RASSETOM

SCHEDULING STATUS S3

1. NAME OF THE MEDICINE

RASSETOM 250 mg film coated tablets
RASSETOM 500 mg film coated tablets
RASSETOM 750 mg film coated tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each RASSETOM 250 mg tablet contains levetiracetam 250 mg.
Each RASSETOM 500 mg tablet contains levetiracetam 500 mg.
Each RASSETOM 750 mg tablet contains levetiracetam 750 mg.
RASSETOM tablets are sugar free.
Essentially 'sodium free'.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Film coated tablets.
RASSETOM 250 mg:
Blue, oblong-shaped, biconvex film coated tablets debossed with '250' on one side and a score line on the other side.
RASSETOM 500 mg:
Yellow, oblong-shaped, biconvex film coated tablets debossed with '500' on one side and a score line on the other side.
RASSETOM 750 mg:
Peach coloured, oblong-shaped, biconvex film coated tablets debossed with '750' on one side and a score line on the other side.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

RASSETOM is indicated as monotherapy in the treatment of partial onset seizures with or without secondary generalisation in patients from 16 years of age with newly diagnosed epilepsy.

RASSETOM is indicated as adjunctive therapy:
- in the treatment of partial onset seizures with or without secondary generalisation in adults and children over 16 years of age with epilepsy
- in the treatment of myoclonic seizures in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
- in the treatment of primary generalised tonic-clonic seizures in adults and children from 16 years of age with idiopathic generalised epilepsy.

4.2 Posology and method of administration

Posology
Monotherapy:
Adults and adolescents from 16 years of age:
The starting dose is 250 mg twice daily, which should be increased to an initial therapeutic dose of 500 mg twice daily after two weeks. The dose can be further increased by 250 mg twice daily, every two weeks, depending on the clinical response. The maximum daily dose is 1 500 mg twice daily.

Add-on therapy:
Adults and adolescents older than 12 years (weighing 50 kg or more when indicated (see section 4.1)):
As adjunctive therapy, the therapeutic dose is 500 mg twice daily. The dose can be started on the first day of treatment. Depending upon the clinical response and tolerance, the daily dose can be increased up to 1 500 mg twice daily. Dose changes can be made in 500 mg twice daily increments or decrements every two to four weeks. The maximum daily dose is 3 000 mg.

Special populations
Elderly:
Adjustment of the dose is recommended in elderly patients with compromised renal function (see *Patients with renal impairment* below).
Patients with renal impairment:
The RASSETOM dose should be individualised according to renal function. Refer to the table below and adjust the dose as indicated.
Dosing adjustment for adult patients with impaired renal function:

Group	Creatinine clearance (mL/min)	Dosage and frequency
Normal	> 80	500 - 1 500 mg twice daily
Mild	50 - 79	500 - 1 000 mg twice daily
Moderate	30 - 49	250 - 750 mg twice daily
Severe	< 30	250 - 500 mg twice daily
End-stage renal disease patients undergoing dialysis[2]	——	500 - 1 000 mg once daily[2]

[1] A 750 mg loading dose is recommended on the first day of treatment with RASSETOM.
[2] Following dialysis, a 250 mg to 500 mg supplemental dose is recommended.

To use this dosing table, an estimate of the patient's creatinine clearance (eCL_{cr}) in mL/min is needed.
The CL_{cr} can be estimated from the serum creatinine (S_{cr}) concentration using the modified formula of Cockfort and Gault (for use in adults):

$$eCL_{cr}\ (mL/min) = \frac{[140 - age]\ x\ Wt\ (kg)\ x\ constant^{*}}{S_{cr}\ (\mu mol/L)}$$

*Constant = 1,23 for males and 1,04 for females (0,85 x 1,23 = 1,04)

Patients with hepatic impairment:
No dose adjustment is needed in patients with mild to moderate hepatic impairment. In patients with severe hepatic impairment, the creatinine clearance may underestimate the renal insufficiency. Therefore a 50 % reduction of the daily maintenance dose is recommended when the creatinine clearance is < 70 mL/min.

Paediatric population
Monotherapy
Infants and children under the age of 12 years:
The safety and efficacy of RASSETOM in children and adolescents below 16 years as monotherapy treatment have not been established. No data are available.

Add-on therapy
Infants and children under the age of 12 years:
There are insufficient data available for the use of RASSETOM in children under the age of 12 years.

