rash with red bumps on a flat, red patch of skin
- muscle cramps, muscle tightness, muscle twitching, muscle pain
- blood in urine
- breast enlargement in males
- decrease in number of blood cells (red cells, white cells and platelets), blood test for alkaline phosphatase increased, heart murmur, liver enzyme increased (as per blood test).

The following side effects have been reported but the frequency for them to occur is not known:
- nosebleeds
- delusions, thought disturbances, lack of feeling or emotion
- migraine, convulsions/fits, inflammation and/or blocking of central nervous system arteries
- double vision
- abnormal heartbeats
- swelling of face and throat, redness of the skin, large red blotches on the skin appearing within a few hours of taking the medicine
- lockjaw
- incontinence (loss of bladder control)
- erectile dysfunction
- chest discomfort, extreme fever.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects
If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.
By reporting side effects, you can help provide more information on the safety of METHYCAP LA. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store METHYCAP LA
Store all medicines out of reach of children.
Store at or below 30 °C and protect from moisture.
Keep blisters in carton until required for use.
Do not use after the expiry date stated on the carton.
Return all unused medicine to your pharmacist.
Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information
What METHYCAP LA contains:
The active ingredient is methylphenidate hydrochloride, 10 mg, 20 mg, 30 mg and 40 mg respectively.

The other ingredients are:
Capsule content:
Ammonio methacrylate copolymer, methacrylic acid-methyl methacrylate copolymer, povidone, sugar spheres (sucrose and maize starch), talc, triethyl citrate.

Hard gelatin capsule size 2 (10 mg, 30 mg) and hard gelatin capsule size 1 (40 mg):
Gelatin, titanium dioxide, yellow iron oxide

Hard gelatin capsule size 2 (20 mg):
Gelatin, titanium dioxide

Red printing ink
Potassium hydroxide, propylene glycol, red iron oxide, shellac glaze, strong ammonia solution

What METHYCAP LA looks like and contents of the pack
METHYCAP 10 mg LA: Hard gelatin capsule size 2, with a dark yellow opaque cap and a white opaque body, imprinted with "RUB" in red ink on the cap and "M10" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.
METHYCAP 20 mg LA: Hard gelatin capsule size 2, white opaque capsule, imprinted with "RUB" in red ink on the cap and "M20" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.
METHYCAP 30 mg LA: Hard gelatin capsule size 2, ivory opaque capsule, imprinted with "RUB" in red ink on the cap and "M30" in red ink on the body, containing white and whitish pellets. Capsule length: 18 mm.
METHYCAP 40 mg LA: Hard gelatin capsule size 1, dark yellow opaque, imprinted with "RUB" in red ink on the cap and "M40" in red ink on the body, containing white and whitish pellets. Capsule length: 20 mm.

Peelable child-resistant blisters (Aclar/PVC/Al/PET) cross-perforated, packed inside an outer carton.
Each pack contains 30 capsules.

Holder of Certificate of Registration
Pharma Dynamics (Pty) Ltd
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or 0860-PHARMA (742 762)

This leaflet was last revised in
July 2025

Registration numbers
METHYCAP 10 mg LA: A57/1.2/0792
METHYCAP 20 mg LA: A57/1.2/0793
METHYCAP 30 mg LA: A57/1.2/0794
METHYCAP 40 mg LA: A57/1.2/0795

pharma dynamics

A5872

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS S6

METHYCAP 10 mg LA gewysigdevrystelling harde kapsules
METHYCAP 20 mg LA gewysigdevrystelling harde kapsules
METHYCAP 30 mg LA gewysigdevrystelling harde kapsules
METHYCAP 40 mg LA gewysigdevrystelling harde kapsules
Metielfenidaathidrochloried
METHYCAP 10/20/30/40 mg LA bevat suiker
(sukrose: 10 mg: 59,7 mg; 20 mg: 119,5 mg; 30 mg: 179,2 mg; en 40 mg: 238,9 mg onderskeidelik)

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om METHYCAP LA te neem
- Hou hierdie inligtingsblad. Dit mag nodig wees vir u om dit weer te lees.
- Indien u verdere vrae het, vra asseblief u dokter of u apteker, verpleegkundige of ander gesondheidsorgverskaffer.
- METHYCAP LA is vir u persoonlik voorgeskryf en u moet nie u medisyne met ander mense deel nie. Dit mag skadelik wees vir hulle, selfs al is hulle simptome dieselfde as u eie.

