PRODYNA XR

SCHEDULING STATUS S5

1. NAME OF THE MEDICINE
PRODYNA 150 mg XR extended release tablets
PRODYNA 300 mg XR extended release tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION
Each PRODYNA 150 mg XR tablet contains bupropion hydrochloride 150 mg.
Each PRODYNA 300 mg XR tablet contains bupropion hydrochloride 300 mg.
PRODYNA XR is sugar free.

For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM
Extended release tablets.
PRODYNA 150 mg XR: Off-white to pale yellow, round, biconvex, coated tablets, imprinted with "L015" in black ink on one side and plain on other side.
PRODYNA 300 mg XR: Off-white to pale yellow, round, biconvex, coated tablets, imprinted with "L016" in black ink on one side and plain on other side.

4. CLINICAL PARTICULARS
4.1 Therapeutic indications
PRODYNA XR is indicated for the treatment of depression as defined by DSM (diagnostic and statistical manual of mental disorders) IV Criteria. Following a satisfactory response, continuation with PRODYNA XR therapy is effective in preventing relapse and preventing recurrence of further depressive episodes.

4.2 Posology and method of administration
Therapy should be initiated by medical practitioners experienced in the treatment of depression.

Posology
Initial treatment:
The initial dose of PRODYNA XR is 150 mg taken as a single daily dose in the morning. Patients who are not responding adequately to a dose of 150 mg/day may benefit from an increase to the usual adult target dose of 300 mg/day, given once daily. There should be an interval of at least 24 hours between successive doses.

Insomnia is a very common adverse event which is often transient. Insomnia may be reduced by avoiding dosing at bedtime (provided there is at least 24 hours between doses) or, if clinically indicated, dose reduction.

Switching patients from sustained release tablets:
When switching patients from sustained release tablets to extended release tablets; give the same total daily dose when possible. Patients who are currently being treated with sustained release tablets at 300 mg/day (e.g. 150 mg twice daily) may be switched to extended release tablets 300 mg once daily.

Special populations
Elderly: Greater sensitivity of some elderly individuals to PRODYNA XR cannot be ruled out, hence a reduced frequency and/or dose may be required (see section 4.4).

Renal Impairment: Treatment of patients with renal impairment should be initiated at a reduced frequency and/or dose, as bupropion and its metabolites may accumulate in such patients to a greater extent than usual (see section 4.4).

Liver Impairment: PRODYNA XR should be used with caution in patients with mild liver impairment. Because of increased variability in the pharmacokinetics in patients with mild hepatic cirrhosis, a reduced frequency of dosing should be considered (see sections 4.4 and 4.8). PRODYNA XR is contraindicated in patients with moderate to severe hepatic cirrhosis.

Paediatric population
PRODYNA XR is not indicated for use in children or adolescents aged less than 18 years (see section 4.3).

Method of administration
PRODYNA XR tablets should be swallowed whole. The tablets should not be cut, crushed or chewed as this may lead to an increased risk of adverse effects including seizures.

Missed dose
Medical practitioners should advise patients who forget to take PRODYNA XR to wait and take the next tablet at the usual time. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications
PRODYNA XR is contraindicated in:
- hypersensitivity to bupropion or to any of the excipients listed in 6.1
- patients under 18 years
- PRODYNA XR is contraindicated in patients with a seizure disorder
- PRODYNA XR should not be administered to patients currently being treated with any other preparation containing bupropion, as the incidence of seizures is dose dependent
- PRODYNA XR is contraindicated in patients undergoing abrupt discontinuation of alcohol or sedatives
- PRODYNA XR is contraindicated in patients with a current or previous diagnosis of bulimia or anorexia nervosa as a higher incidence of seizures was seen in this patient population when bupropion was administered
- concomitant administration of PRODYNA XR with monoamine oxidase inhibitors (MAOIs) is contraindicated. At least 14 days should elapse between the discontinuation of MAOIs and initiation of treatment with PRODYNA XR
- liver disease, Child-Pugh grades B and C, range 7 - 13.

4.4 Special warnings and precautions for use
Seizures:
The recommended dose of PRODYNA XR should not be exceeded, since bupropion is associated with a dose-related risk of seizure.
PRODYNA XR should be discontinued promptly if patients experience hypersensitivity reactions during treatment (see section 4.8). Medical practitioners should be aware that symptoms may persist beyond the discontinuation of PRODYNA XR and clinical management should be provided accordingly.
The overall incidence of seizure with bupropion hydrochloride in clinical trials was approximately 0,1 %.

There is an increased risk of seizures occurring with the use of PRODYNA XR in the presence of predisposing risk factors, which lower the seizure threshold. Therefore, PRODYNA XR should not be administered to patients with one or more conditions predisposing to a lowered seizure threshold, which include:
- history of head trauma
- central nervous system (CNS) tumour
- history of seizures
- concomitant administration of other medications known to lower the seizure threshold, excessive use of alcohol or sedatives (see section 4.3), diabetes treated with hypoglycaemics or insulin and use of stimulants or anorectic medicines.

PRODYNA XR should be discontinued and not recommenced in patients who experience a seizure while on treatment.

Clinical worsening and suicide risk in adults associated with psychiatric disorders:
Patients with major depressive disorder, may experience worsening of their depression and or the emergence of suicidal ideation and behaviour, whether or not they are taking antidepressant medicines. This risk may persist until significant remission occurs. A causal role, however, for antidepressant medicine in inducing such behaviour has not been established. As improvement may occur during the first few weeks or more of treatment, patients being treated with PRODYNA XR should, nevertheless, be observed closely for clinical worsening (including development of new symptoms) and suicidality, especially at the beginning of a course of therapy or at any time of dose changes, either increases or decreases. Patients with a history of suicidal behaviour or thoughts, young adults and those patients exhibiting a significant degree of suicidal ideation prior to commencement of treatment are at a greater risk of suicidal thoughts or suicide attempts and should receive careful monitoring during treatment.
The following symptoms have been reported in patients being treated with antidepressants for major depressive disorder as well as for other indications, both psychiatric and non-psychiatric: anxiety, agitation, panic attacks, insomnia, irritability, hostility, aggressiveness, impulsivity, akathisia, hypomania, and mania.
In addition, a meta-analysis of placebo controlled clinical trials of antidepressant medicines in adults with major depressive disorder and other psychiatric disorders showed an increased risk of suicidal thinking and behaviour associated with antidepressant use compared to placebo in patients less than 25 years old.

Patients (and caregivers of patients) should be alerted about the need to monitor for any worsening of their condition (including development of new symptoms) and/or the emergence of suicidal ideation/behaviour or thoughts of harming themselves and to seek medical advice immediately if these symptoms present. It should be recognised that the onset of neuropsychiatric symptoms could be related either to the underlying disease state or the medicine therapy and an appropriate patient assessment should be undertaken (see section 4.8).

Consideration should be given to changing the therapeutic regimen, including possibly discontinuing PRODYNA XR, in patients who experience clinical worsening (including development of new symptoms) and/or the emergence of suicidal ideation/behaviour, especially if these symptoms are severe, abrupt in onset, or were not part of the patient's presenting symptoms. Although there is no need to taper PRODYNA XR upon discontinuation, the patient should be monitored for worsening of depressive symptoms following discontinuation.