Adolescents (12 - 17 years) weighing less than 50 kg, when indicated (see section 4.1):
The initial therapeutic dose is 10 mg/kg twice daily. This dose can be started on the first day of treatment. Depending upon the clinical response and tolerability, the dose can be increased up to 30 mg/kg twice daily. Dose changes should not exceed increases or decreases of 10 mg/kg twice daily every two weeks. The lowest effective dose should be used. Dosage in children 50 kg or greater is the same as in adults. The doctor should prescribe the most appropriate pharmaceutical form and strength according to weight and dose.

Recommended dosage for children and adolescents with normal renal function:

Weight	Starting dose (10 mg/kg twice daily)	Maximum dose (30 mg/kg twice daily)
15 kg*	150 mg twice daily	450 mg twice daily
20 kg*	200 mg twice daily	600 mg twice daily
25 kg	250 mg twice daily	750 mg twice daily
From 50 kg**	500 mg twice daily	1 500 mg twice daily

* Another formulation of levetiracetam should be used.
** Dosage in children and adolescents 50 kg or more is the same as in adults.

Method of administration
The film coated tablets should be taken orally, swallowed with liquid, and may be taken with or without food. The daily dose is administered in two equally divided doses.

Missed dose
Medical practitioners should advise patients who forget to take RASSETOM to take a dose as soon as possible and then continue with the normal dose. Patients should not take a double dose to compensate for the missed dose.

4.3 Contraindications

RASSETOM is contraindicated in:
- patients with hypersensitivity to levetiracetam or other pyrrolidine derivatives or to any of the ingredients of RASSETOM
- pregnancy and lactation.

4.4 Special warnings and precautions for use

Suicide
Suicide, suicide attempt, suicidal ideation and behaviour have been reported in patients treated with antiepileptic medicines (including levetiracetam as in RASSETOM). Analysis of randomized placebo-controlled trials of antiepileptic medicines has shown a small increased risk of suicidal thoughts and behaviour. The mechanism of this risk is not known. Patients should be monitored for signs of depression and/or suicidal ideation and behaviours and appropriate treatment should be considered. Patients (and caregivers of patients) should be advised to seek medical advice should signs of depression and/or suicidal ideation or behaviour emerge (see section 4.8).

Renal impairment
Reduced doses of RASSETOM are recommended for patients with renal impairment (see section 4.2).
Patients receiving dialysis may be given a loading dose of 750 mg when starting RASSETOM followed by doses of 500 - 1 000 mg once daily, a supplemental dose of 250 - 500 mg is recommended after dialysis. In patients with severely impaired hepatic function, assessment of renal function is recommended before dose selection (see section 4.2).

Acute kidney injury
The use of RASSETOM has been very rarely associated with acute kidney injury, with a time to onset ranging from a few days to several months.

Severe hepatic impairment
RASSETOM should be used with caution in patients with severe hepatic impairment. No dose adjustment is needed in patients with mild to moderate hepatic impairment.
In patients with severe hepatic impairment, see section 4.2.

Blood cell counts
Rare cases of decreased blood cell counts (neutropenia, agranulocytosis, leucopenia, thrombocytopenia, and pancytopenia) have been described in association with RASSETOM administration, generally at the beginning of the treatment. Complete blood cell counts are advised in patients experiencing important weakness, pyrexia, recurrent infections, or coagulation disorders (see section 4.8).

Drug reaction with eosinophilia and systemic symptoms (DRESS)
Drug reactions with eosinophilia and systemic symptoms (DRESS), also known as hypersensitivity syndrome (HSS), is associated with a variable pattern of systemic symptoms including fever, lymphadenopathy, facial oedema, abnormalities of the blood, liver and kidney. Other common manifestations include arthralgias, jaundice, hepatomegaly, leucocytosis and eosinophilia. It is important to note that early manifestations of hypersensitivity, such as fever and lymphadenopathy, may be present even though rash is not evident. Patients at higher risk of developing HSS/DRESS include black patients, patients who have experience the syndrome in the past, patients who have a family history of this syndrome and immune-suppressed patients. This syndrome is more severe in previously sensitized individuals.
If any signs and symptoms are present, the patient should be evaluated immediately, and treatment discontinued if an alternate treatment cannot be established.

Abnormal and aggressive behaviours
RASSETOM may cause psychotic symptoms and behavioural abnormalities including irritability and aggressiveness. Patients treated with RASSETOM should be monitored for developing psychiatric signs suggesting important mood and/or personality changes. If such behaviours are noticed, treatment adaptation or gradual discontinuation should be considered.

Withdrawal of treatment
Withdrawal of RASSETOM or transition to or from another type of antiepileptic therapy should be made gradually (e.g. 500 mg twice daily decrements every two to four weeks in adults; 10 mg/kg twice daily decrements every two weeks in children) to avoid precipitating an increase in the frequency of seizures.