Inhoud van hierdie inligtingsblad

1. Wat METHYCAP LA is en waarvoor dit gebruik word
2. Wat u nodig het om te weet, voordat u METHYCAP LA neem
3. Hoe om METHYCAP LA te neem
4. Moontlike newe-effekte
5. Hoe om METHYCAP LA te bewaar
6. Verpakkingsinhoud en ander inligting

1. Wat METHYCAP LA is en waarvoor dit gebruik word
METHYCAP LA verbeter die aktiwiteit van seker onaktiewe gedeeltes van die brein. Die medisyne kan help om aandag (aandagsomvang) en konsentrasievermoë te verbeter en impulsiewe optrede, te verminder.
METHYCAP LA word gebruik vir aandaggebrek-hiperaktiwiteitsteuring (AGHS) by kinders ouer as 6 jaar, asook deur volwassenes met AGHS wat tydens hul kinderjare begin het.

AGHS is 'n mediese toestand, waar die kind of volwassene dit moeilik vind om aandag te skenk en gefokus te bly op meeste take wat aan hulle gegee word. Hulle is ook geneig om baie rond te beweeg en is baie woelig (maak onnodige ophef).

METHYCAP LA word slegs deur 'n spesialis voorgeskryf, vir gedragsteurings. Die spesialis sal ook u verdere behandeling opvolg. 'n Deeglike ondersoek word benodig. Indien u 'n volwassene is en nie voorheen behandel was nie, sal die spesialis toetse aanvra, om te bevestig dat u vanaf u kinderjare aan AGHS gely het. Behandelingsprogramme wat gebruik word, asook medisyne, help om AGHS te beheer.

2. Wat u nodig het om te weet voordat u METHYCAP LA neem
Moet nie METHYCAP LA neem:
- indien u hipersensitief (allergies) is vir metielfenidaathidrochloried, of vir enige van die ander bestanddele van METHYCAP LA nie (sien afdeling 6)
- indien u aan angstigheid, spanning of agitasie ly nie
- indien u onbeheerde spraak en liggaamsbewegings ervaar nie (Tourette se sindroom), of indien enige ander familielid aan Tourette se sindroom ly nie
- indien u 'n skildklierprobleem het nie
- indien u geestesgesondheidsprobleme ervaar soos:
  - ◆ 'n "psigopatiese", of "grenslyn" persoonlikheidsprobleem
  - ◆ abnormale denke of visies ervaar, of 'n siekte het wat "skisofrenie" genoem word, tekens van 'n erge gemoedsprobleem, soos 'n gevoel om selfmoord te pleeg, erge depressie (waar u baie hartseer, waardeloos en hopeloos voel), manie (waar u opgewonde, ooraktief, uitbundig voel), anoreksie
- indien u verhoogde oogdruk het nie (gloukoom)
- indien u 'n gewas aan u adrenale klier het nie (feochromositoom)
- indien u ooit hartprobleme, soos 'n hartaanval, onreëlmatige hartklop, pyn en ongemak in die bors, hartversaking, hartsiekte gehad het, of 'n aangebore hartprobleem het nie
- indien u baie hoë bloeddruk, of 'n vernouing van bloedvate, wat pyn in die arms en bene kan veroorsaak, het nie
- u 'n probleem met bloedvate in u brein, soos 'n beroerte, swelling en verswakking van 'n gedeelte van 'n bloedvat (aneurisme), bloedvate wat vernou of versper is, of inflammasie van die bloedvate (vaskulitis), het nie
- indien u 'n medisyne, wat "mono-amienoksidase inhibitor" (MAOI) genoem word en vir depressie gebruik word neem, of 'n MAOI tydens die vorige 2 weke geneem het nie
- indien u swanger is, of u baba borsvoed nie.