Neuropsychiatric symptoms including mania and bipolar disorder:
Neuropsychiatric symptoms have been reported (see section 4.8). In particular, psychotic and manic symptomatology has been observed, mainly in patients with a known history of psychiatric illness. Aggression, rage and violent behaviour may occur. Additionally, a major depressive episode may be the initial presentation of bipolar disorder. It is generally believed (though not established in controlled trials) that treating such an episode with an antidepressant alone can increase the likelihood of precipitation of a mixed/manic episode in patients at risk for bipolar disorder. Limited clinical data on use of bupropion in combination with mood stabilisers in patients with a history of bipolar disorder suggests a low rate of switch to mania.
Prior to initiating treatment with PRODYNA XR, patients 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.

Hepatic impairment:
Bupropion is extensively metabolised in the liver to active metabolites, which are further metabolised. No statistically significant differences in the pharmacokinetics of bupropion were observed in patients with mild hepatic cirrhosis compared with healthy volunteers, but bupropion plasma levels showed a higher variability between individual patients.
Therefore, PRODYNA XR should be used with caution in patients with mild hepatic impairment and reduced frequency of dosing should be considered (see sections 4.3 and 5.2).

Renal impairment and elderly patients:
Bupropion is extensively metabolised in the liver to active metabolites which are further metabolised and excreted by the kidneys. Therefore, treatment of patients with renal impairment should be initiated at reduced frequency and/or dose as bupropion and its metabolites may accumulate in such patients to a greater extent than usual. The patient should be closely monitored for possible adverse effects (e.g. insomnia, dry mouth, seizures) that could indicate high bupropion or metabolite levels, toxic effects of elevated blood and tissue levels of bupropion and metabolites.

Clinical experience with PRODYNA XR has not identified any differences in tolerability between elderly and other adult patients, However, greater sensitivity of some elderly individuals cannot be ruled out, hence a reduced frequency and/or dose may be required (see section 5.2).

Cardiovascular disease:
There is limited clinical experience of the use of PRODYNA XR to treat depression in patients with cardiovascular disease. A causal relationship between the use of PRODYNA XR and sudden death cannot be excluded. Care should be exercised if PRODYNA XR is used in these patients.

Brugada syndrome:
Cardiac conduction disorders–bupropion may unmask cardiac conduction syndromes e.g. Brugada syndrome, a rare hereditary disease of the cardiac sodium channel with characteristic electrocardiogram (ECG) changes (right bundle branch block and ST segment elevation in right precordial leads), which may lead to cardiac arrest and or sudden death. Caution is advised in patients with Brugada syndrome or family history of cardiac arrest or sudden death.

Paediatric population
The safety and efficacy with the treatment of PRODYNA XR tablets in patients under 18 years of age have not been established. Treatment with antidepressants is associated with an increased risk of suicidal thinking and behaviour in children and adolescents with major depressive disorder and other psychiatric disorders (see section 4.3).

4.5 Interaction with other medicines and other forms of interaction
Medicines known to affect the CYP2B6 isoenzyme:
Bupropion is metabolised to its major active metabolite hydroxybupropion primarily by the cytochrome P450 IIB6 (CYP2B6) (see section 5.2).

Care should therefore be exercised when PRODYNA XR is co-administered with medicines known to affect the CYP2B6 isoenzyme (e.g. orphenadrine, cyclophosphamide, ifosfamide, ticlopidine, clopidogrel).

Medicines metabolized by CYP2D6:
Although bupropion is not metabolised by the CYP2D6 isoenzyme, *in vitro* human P450 studies have shown that bupropion and hydroxybupropion are inhibitors of the CYP2D6 pathway.
In a human pharmacokinetic study, administration of bupropion increased plasma levels of desipramine. This effect was present for at least 7 days after the last dose of bupropion. Concomitant therapy with medicines predominantly metabolised by this isoenzyme (such as certain beta blockers, antidysrhythmics, selective serotonin re-uptake inhibitors (SSRIs), tricyclic antidepressants (TCAs), antipsychotics) should be initiated at the lower end of the dose range of the concomitant medicine. If PRODYNA XR is added to the treatment regimen of a patient already receiving a medication metabolised by CYP2D6, the need to decrease the dose of the original medication should be considered, particularly for those concomitant medications with a narrow therapeutic index (see section 5.2).

Citalopram:
Although citalopram is not primarily metabolised by CYP2D6, in one study, bupropion increased the C_{max} and area under the plasma concentration-timed curve (AUC) of citalopram by 30 % and 40 %, respectively.

Medicines known to induce metabolism:
Since bupropion is extensively metabolised, the co-administration of medicines known to induce metabolism (e.g. carbamazepine, phenobarbitone, phenytoin) or inhibit metabolism may affect its clinical activity.

Ritonavir:
In a series of studies in healthy volunteers, ritonavir (100 mg twice daily or 600 mg twice daily) or ritonavir 100 mg plus lopinavir 400 mg twice daily, reduced the exposure of bupropion and its major metabolites in a dose dependent manner by approximately 20 % - 80 %. This effect is thought to be due to the induction of bupropion metabolism. Patients receiving ritonavir may need increased doses of PRODYNA XR but the maximum recommended dose of PRODYNA XR should not be exceeded.

Alcohol:
There have been reports of adverse neuropsychiatric events or reduced alcohol tolerance in patients drinking alcohol during bupropion hydrochloride treatment. The consumption of alcohol during PRODYNA XR treatment should be minimised or avoided.

Levodopa or amantadine:
Limited clinical data suggest a higher incidence of adverse events in patients receiving concurrent administration of bupropion and levodopa. Administration of PRODYNA XR to patients receiving either levodopa or amantadine concurrently should be undertaken with caution.

Nicotine:
Concomitant use of PRODYNA XR and a nicotine transdermal system (NTS) may result in elevations of blood pressure.

Monoamine oxidase inhibitors (MAOIs):
Bupropion inhibits the reuptake of dopamine and noradrenaline (norepinephrine). Concomitant use of monoamine oxidase inhibitors (MAOIs) and bupropion is contraindicated because there is an increased risk of hypertensive reactions if bupropion is used concomitantly with MAOIs. At least 14 days should elapse between discontinuation of an MAOI intended to treat depression and initiation of treatment with PRODYNA XR. Conversely, at least 14 days should be allowed after stopping PRODYNA XR before starting a MAOI antidepressant.

Bupropion has been classified as possibly porphyrinogenic. It should be used only when no safe alternative is available, and precautions should be considered in vulnerable patients.

4.6 Fertility, pregnancy and lactation
Safety in pregnancy and lactation has not been established.

Pregnancy
Epidemiological studies of pregnancy outcomes following maternal exposure to bupropion in the first trimester have reported an association with increased risk of some congenital cardiovascular malformations, including ventricular septal defects and left ventricular outflow tract defects. These findings are not consistent across studies.

Breastfeeding
As bupropion and its metabolites are excreted in human breast milk, mothers should be advised not to breastfeed while taking PRODYNA XR.

Fertility
There is no data on fertility with PRODYNA XR.

4.7 Effects on ability to drive and use machines
Patients should exercise caution before driving or use of machinery until they are reasonably certain PRODYNA XR tablets do not adversely affect their performance as dizziness, visual disturbances and hallucinations have been reported as occurring side effects.

4.8 Undesirable effects
Tabulated list of adverse reactions

System Organ Class	Frequency	Side effects
Blood and lymphatic system disorders	*Frequency unknown*	Ecchymosis, anaemia, leukocytosis, leukopaenia, lymphadenopathy, pancytopaenia, and thrombocytopaenia, altered prothrombin time (PT) and/or international normalised ratio (INR), associated with haemorrhagic or thrombotic complications, when co-administered with warfarin
Immune system disorders	*Frequent* *Less frequent*	Hypersensitivity reactions such as urticaria More severe hypersensitivity reactions including angioedema, dyspnoea/bronchospasm and anaphylactic shock, arthralgia, myalgia, fever, rash (symptoms resemble serum sickness)
Endocrine disorders	*Frequency unknown*	Hyperglycaemia, hypoglycaemia, syndrome of inappropriate antidiuretic hormone secretion
Metabolism and nutrition disorders	*Frequent* *Less frequent* *Frequency unknown*	Anorexia, weight loss Blood glucose disturbances Glycosuria
Psychiatric disorders	*Frequent* *Less frequent* *Frequency unknown*	Insomnia, agitation, anxiety Confusion, depression, aggression, hostility, irritability, restlessness, hallucinations, abnormal dreams, depersonalisation, delusions, paranoid ideation Suicide attempt
Nervous system disorders	*Frequent* *Less frequent* *Frequency unknown*	Headache, tremor, dizziness, taste disorders Concentration disturbances, seizures (see section 4.4), dystonia, ataxia, parkinsonism, incoordination, memory impairment, paraesthesia, syncope Emotional lability, derealisation, euphoria, abnormal coordination, hyperkinesia, hypertonia, hyperesthesia, vertigo, amnesia, abnormal electroencephalogram (EEG), akinesia, aphasia, coma, dysarthria, dyskinesia, extrapyramidal syndrome, hypokinesia, increased libido, neuralgia, neuropathy, unmasking tardive dyskinesia
Eye disorders	*Frequent* *Frequency unknown*	Visual disturbance Accommodation abnormality, dry eye, increased intraocular pressure angle-closure glaucoma, mydriasis
Ear and labyrinth disorders	*Frequent* *Frequency unknown*	Tinnitus Deafness
Cardiac disorders	*Less frequent* *Frequency unknown*	Tachycardia, palpitations Complete atrioventricular block, extrasystoles, myocardial infarction
Vascular disorders	*Frequent* *Less frequent* *Frequency unknown*	Increased blood pressure (sometimes severe), flushing Vasodilation, postural hypotension Hypertension, stroke, phlebitis, pulmonary embolism
Respiratory, thoracic and mediastinal disorders	*Frequency unknown*	Bronchospasm, pneumonia
Gastrointestinal disorders	*Frequent* *Frequency unknown*	Dry mouth, gastrointestinal disturbance including nausea and vomiting, abdominal pain, constipation Gastric reflux, stomatitis, thirst, colitis, esophagitis, gastrointestinal haemorrhage, intestinal perforation, stomach ulcer
Hepatobiliary disorders	*Less frequent* *Frequency unknown*	Elevated liver enzymes, jaundice, hepatitis Abnormal liver function, liver damage, pancreatitis
Skin and subcutaneous tissue disorders	*Frequent* *Less frequent* *Frequency unknown*	Rash, pruritus, sweating Erythema multiforme and Stevens-Johnson syndrome Maculopapular rash, alopecia, angioedema, exfoliative dermatitis and hirsutism
Musculoskeletal, connective tissue and bone disorders	*Less frequent* *Frequency unknown*	Twitching Leg cramps, fever/rhabdomyolysis, and muscle weakness
Renal and urinary disorders	*Less frequent* *Frequency unknown*	Urinary frequency and/or retention Dysuria, urinary incontinence, cystitis
Reproductive system and breast disorders	*Frequency unknown*	Impotence, prostate disorder, abnormal ejaculation, dyspareunia, gynaecomastia, menopause, painful erection, salpingitis, vaginitis
General disorders and administrative site conditions	*Frequent* *Frequency unknown*	Fever, asthenia, chest pain Bruxism, gingivitis, glossitis, increased salivation, mouth ulcers, oedema of tongue, gum haemorrhage

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 the SAHPRA website.
An email can be sent directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of PRODYNA XR.

4.9 Overdose
Signs and symptoms
Drowsiness, loss of consciousness and ECG changes such as conduction disturbances (including QRS prolongation) or dysrhythmias.
Acute ingestion of doses more than 10 times the maximum therapeutic dose has been reported.

Management of overdose
In the event of overdose, hospitalisation is advised.
ECG and vital signs should be monitored.
Ensure an adequate airway, oxygenation and ventilation. The use of activated charcoal is recommended. No specific antidote for bupropion is known.
Further management should be as clinically indicated or as recommended by the national poisons centre, where available.

5. PHARMACOLOGICAL PROPERTIES
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Other antidepressants
ATC code: N06AX12
Pharmacological classification: A.1.2 Psychoanaleptics (antidepressants)

Bupropion is an inhibitor of the neuronal re-uptake of catecholamines (noradrenaline (norepinephrine) and dopamine) with minimal effect on the re-uptake of indolamines (serotonin) and does not inhibit monoamine oxidase. The mechanism of action of bupropion is unknown.

5.2 Pharmacokinetic properties
Absorption
Following oral administration of bupropion tablets to healthy volunteers, time to peak plasma concentrations for bupropion was approximately 5 hours. The absorption of bupropion is not significantly affected when taken with food. Bupropion and its metabolites exhibit linear kinetics following chronic administration of 150 - 300 mg per day.

Distribution
Bupropion is widely distributed with an apparent volume of distribution of approximately 2000 L. Bupropion and hydroxybupropion are moderately bound to plasma proteins (84 % and 77 %, respectively).
The extent of protein binding of the threohydrobupropion metabolite is about half that seen with bupropion.

Biotransformation
Bupropion is extensively metabolised in humans. Three pharmacologically active metabolites have been identified in plasma: hydroxybupropion and the amino alcohol isomers, threohydrobupropion and erythrohydrobupropion. These have clinical importance, as their plasma concentrations are as high as or higher than those of bupropion.

Peak plasma concentrations of hydroxybupropion occur approximately 7 hours following administration of bupropion.
Erythrohydrobupropion cannot be measured in the plasma after a single dose of bupropion. The active metabolites are further metabolised to inactive metabolites and excreted in the urine.
In vitro studies indicate that bupropion is metabolised to its major active metabolite hydroxybupropion primarily by CYP2B6, while cytochrome P450s are not involved in the formation of threohydrobupropion (see section 4.5).
Bupropion and hydroxybupropion are both relatively weak competitive inhibitors of the CYP2D6 isoenzyme with K_i values of 21 and 13,3 µM (micrometers), respectively. In human volunteers known to be extensive metabolisers of the CYP2D6 isoenzyme, co-administration of bupropion and desipramine has resulted in 2- and 5-fold increases in the C_{max} and AUC, respectively, of desipramine. This effect was present for at least 7 days after the last dose of bupropion. Since bupropion is not metabolised by the CYP2D6 pathway, desipramine is not anticipated to affect the pharmacokinetics of bupropion. Caution is advised when bupropion is administered with substrates for the CYP2D6 pathway (see section 4.5).