Moet nie METHYCAP LA neem, indien enige van bogenoemde op u van toepassing is nie. Indien u onseker is, praat met u dokter of apteker, voordat u METHYCAP LA neem. Dit is omdat METHYCAP LA hierdie probleme mag vererger.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met METHYCAP LA indien u, of u kind:
- onverwags, 'n langdurige ereksie tydens behandeling ondervind (dit geld vir beide kinders en volwassenes). Dit mag pynlik wees en kan op enige tydstip voorkom. Dit is belangrik om u dokter onmiddellik te kontak, indien u ereksie vir langer as 2 uur duur, veral indien dit pynlik is
- 'n kombinasie van die volgende simptome ervaar: veranderinge in gemoedstemming (bv. agitasie, hallusinasies, delirium en koma), 'n wanfunksie van die senuwees wat die onwillekeurige liggaamsfunksies beheer, soos harttempo, bloeddruk en sweet, onreëlmatige hartklop, tydelike hoë bloeddruk, duiseligheid, uitermatige gesweet, blosvorming en oorverhitting, spierprobleme (bv. tremor, styfheid, spierrukkings, ooraktiewe, oorreagerende liggaamsreflekse, wankoördinasie), aanvalle/stuipe n gastrointestinale probleme (naarheid, braking, diarree), terwyl u METHYCAP LA saam met medisyne wat die serotonienvlak in die liggaam verhoog, neem (serotonergiese medisyne bv. die wat gebruik word vir depressie, soos sertralien en venlafaksien). Staak die behandeling met METHYCAP LA en medisyne wat die serotonienvlak in die liggaam verhoog en raadpleeg u dokter onmiddellik
- indien u 'n geskiedenis van dwelm-, of alkoholmisbruik het
- indien u stuipe, epilepsie, konvulsies of aanvalle gehad het
- indien u hoë bloeddruk het (hipertensie)
- indien u enige hartafwykings het (bv. strukturele hartabnormaliteit), of enige ander huidige, of vorige hartprobleme
- indien u enige versteuring van die bloedvate van die brein het, of gehad het bv. verswakking van bloedaneurisme, beroerte, inflammasie van bloedvate (vaskulitis) – simptome van vaskulitis sluit erge hoofpyn, gevoelloosheid, swakheid, verlamming en belemmering van koördinasie, sig, spraak, taal, of geheue, in
- indien u akute geestesversteurings het, wat abnormale denke en insig, psigose, ongewone opgewondenheid, ooraktiwiteit en uitbundigheid veroorsaak (akute manie). U dokter sou aangedui het, indien u hieraan ly
- indien u aan depressie, anorexia nervosa/anoreksiese versteurings ('n eetsteuring waar mense obsessief is omtrent hulle gewig en wat hulle eet), selfmoordneigings, psigotiese simptome, erge gemoedsveranderinge, manie (uiters verhewe en opgewonde bui), skisofrenie ('n versteuring wat die persoon se vermoë om helder te dink, voel en op te tree, aantas), psigopatiese/grenslyn persoonlikheidsteuring ('n geestesversteuring wat gekenmerk word deur onstabiele buie, optrede en verhoudings)
- indien u psigotiese simptome, soos om dinge te sien of hoor wat nie regtig teenwoordig is, ervaar (hallusinasies)
- indien u alreeds, of begin om aggressiewe optrede te toon
- indien u enige selfmoordgedagtes, of optrede, ervaar
- indien u alreeds, of begin om moeilik beheerbare, herhaalde trekkings van enige gedeelte van die liggaam ervaar, of u klanke en woorde herhaal, of indien enige van u familielede aan spiertrekkings ly
- indien u gediagnoseer is met enige vorm van bipolêre steuring (sien Moet nie METHYCAP LA neem)
- indien u stadig gewig optel en stadiger groei, wanneer METHYCAP LA oor 'n lang tydperk geneem word.

Daar is bewyse dat pasiënte met AGHS verslaaf mag raak aan METHYCAP LA, veral pasiënte wie 'n geskiedenis van dwelm-, of alkoholmisbruik het. METHYCAP LA sal aan u of u kind gegee word, onder noukeurige mediese toesig en na 'n behoorlike diagnose.