In humans, there is no evidence of enzyme induction of bupropion or hydroxybupropion in volunteers or patients receiving recommended doses of bupropion for 10 - 45 days.

Elimination
Following oral administration of 200 mg of ^{14}C-bupropion in humans, 87 % and 10 % of the radioactive dose were recovered in the urine and faeces, respectively. The fraction of the dose of bupropion excreted unchanged was only 0,5 %, a finding consistent with the extensive metabolism of bupropion. Less than 10 % of this ^{14}C dose was accounted for in the urine as active metabolites.
The mean apparent clearance following oral administration of bupropion is approximately 200 L/hr and the mean elimination half-life of bupropion is approximately 20 hours.
The elimination half-life of hydroxybupropion is approximately 20 hours and its area under the plasma drug concentration versus time curve (AUC) at steady state is approximately 17 times that of bupropion. The elimination half-lives for threohydrobupropion and erythrohydrobupropion are longer (37 and 33 hours, respectively) and steady-state AUC values are 8 and 1,6 times higher than that of bupropion, respectively. Steady-state for bupropion and its metabolites is reached within 8 days.

Pharmacokinetics in special patient groups
Elderly
Pharmacokinetic studies in the elderly have shown variable results. A single dose study showed that the pharmacokinetics of bupropion and its metabolites in the elderly do not differ from those in the younger adults. Another pharmacokinetic study, single and multiple doses, has suggested that accumulation of bupropion and its metabolites may occur to a greater extent in the elderly. Clinical experience has not identified differences in tolerability between elderly and younger patients, but greater sensitivity in older patients cannot be ruled out.

Patients with renal impairment
The elimination of bupropion and its major metabolites may be reduced by impaired renal function (see section 4.4).

Patients with hepatic impairment
The pharmacokinetics of bupropion and its active metabolites were not statistically significantly different in patients with mild cirrhosis (Child-Pugh grade A, range 5 - 6) when compared to healthy volunteers, although more variability was observed between individual patients. For patients with moderate to severe hepatic cirrhosis (Child-Pugh grades B and C, range 7 - 13), a single dose of bupropion produced a C_{max} and AUC that were substantially increased (mean difference approximately 70 % and 3-fold, respectively) and more variable when compared to the values in healthy volunteers; the mean half-life was also longer (by approximately 40 %). For the metabolites, the mean C_{max} was lower (by approximately 30 % - 70 %), the mean AUC tended to be higher (by approximately 30 % - 50 %), the median T_{max} was later (by approximately 20 hrs), and the mean half-lives were longer (by approximately 2 to 4-fold) than in healthy volunteers (see section 4.3).

6. PHARMACEUTICAL PARTICULARS
6.1 List of excipients
Cores:
Glyceryl behenate
Hydrophobic colloidal silica
L-cysteine hydrochloride monohydrate
Polyvinyl alcohol

Coating:
Colloidal silicon dioxide
Dibutyl sebacate
Ethyl cellulose
Hydroxypropyl cellulose
Methacrylic acid copolymer dispersion
Povidone
Triethyl citrate

Imprinting ink – Opacode black:
Ammonium hydroxide
Iron oxide black
Isopropyl alcohol
N-butyl alcohol
Propylene glycol
Shellac glaze

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
24 months

6.4 Special precautions for storage
Store at or below 25 °C.

6.5 Nature and contents of container
150 mg:
30's: White opaque 100 mL HDPE bottle containing 30 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabiliOx® strip form sachet closed with white child resistant closure.
90's: White opaque 150 mL HDPE bottle containing 90 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabiliOx® strip form sachet closed with white child resistant closure.
500's: White opaque 500 mL HDPE bottle containing 500 tablets along with one molecular sieve 5 g sachet, one activated carbon 5 g sachet and one StabiliOx® strip form sachet closed with white non child resistant closure.

300 mg:
30's: White opaque 100 mL HDPE bottle containing 30 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabiliOx® strip form sachet closed with white child resistant closure.
90's: White opaque 250 mL HDPE bottle containing 90 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabiliOx® strip form sachet closed with white child resistant closure.
500's: White opaque 500 mL HDPE bottle containing 500 tablets along with one molecular sieve 5 g sachet, one activated carbon 5 g sachet and one StabiliOx® strip form sachet closed with white non child resistant closure.
Not all pack sizes may be marketed.

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
PRODYNA 150 mg XR: A54/1.2/0181
PRODYNA 300 mg XR: A54/1.2/0182

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION
27 June 2023

10. DATE OF REVISION OF THE TEXT
15 November 2024

pharma dynamics

700.00 mm
450.00 mm
5.00 mm

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S5

PRODYNA 150 mg XR extended release tablets
PRODYNA 300 mg XR extended release tablets
Bupropion hydrochloride
Sugar free.

Read all of this leaflet carefully before you start taking PRODYNA XR
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- PRODYNA XR 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 PRODYNA XR is and what it is used for
PRODYNA XR contains bupropion, one of a group of medicines called antidepressants.
PRODYNA XR is a medicine to treat your depression.

2. What you need to know before you take PRODYNA XR
Do not take PRODYNA XR:
- if you are hypersensitive (allergic) to bupropion or any of the other ingredients of PRODYNA XR (see section 6)
- if you are under 18 years old
- if you suffer from fits or seizures
- if you are taking any medicine which already contains bupropion hydrochloride
- if you have abruptly stopped drinking alcohol or using sedatives
- if you have or had been diagnosed with the eating disorders bulimia (binge eating followed by making yourself vomit) or anorexia (abnormal low body weight with an intense fear of gaining weight)
- if you are taking a medicine which is a monoamine oxidase inhibitor (MAOI) (antidepressants)
- if you have a liver disease.

Warnings and precautions
Take special care with PRODYNA XR:

Seizures:
You should not exceed the dose of PRODYNA XR as prescribed by your doctor as the risk of seizures increases.
Your risk of seizures also increases in the following situations, therefore inform your doctor if any of the below pertains to you:
- if you've ever had any fits or seizures
- if you have ever had a serious head injury
- if you have a brain tumour
- if you are taking medicine for seizures
- if you have diabetes for which you use insulin or tablets
- if you regularly drink a lot of alcohol
- if you have had any mental illness other than depression, including eating disorders.

If you experience a seizure (fit) during treatment, stop taking PRODYNA XR and contact your doctor immediately.

Thoughts of suicide or worsening of your condition:
If you are depressed, you can sometimes have thoughts of harming or killing yourself. These thoughts may be increased when first starting antidepressants. These medicines all take time to work – usually about two weeks, but sometimes longer. You may be more likely to think like this:
- if you have previously had thoughts about killing or harming yourself
- if you are under 25 years old.

If you have thoughts of harming or killing yourself at any time: Get medical advice as soon as possible (from a doctor or at a hospital).

You should talk to your doctor, especially if:
- you have uncontrolled coronary artery disease (a heart disease caused by poor blood flow in the blood vessels of the heart) with symptoms such as angina (characterised by chest pain) or a recent heart attack
- if you have liver or kidney problems
- you have a history of mania (feeling elated or over-excited, which causes unusual behaviour)
- if you are elderly.

Children and adolescents
PRODYNA XR should not be used in children and adolescents below 18 years.

Other medicines and PRODYNA XR
Always tell your healthcare provider if you are taking any other medicine (this includes complementary or traditional medicines).
Your doctor may alter your dose of PRODYNA XR or suggest a change in your other medicines.

Do not take PRODYNA XR with:
- **Monoamine oxidase inhibitors** (medicines to treat depression or Parkinson's disease) such as phenelzine, selegiline, or rasagiline. You must stop taking these medicines for at least 14 days before starting PRODYNA XR (see Do not take PRODYNA XR).

Tell your doctor if you are taking any of the following medicines, as your doctor will closely monitor you for side effects:
- orphenadrine (to treat muscle cramps), cyclophosphamide and ifosfamide (to treat certain types of cancer), ticlopidine (used to reduce the risk of a stroke), clopidogrel (used to reduce the risk of heart disease and stroke)
- medicines which make seizures (fits) more likely e.g. theophylline for asthma or lung disease, tramadol a strong painkiller
- antidepressants, tranquillisers or sedatives, e.g. citalopram, desipramine, amitriptyline, fluoxetine, sertraline, or any other medicine for depression or mental illness, or if you are going to stop them while you're taking PRODYNA XR
- medicine for high blood pressure or heart disease (beta blockers or antidysrhythmics), e.g. propranolol, amiodarone
- medicine called ritonavir used to treat human immunodeficiency virus (HIV)
- medicine to treat Parkinson's disease that contains levodopa or amantadine
- medicines used to treat epilepsy such as carbamazepine, phenytoin or phenobarbitone
- stimulants or medicine used for lowering your appetite
- nicotine patches to stop smoking.

Talk to your doctor or pharmacist before taking PRODYNA XR:
Cardiac conduction disorders e.g. Brugada syndrome – If you have a condition called Brugada syndrome (a rare hereditary syndrome that affects the heart rhythm) or if cardiac arrest or sudden death occurred in your family.

PRODYNA XR with food, drink and alcohol
Excessive use of alcohol while being treated with PRODYNA XR might increase the risk for fits (seizures), mental disorder events or might reduce alcohol tolerance. Your doctor may suggest you do not drink alcohol while you are taking PRODYNA XR or try to drink as little as possible. If you do drink a lot now, do not just stop suddenly, because that may put you at risk of having a fit.

Pregnancy and breastfeeding
If you are pregnant or breastfeeding 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 PRODYNA XR.

Studies have reported an increase in the risk of birth defects, particularly heart defects, in babies whose mothers were taking PRODYNA XR. Thus, PRODYNA XR should not be used during pregnancy, or while breastfeeding.

Driving and using machines
PRODYNA XR may make you dizzy or light-headed.
It is not always possible to predict to what extent PRODYNA XR 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 PRODYNA XR affects you.

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

Adults:
The usual starting dose for adults is one 150 mg tablet every day.
Your doctor may increase your dose to 300 mg once a day if your depression does not improve after several weeks.
Take your dose of PRODYNA XR early in the morning.
Do not take PRODYNA XR more than once each day.
Your doctor may alter your dose:
- if you have liver or kidney problems
- if you are over 65 years of age.

Swallow the tablets whole. Do not chew them, crush them or split them – if you do, the medicine will be released into your body too quickly. If this happens you may be more likely to get side effects including seizures (fits).

Your doctor will tell you how long your treatment with PRODYNA XR will last. Do not stop treatment early because your depression may return.
If you have the impression that the effect of PRODYNA XR is too strong or too weak, tell your doctor or pharmacist.

If you take more PRODYNA XR 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:
- drowsiness, loss of consciousness, irregular heartbeat.

If you forget to take PRODYNA XR
If you forget to take PRODYNA XR, wait, then continue to take PRODYNA XR at the usual times. Do not take a double dose to make up for forgotten individual doses.

If you stop taking PRODYNA XR
It is important that you continue the course of treatment even if you begin to feel better after a few days. If you suddenly stop taking this medicine, the depression symptoms may come back or unwanted effects such as fits may appear.

4. Possible side effects
PRODYNA XR can have side effects.
Not all side effects reported for PRODYNA XR are included in this leaflet. Should your general health worsen, or if you experience any untoward effects while using PRODYNA XR, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop using PRODYNA XR 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
- seizures, fainting.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to PRODYNA XR. 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), increased, irregular or fast heartbeat (tachycardia), heart attack, stroke
- mood changes or mood swings or changes in personality, confusion, depression, aggression, delusions, abnormal behaviour
- thinking about or feeling like killing yourself, suicide attempt
- hallucinations (hearing voices or seeing things which are not there), believing things that are not true or being suspicious
- sudden chest pain due to blood clots in your lungs
- Stevens-Johnson syndrome (a rare skin condition with severe blisters and bleeding in the lips, eyes, mouth, nose and genitals)
- yellowing of the skin and eyes, also called jaundice and inflammation of the liver.

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:
- hypersensitivity reactions like hives
- anorexia/lack of appetite, weight loss
- insomnia (sleep disorder), agitation, anxiety
- headache, tremor, dizziness, taste disorders
- vision disorders, ringing or buzzing in the ears
- high blood pressure, flushing (hot flush)
- dry mouth, nausea, vomiting, abdominal pain, constipation
- rash, itching, sweating
- fever, chest pain, lack of energy.

Less frequent side effects:
- blood glucose disturbances
- confusion, depression, aggression, feelings of opposition, unkindness or unfriendliness toward something or someone, irritability, restlessness, abnormal dreams
- unable to concentrate, unable to control muscle movements leading to abnormal walk, speech and abnormal eye movements, coordination problems, Parkinsonism (a disorder of the central nervous system that affects movement, often including tremors), loss of memory, "pins and needles"
- a form of low blood pressure that happens when standing up from sitting or lying down
- a skin reaction that can be triggered by an infection or some medicines
- blood tests showing increased level of liver enzymes
- twitching
- need to urinate often or unable to urinate.