METHYCAP LA word nie aangedui vir gebruik deur kinders jonger as 6 jaar oud nie.

Ander medisyne en METHYCAP LA
Vertel altyd u gesondheidsorgverskaffer, indien u enige ander medisyne neem (Dit sluit aanvullende, of tradisionele medisyne in).

Moet nie METHYCAP LA gebruik, indien u die volgende neem nie:
- 'n medisyne wat 'n mono-amienoksidase inhibitor (MAOI) genoem word en gebruik word om depressie te behandel, of 'n MAOI in die vorige 2 weke geneem het nie. Die gebruik van 'n MAOI saam met METHYCAP LA mag 'n skielike verhoging in u bloeddruk veroorsaak.

Dit is veral belangrik dat u die dokter of apteker vertel, indien u of u kind enige van die volgende medisyne neem:
- medisyne wat gebruik word om hoë bloeddruk te behandel
- medisyne wat bloeddruk verhoog
- trisikliese antidepressante en DOPA (gebruik om depressie te behandel)
- medisyne wat die dopamienvlak in die liggaam beïnvloed (dopaminergiese medisyne wat gebruik word om Parkinson se siekte, of psigose te behandel bv. haloperidol)
- warfarien (teenstolmiddel wat gebruik word om bloedklonte te verhoed)
- alpha-2 agoniste bv. klonidien en deksmedetomidien (gebruik om hoë bloeddruk te behandel)
- sommige teenstuipwekkers (gebruik om aanvalle te behandel bv. fenobarbitaal, fenitoïen, primidoon)
- medisyne wat die serotonienvlak in die liggaam verhoog (serotonergiese medisyne, byvoorbeeld die wat gebruik word om depressie te behandel, soos sertralien en venlafaksien).

Indien u 'n operasie moet ondergaan, vertel die dokter dat u METHYCAP LA neem. U moet nie METHYCAP LA op die dag van u operasie neem, indien 'n sekere tipe narkosemiddel gebruik word nie.
Dit is omdat daar 'n moontlikheid bestaan vir 'n skielike verhoging in bloeddruk tydens die operasie.

Hierdie medisyne mag 'n positiewe resultaat lewer, wanneer daar vir dwelmgebruik getoets word. Dit sluit sporttoetse in.

METHYCAP LA saam met kos en drinkgoed
METHYCAP LA kan saam met, of sonder kos geneem word. Moet nie alkohol gebruik terwyl u hierdie medisyne neem nie. Alkohol mag die newe-effekte van die medisyne, vererger. Alkohol mag ook die bedekking van die kapsuulinhoud aantas en vinnige vrystelling, in plaas van stadige vrystelling van METHYCAP LA veroorsaak, wat tot toksisiteit mag lei.

Swangerskap, borsvoeding en fertiliteit
Indien u swanger is, of u baba borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat u METHYCAP LA neem.

Moet nie METHYCAP LA neem, indien u swanger is, of u baba borsvoed nie (sien Moet nie METHYCAP LA neem).

Fertiliteit
Geen menslike data van die effek van metielfenidaat op fertiliteit, is beskikbaar nie.

Bestuur en die hantering van masjiene
METHYCAP LA mag duiseligheid, lomerigheid, wasige sig, hallusinasie, of ander effekte van die sentrale senuweestelsel, wat konsentrasie beïnvloed, veroorsaak. Indien u sulke simptome ervaar, moet nie bestuur, of masjiene hanteer, of by enige ander aktiwiteite betrokke raak, wat vinnige reaksies benodig nie.
Dit is nie altyd moontlik om te voorspel, tot watter mate METHYCAP LA met u daaglikse aktiwiteite inmeng nie. U moet verseker dat u nie by bogenoemde aktiwiteite betrokke raak, totdat u bewus is tot watter mate METHYCAP LA u aantas nie.

METHYCAP LA bevat sukrose
Indien u dokter aangedui het, dat u 'n onverdraagsaamheid teenoor sommige suikers toon, kontak u dokter voordat u hierdie medikasie neem.