The following side effects have been reported but the frequency for them to occur is not known:
- bruising, reduction in red blood cells which can make the skin pale and cause weakness or breathlessness, increase in number of white blood cells, low white blood cell count, enlargement of lymph node, severe reduction in blood cells which can cause weakness, bruising or make infections more likely, reduction in blood platelets, which increases risk of bleeding or bruising
- bleeding into the tissues, bruising, and slow blood clotting after injury
- too much or too little glucose in the bloodstream, a condition in which the body makes too much antidiuretic hormone (ADH) – a hormone that helps the kidneys control the amount of water your body loses through the urine
- excess of sugar in the urine
- mood changes where strong emotions or feelings (uncontrollable laughing or crying or feeling very irritable or temper) occur, feeling detached from your surroundings
- problems with walking or coordination, muscle spasm, too much muscle tone, sensitivity of any of your senses, such as sight, sound, touch, and smell, feeling off-balance (vertigo), memory loss, abnormal electrical activity in the brain as measured by an EEG (electroencephalogram), loss of voluntary movement, speech impairment or slurred speech, coma, uncontrolled involuntary muscle movement, increased sexual desire, slow movement, stabbing, burning, and often severe pain due to an irritated or damaged nerve
- damage to the nerves which can cause numbness, pain and weakness, involuntary, repetitive body movements including grimacing, sticking out the tongue, or smacking the lips
- difficulty in sight when changing focus from far objects to nearby objects, dry eyes, increase in pressure in the eye, dilated pupils
- deafness
- high blood pressure, vein inflammation
- tight chest, lung infection
- heartburn, mouth sores, inflammation of the mouth, thirst, inflammation of your colon which causes abdominal pain or diarrhoea, inflammation of the tube running from your throat to your stomach, bleeding in the stomach and intestines, tear in intestines, stomach ulcer
- abnormal liver function, liver damage, inflammation of the pancreas, which causes severe pain in the abdomen and back
- red area on the skin that is covered with small merging bumps, hair loss, painless swelling under the skin, redness and peeling of the skin over large areas of the body, abnormal hair growth
- leg cramps, fever, abnormal muscle breakdown which can lead to kidney problems, muscle weakness
- pain/discomfort when urinating, leakage of urine, bladder infection
- inability in a man to achieve an erection or orgasm, prostate problems, discharge of semen, difficult or painful sexual intercourse, enlarged breasts in males, menopause, painful erection, inflammation of the fallopian tubes, inflammation of the vagina that can result in discharge, itching and pain
- a condition in which you grind, crash or clench your teeth, red, swollen and inflamed tongue, gum disease, increase in saliva, sores in mouth, swelling of tongue, bleeding of the gums.

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, pharmacist or nurse. You can also report any side effects to SAHPRA via the Med Safety APP (MedsafetY X SAHPRA) and eReporting platform (who-umc.org) found on the SAHPRA website. By reporting side effects, you can help provide more information on the safety of PRODYNA XR. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure the safety of PRODYNA XR.

5. How to store PRODYNA XR
Store all medicines out of reach of children.
Store at or below 25 °C in original container.
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 PRODYNA XR contains:
The active substance is bupropion hydrochloride.
Each PRODYNA 150 mg XR tablet contains bupropion hydrochloride 150 mg.
Each PRODYNA 300 mg XR tablet contains bupropion hydrochloride 300 mg.

The other ingredients are:
Cores: glyceryl behenate, hydrophobic colloidal silica, L-cysteine hydrochloride monohydrate, polyvinyl alcohol.
Coating: colloidal silicon dioxide, dibutyl sebacate, ethyl cellulose, hydroxypropyl cellulose, methacrylic acid copolymer dispersion, povidone, triethyl citrate.
***Imprinting ink* – Opacode black:** ammonium hydroxide, iron oxide black, isopropyl alcohol, N-butyl alcohol, propylene glycol, shellac glaze.
PRODYNA XR is sugar free.

What PRODYNA XR looks like and contents of the pack
PRODYNA 150 mg XR: Off-white to pale yellow, round, biconvex, coated tablets, imprinted with "L015" in black ink on one side and plain on other side.
PRODYNA 300 mg XR: Off-white to pale yellow, round, biconvex, coated tablets, imprinted with "L016" in black ink on one side and plain on other side.

PRODYNA XR is packed into:
150 mg:
30's: White opaque 100 mL HDPE bottle containing 30 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabiliOx® strip form sachet closed with white child resistant closure.
90's: White opaque 150 mL HDPE bottle containing 90 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabiliOx® strip form sachet closed with white child resistant closure.
500's: White opaque 500 mL HDPE bottle containing 500 tablets along with one molecular sieve 5 g sachet, one activated carbon 5 g sachet and one StabiliOx® strip form sachet closed with white non child resistant closure.

300 mg:
30's: White opaque 100 mL HDPE bottle containing 30 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabiliOx® strip form sachet closed with white child resistant closure.
90's: White opaque 250 mL HDPE bottle containing 90 tablets along with one molecular sieve 1 g sachet, one activated carbon 1 g sachet and one StabiliOx® strip form sachet closed with white child resistant closure.
500's: White opaque 500 mL HDPE bottle containing 500 tablets along with one molecular sieve 5 g sachet, one activated carbon 5 g sachet and one StabiliOx® strip form sachet closed with white non child resistant closure.
**Not all pack sizes may be marketed.*

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pharma dynamics

This scissor cut mark are required in printing, it is not perforation

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S5

PRODYNA 150 mg XR langwerkende tablette
PRODYNA 300 mg XR langwerkende tablette
Bupropioenhidrochloried
Suikervry.

Lees hierdie hele inligtingsblad deeglik deur, voordat u begin om PRODYNA XR te gebruik
- 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.
- PRODYNA XR 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 ele.

Inhoud van hierdie inligtingsblad

1.Wat PRODYNA XR is en waarvoor dit gebruik word
PRODYNA XR bevat bupropion, een van 'n groep medisyne wat antidepressante genoem word.
PRODYNA XR is 'n medisyne wat gebruik word om u depressie te behandel.

2. Wat u nodig het om te weet, voordat u PRODYNA XR neem
Moet nie PRODYNA XR neem:
- indien u hipersensitief (allergies) is vir bupropion of vir enige van die ander bestanddele van PRODYNA XR nie (sien afdeling 6)
- indien u jonger as 18 jaar oud is nie
- indien u aan stuipe of aanvalle ly nie
- indien u enige medisyne neem, wat alreeds bupropienhidrochloried bevat nie
- indien u alkoholverbruik of die gebruik van kalmeermiddels, skielik gestaak het nie
- indien u tans of voorheen met die eetversteuring bulimie (eetwergryp, gevolg deur geforseerde braking), of anoreksie (abnormaal lae liggaamsgewig, met 'n intense vrees vir gewigstoename), gediagnoseer is nie
- indien u 'n medisyne wat 'n monoamieonoksidase-inhibitor (MAOI) is (antidepressante), neem nie
- indien u 'n lewersiekte het nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met PRODYNA XR:

Aanvalle:
U moet nie die PRODYNA XR dosis, soos deur u dokter voorgeskryf is, oorskry nie, aangesien die risiko vir aanvalle, verhoog.
U risiko vir aanvalle neem ook toe onder die volgende omstandighede en u moet dus u dokter raadpleeg indien enige van die volgende op u van toepassing is:
- indien u ooit enige stuipe of aanvalle ervaar het
- indien u ooit 'n ernstige hoofbesering gehad het
- indien u 'n breingewas het
- indien u enige medisyne vir aanvalle neem
- indien u diabetes het, waarvoor insulien of tablette gebruik word
- indien u gereeld, groot hoeveelhede alkohol gebruik
- indien u aan enige geestesongesteldheid (bulten depressie), insluitend eetversteurings, ly.

Indien u aanvalle (stuipe) ervaar tydens behandeling, staak die gebruik van PRODYNA XR en kontak u dokter onmiddellik.

Selfmoordgedagtes of agteruitgang van u toestand:
Indien u depressief is, mag u somtyds selfbesering- of selfmoordgedagtes ervaar. Hierdie gedagtes mag toeneem wanneer antidepressante vir die eerste maal gebruik word. Al hierdie medisyne neem tyd om te werk – gewoonlik ongeveer twee weke, maar somtyds langer.
U mag meer waarskynlik hierdie gedagtes ervaar:
- indien u voorheen selfbesering- of selfmoordgedagtes ervaar het
- indien u jonger as 25 jaar oud is.

Indien u selfbesering- of selfmoordgedagtes op enige tydstip ervaar: Verkry mediese advies so gou as moontlik (vanaf 'n doktar, of by 'n hospitaal).

U moet u dokter raadpleeg, veral indien:
- u onbehoerde koronêre arteriesiekte het ('n hartsiekte wat veroorsaak word deur swak bloedsirkulasie in die bloedvate van die hart), met simptome soos angina (gekenmerk deur borspyn), of 'n onlangse hartaanval gehad het
- indien u lewer- of nierprobleme het
- indien u 'n geskiedenis van manie het (voel verheug of hiperopgewonde, wat ongewone optrede tot gevolg het)
- indien u bejaard is.

Kinders en adolessente
PRODYNA XR moet nie deur kinders en adolessente jonger as 18 jaar oud, gebruik word nie.

Ander mediisyne en PRODYNA XR
Vertel altyd u gesondheidsorgverskaffer indien u enige ander mediisyne neem (dit sluit aanvullende of tradisionele mediisyne in).
U doktar mag u PRODYNA XR dosis aanpas, of 'n verandering in u bestaande mediisyne voorstel.

Moet nie PRODYNA XR neem saam met:
- **Monoamieoksidase-inhibitore** (mediisyne om depressie of Parkinson se siekte te behandel), soos fenelsien, selegilien, of rasagiliien. U moet die gebruik van hierdie mediisyne staak vir ten minste 14 dae, voordat u begin om PRODYNA XR te neem (sien Moet nie PRODYNA XR neem).

Vertel u dokter indien u enige van die volgende mediisyne neem, aangesien u dokter u noukeurig sal monitor vir newe-effekte:
- orfenadrien (om spierkrampe te behandel), siklofosfamied en ifosfamied (om sekere tipes kanker te behandel), tiklopidien (gebruik om die risiko vir 'n beroerte te verlaag), klopidogrel (gebruik om die risiko vir 'n hartsiekte en beroerte te verlaag)
- mediisyne wat die moontlikheid vir aanvalle (stuipe) verhoog bv. teofilien vir asma of longsiekte, tramadol ('n stark pynstiller)
- antidepressante, kalmeermiddels of sedeermiddels, bv. sitalopram, desipramien, amitriptilien, fluoksetien, sertralien, of enige ander mediisyne vir depressie of geestesongesteldheid, of indien u dit gaan staak, terwyl u PRODYNA XR neem
- mediisyne vir hoë bloeddruk of hartsiekte (betablokkers of antidisritmiese middels) bv. propranolol, amiodaroon
- mediisyne wat ritonavir genoem word en gebruik word om menslike immuniteitsgebrekvirus (MIV) te behandel
- mediisyne wat gebruik word om Parkinson se siekte te behandel en levodopa of amantadien bevat
- mediisyne wat gebruik word om epilepsie te behandel, soos karbamasepien, fenitoïien, of fenobarbitoon
- stimulante of mediisyne wat gebruik word om u eetlus te verminder
- nikotienplakkers om die rookgewoonte te staak.

Praat met u dokter of apteker voordat u PRODYNA XR neem:
Hartgeleidingsteurnisseurings bv. Brugada-sindroom – indien u aan 'n toestand wat Brugada-sindroom genoem word, ly ('n skaars, oorerflike sindroom wat die hartritme aantas), of indien hartaanval of skielike sterfte in u familie voorgekom het.

PRODYNA XR saam met kos, drinkgoed en alkohol
Uitermatige alkoholverbruik tydens u behandeling met PRODYNA XR, mag die risiko vir stuipe (aanvalle) en geestesversteuringsvoorvalle verhoog en alkoholverdraagsaamheid verminder. U doktar mag voorstel dat u geen alkohol inneem tydens u behandeling met PRODYNA XR nie, of om so min as moontlik te probeer drink. Indien u tans groot hoeveelhede alkohol inneem, moet u nie skielik ophou nie, aangesien u risiko vir stuipe, mag verhoog.

Swangerskap en borsvoeding
Indien u swanger is of borsvoed, vermoed dat u swanger is, of 'n baba beplan, raadpleeg asseblief u dokter, apteker, of ander gesondheidsorgverskaffer vir advies, voordat u PRODYNA XR gebruik.

Navorsing het aangedui dat daar 'n hoër risiko vir aangebore gebreke is, veral hartgebreke by babas wie se moeders PRODYNA XR gebruik het. Dus moet PRODYNA XR nie tydens swangerskap, of borsvoeding gebruik word nie.

Bestuur en die hantering van maasjiene:
PRODYNA XR mag u duiseling of ligkoppigheid maak.
Dit is nie altyd moontlik om te voorspel tot watter mate PRODYNA XR met u daaglikse aktiwiteite mag inmeng nie. U moet verseker dat u nie by bogenoemde aktiwiteite betrokke raak, totdat u bewus is hoe PRODYNA XR u aantas nie.

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

Volwassenes:
Die gewone aanvangsdosis vir volwassenes is een 150 mg tablet elke dag.
U doktar mag u dosis verhoog na 300 mg een keer 'n dag, indien u depressie nie verbeter na etlike weke nie.
Neem u PRODYNA XR dosis vroeg in die oggend.
Moet nie PRODYNA XR meer as een keer per dag neem nie.
U doktar mag u dosis aanpas:
- indien u lewer- of nierprobleme het
- indien u ouer as 65 jaar is.

Sluk die tablette heel in. Moet dit nie kou, verkrummel, of breek nie – indien u dit wel doen, sal die mediisyne te vinnig in u liggaam vrygestel word. Indien dit gebeur, mag u meer waarskynlik newe-effekte, insluitend aanvalle (stuipe) ervaar.

U doktar sal u vertel vir hoe lank u behandeling met PRODYNA XR sal duur. Moet nie behandeling vroegtydig staak nie, aangesien u depressie mag terugkeer.
Indien u onder die indruk is dat die uitwerking van PRODYNA XR tê sterk of tê swak is, vertel u doktar of apteker.

Indien u meer PRODYNA XR gebruik as wat u behoort:
In die geval van oordosering, raadpleeg u doktar of apteker. Indien beide nie beskikbaar is nie, kontak u naaste hospitaal, of gifbeheersentrum.

Simptome van oordosering mag die volgende insluit:
- lomerigheid, bewussynsverlies, onreëlmatige hartklop.

Indien u vergeet om PRODYNA XR te neem:
Indien u vergeet om PRODYNA XR te neem, wag en gaan dan voort om PRODYNA XR op die gewone tydstip te neem. Moet nie 'n dubbeldosis neem om op te maak vir die vergete individuele doserings nie.

Indien u die gebruik van PRODYNA XR staak
Dit is belangrik dat u voortgaan met die behandelingskursus, selfs al begin u beter voel na 'n paar dae. Indien u skielik die gebruik van hierdie mediisyne staak, mag die depressie-simptome terugkeer, of ongunstige effekte soos stuipe, mag voorkom.