3. Hoe om METHYCAP LA te neem
Moet nie medisyne wat vir u voorgeskryf is, met enige ander persoon deel nie. Gebruik METHYCAP LA altyd presies soos deur u dokter aanbeveel word. U moet u dokter of apteker raadpleeg, indien u onseker is.

Volwassenes
U dokter sal aandui hoeveel kapsules om te neem. Die gewone aanvangsdosis vir pasiënte wie METHYCAP LA vir die eerste maal gebruik, is 20 mg daagliks.
Indien u voorheen met 'n korter-werkende medisyne wat metielfenidaat bevat, vir AGHS behandel was, sal u dokter u inlig omtrent die dosis wat gepas is vir u.
U dokter sal u vordering monitor en mag u dosis met 20 mg weeklikse tussenposes, verhoog.

Die hoogste aanbevole dosis vir volwassenes is 80 mg.

Kinders en adolessente (6 jaar en ouer):
Die dokter sal u vertel hoeveel METHYCAP LA kapsules om vir u kind te gee. Die gewone aanvangsdosis is 20 mg een keer daagliks, wat geleidelik verhoog word, totdat verbetering opgemerk word. 'n Laer aanvangsdosis van 10 mg, mag deur u dokter aanbeveel word. Die hoogste algehele daaglikse dosis is 60 mg.

Wanneer en hoe om METHYCAP LA te neem
Neem METHYCAP LA een keer daagliks in die oggend, saam met, of sonder kos. Sluk die kapsule heel, met water. Moet nie verkrummel, kou, of die kapsuulinhoud halveer nie.

Indien u of u kind, nie instaat is om die METHYCAP LA kapsule te sluk nie, sprinkel die inhoud op 'n klein hoeveelheid kos, soos volg:
- maak die kapsule versigtig oop en sprinkel die korreltjies op 'n klein gedeelte van sagte kos (bv. appelsous)
- die kos moet nie warm wees nie, aangesien dit die spesiale eienskappe van die korreltjies mag beïnvloed
- sluk al die medisyne/kosmengsel dadelik in
- die sagte kosmengsel moet nie gekou word nie, dit moet slegs gesluk word
- moet nie enige medisyne/kosmengsel bewaar vir toekomstige gebruik nie.

Instruksies om die stulpstrook oop te maak
METHYCAP LA is beskikbaar in aftrekbare, peuterbestande stulpstroke. Sien die volgende instruksies om die stulpstrook oop te maak:
1. Moet nie die kapsule uit die stulpstrook druk nie, dit sal die kapsule breek.
2. Neem die stulpstrook, sodat die gedrukte foelie opwaarts wys, en buig na agter langs die geperforeerde lyn. Buig die stulpstrook dan in die teenoorgestelde rigting en herhaal 'n paar keer. Skeur langs die kruis-perforasie om 'n enkel dosering af te trek.



3. Om die kapsule uit te haal, trek bedekkings-foelie versigtig af. Begin by die hoek, soos deur die pyltjie aangedui, en trek die foelie weg.



Indien u nie beter voel nie, vertel u dokter. Hulle mag besluit of u 'n alternatiewe behandeling benodig.

U dokter sal u vertel vir hoe lank u behandeling met METHYCAP LA sal duur. Moet nie behandeling vroegtydig staak nie, aangesien onmiddellike onttrekking, ongunstige newe-effekte mag veroorsaak. Hierdie medisyne mag tot verslawing lei, indien dit nie behoorlik gebruik word nie. Behandeling vir AGHS wissel in duur, van pasiënt tot pasiënt. Die dokter mag METHYCAP LA periodiek onttrek, om te bepaal of dit nog benodig word.
Indien u onder die indruk is dat die effek van METHYCAP LA té sterk, of té swak is, vertel u dokter of apteker.

Indien u meer METHYCAP LA neem as wat u moes
In die geval van oordosering, raadpleeg u dokter of apteker. Indien beide nie beskikbaar is nie, kontak die naaste hospitaal, of gifbeheersentrum.

Simptome van oordosering, mag die volgende insluit:
- braking, voel omgekrap, bewing, hiperrefleksie (ooraktiewe, of 'n oorreagering van liggaamsreflekse), spiertrekking, konvuls