4. Moontlike newe-effekte
PRODYNA XR kan newe-effekte hê.
Nie alle newe-effekte wat vir PRODYNA XR aangemeld is, word in hierdie inligtingsblad ingesluit nie. Sou u algemene gesondheid verslieg, of indien u enige ongunstige effekte ervaar, terwyl u PRODYNA XR gebruik, raadpleeg asseblief u doktar, apteker of ander gesondheidsorgdeskundige vir advies.

Indien enige van die volgende gebeur, staak die gebruik van PRODYNA XR en vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal:
- swelling van die hande, voete, enkels, gesig, lippe, mond, of keel, wat sluk en asemhaling mag bemoeilik
- uitslag of gejeuk
- aanvalle, floute.

Hierdie is alles baie ernstige newe-effekte. Indien u dit het, kon u 'n ernstige allergiese reaksie vir PRODYNA XR gehad het. U mag dringende mediese aandag of hospitalisasie benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal, indien u enige van die volgende opmerk:
- onreëlmatige hartklop (palpitasies), verhoogde, onreëlmatige, of vinnige hartklop (taglkardie), hartaanval, beroerte
- gemoedsveranderinge, buierigheid, of persoonlikheidsveranderinge, verwarring, depressie, aggressie, delusies, abnormale gedrag
- drink daaraan, of voel daarna om selfmoord te pleeg, selfmoordpoging
- hallusinasies (hoor stemme of sien dinge wat nie daar is nie), glo dinge wat nie waar is nie, of kom agterdogtig voor
- skielike borspyn weens bloedklonte in u longe
- Stevens-Johnson-sindroom ('n skaars velboestand met erge blaasvorming en bloeding van die lippe, oë, mond, neus en geslagsdele)
- vergeling van die vel en oë, ook geelsug genoem en lewerinflammasie.

Hierdie is alles ernstige newe-effekte. U mag dringende mediese aandag benodig.

Vertel u doktar indien u enige van die volgende opmerk:
Algemene newe-effekte:
- hipersensitiwiteitsreaksies, soos galbulte
- anoreksie/aptytverlies, gewigsverlies
- insomnie (slaapversteuring), agitasie, angstigheid
- hoofpyn, tremor, duiseligheid, smaaksteurnisse
- sigversteurings, geluid of gonsing in die ore
- hoë bloeddruk, blosing (warm gloed)
- droë mond, naarheid, braking, buikpyn, hardlywigheid
- uitslag, gejeuk, sweet
- koors, borspyn, energietekort.

Minder algemene newe-effekte:
- bloedglukose versteurings
- verwarring, depressie, aggressie, gevoel van teenkanting, onvriendelikheid of stuursheid teenoor iets of iemand, prikkelbaarheid, rusteloosheid, abnormale drome
- onvermoë om te konsentreer, onvermoë om spierbeweging te beheer, wat lei tot 'n abnormale stapgewoonte, spraak en oogbewegings, koördinasieprobleme, Parkinsonisme ('n versteuring van die sentrale senuweestelsel wat beweging aantas en dikwels tremors insluit), geheueverlies, "spelde en naalde"
- 'n vorm van lae bloeddruk wat gebeur wanneer u opstaan vanuit 'n sittende of liggende posisie
- 'n veinsaksie wat deur 'n infeksie of sommige mediisyne geaktiveer mag word
- bloedtoetse wat verhoogde lewerensiemvlakke aandui
- spiertrekkings
- wind dit nodig om meer dikwels te urineer, of onvermoë om te urineer.

Hoe PRODYNA XR lyk en die verpakkingsinhoud
PRODYNA 150 mg XR: Naaswit tot ligpeel, ronde bikonvekse bedekte tablette, gestempel met "L015" in swart ink aan een kant en glad aan die teenoorgestelde kant.
PRODYNA 300 mg XR: Naaswit tot ligpeel, ronde bikonvekse, bedekte tablette, gestempel met "L016" in swart ink aan een kant en glad aan die teenoorgestelde kant.

PRODYNA XR word verpak in:
150 mg:
30's: Wit onderuitgitige 100 mL HDPE bottel, wat 30 tablette bevat, saam met een molekulêre 1 g silfaskkie, een geaktiveerde koolstof sakkie en een StabiliOx® strookvorm sakkie, geseël met 'n wit peutervrye deksel.
90's: Wit onderuitgitige 150 mL HDPE bottel, wat 90 tablette bevat, saam met een molekulêre 1 g silfaskkie, een geaktiveerde koolstof 1 g sakkie en een StabiliOx® strookvorm sakkie, geseël met 'n wit peutervrye deksel.
500's: Wit onderuitgitige 500 mL HDPE bottel wat 500 tablette bevat, saam met een molekulêre 5 g silfaskkie, een geaktiveerde koolstof 5 g sakkie en een StabiliOx® strookvorm sakkie, geseël met 'n wit nie-peutervrye deksel.

300 mg:
30's: Wit onderuitgitige 100 mL HDPE bottel wat 30 tablette bevat, saam met een molekulêre 1 g silfaskkie, een geaktiveerde koolstof sakkie en een StabiliOx® strookvorm sakkie, met 'n wit peutervrye deksel.
90's: Wit onderuitgitige 250 mL HDPE bottel, wat 90 tablette bevat, saam met een molekulêre 1 g silfaskkie, een geaktiveerde koolstof 1 g sakkie en een StabiliOx® strookvorm sakkie, geseël met 'n wit peutervrye deksel.
500's: Wit onderuitgitige 500 mL HDPE bottel wat 500 tablette bevat, saam met een molekulêre 5 g silfaskkie, een geaktiveerde koolstof 5 g sakkie en een StabiliOx® strookvorm sakkie met 'n wit nie-peutervrye deksel.
**Alle verpakkingsgroottes word nie noodwendig bemark nie.*

Eienaar van die Registrasiesertifikaat
Pharma Dynamics (Edms.) Bpk.
1de Vloer Grapevine House, Steenberg Office Park
Silverwood Close
Westlake, 7945
Kaapstad, Suid-Afrika
Tel: + 27 21 707 7000
of 0860-PHARMA (7427 62)

Hierdie inligtingsblad was voorheen hersien
15 November 2024

Registrasienommers
PRODYNA 150 mg XR: A54/1.2/0181
PRODYNA 300 mg XR: A54/1.2/0182

B5841

pharma dynamics

Leaflet shall be kept separately inside the carton

280844 LFLT PRODYNA XR TABLET PD ZA R1 (BACK)

Market/Customer :	South Africa/Pharmadynamics	**Location :**	Goa
Prepared On :	19/06/2025	**Tracking No. :**	01
Product Name :	LFLT PRODYNA XR TABLET PD ZA R1		
Material Code :	280844	**Supersedes Material code :**	272875
Open Size :	700 x 450 mm (L x W)	**Pharmacode :**	10304
Folded Size :	80 x 45 mm (L x W)	**Component :**	Leaflet
Substrate :	GSM : 40 gsm	**Font Size :**	NA
	Paper : Bible Paper	**Gluing :**	Yes
Font Name :	NA		
Perforation :	NA		
Pantone Colours :	Black Dieline (does not print)		
Reason for Change :	Change in text matter as per customer requirment		
Unicorn Creation	D/Lupin/Regulatory/South Africa/Prodnya XR Tabs Pharmadynamics South Africa/		

Code No.: GO/DRUGS/654

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ID#: 280844