Worsening of seizures
As with other types of antiepileptic drugs, RASSETOM may rarely exacerbate seizure frequency or severity. This paradoxical effect was mostly reported within the first month after levetiracetam initiation or increase of the dose, and was reversible upon drug discontinuation or dose decrease. Patients should be advised to consult their medical practitioner immediately in case of aggravation of epilepsy.
Lack of efficacy or seizure worsening has for example been reported in patients with epilepsy associated with sodium voltage-gated channel alpha subunit 8 (SCN8A) mutations.

Electrocardiogram (ECG) QT interval prolongation
Rare cases of ECG QT interval prolongation have been observed during the post-marketing surveillance. RASSETOM should be used with caution in patients with QTc-interval prolongation, in patients concomitantly treated with drugs affecting the QTc-interval, or in patients with relevant pre-existing cardiac disease or electrolyte disturbances.

Paediatric population
Available data in children did not suggest impact on growth and puberty. However, long term effects on learning, intelligence, growth, endocrine function, puberty, and childbearing potential in children remain unknown.

Information on excipients of RASSETOM
RASSETOM contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

4.5 Interaction with other medicines and other forms of interaction

- potential interactions with existing antiepileptic medicines (such as phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin, and primidone) have not been demonstrated in adults. As in adults, there is no evidence of clinically significant medicinal product interactions in paediatric patients receiving up to 60 mg/kg/day levetiracetam
- a retrospective assessment of pharmacokinetic interactions in children and adolescents with epilepsy (4 - 17 years) confirmed that adjunctive therapy with orally administered levetiracetam did not influence the steady-state serum concentrations of concomitantly administered carbamazepine and valproate. However, data suggested a 20 % higher levetiracetam clearance in children taking enzyme-inducing antiepileptic medicines. Dose adjustment is not required
- probenecid (500 mg daily), a renal tubular secretion blocking agent, has been shown to inhibit the renal clearance of the primary metabolite but not of levetiracetam. Nevertheless, the concentration of this metabolite remains low. It is expected that other medicines excreted by active tubular secretion could also reduce the renal clearance of the metabolite. The effect of levetiracetam on probenecid was not studied. The effect of levetiracetam on other actively secreted medicines e.g. nonsteroidal anti-inflammatory drugs (NSAIDs) and sulphonamides is unknown
- concomitant administration of levetiracetam and methotrexate has been reported to decrease methotrexate clearance, resulting in increased/prolonged blood methotrexate concentration to potentially toxic levels. Blood methotrexate and levetiracetam levels should be carefully monitored in patients treated concomitantly with the two medicines
- RASSETOM did not influence the pharmacokinetics of oral contraceptives (ethinyl oestradiol and levonorgestrel), endocrine parameters (luteinising hormone (LH) and progesterone) were not modified. RASSETOM 2 000 mg daily did not influence the pharmacokinetics of digoxin and warfarin, prothrombin times were not modified. Co-administration with digoxin, oral contraceptives or warfarin had no influence on the pharmacokinetics of levetiracetam
- no information on the influence of antacids on the absorption of levetiracetam is available
- there have been isolated reports of decreased levetiracetam efficacy when the osmotic laxative macrogol has been concomitantly administered with oral levetiracetam. Therefore, macrogol should not be taken orally for one hour before and for one hour after taking levetiracetam
- the extent of absorption of levetiracetam was not altered by food, but the rate of absorption was slightly reduced
- no information on the interaction of levetiracetam with alcohol is available.

4.6 Fertility, pregnancy and lactation

Women of childbearing potential
Specialist advice should be given to women who are of childbearing potential. Treatment with levetiracetam should be reviewed when a woman is planning to become pregnant. As with all antiepileptic medicines, sudden discontinuation of levetiracetam should be avoided as this may lead to breakthrough seizures that could have serious consequences for the woman and the unborn child. Monotherapy should be preferred whenever possible because therapy with multiple antiepileptic medicines could be associated with a higher risk of congenital malformations than monotherapy, depending on the associated antiepileptics.

Pregnancy
RASSETOM is contraindicated in pregnancy and lactation (see section 4.3).

Breastfeeding
Levetiracetam is excreted in human breast milk. Patients using RASSETOM must not breastfeed.

Fertility
No impact on fertility was detected in animal studies (see section 5.3). No clinical data are available and potential risk for humans is unknown.

4.7 Effects on ability to drive and use machines

RASSETOM has minor or moderate influence on the ability to drive and use machines.
Caution is recommended in patients performing skilled tasks, e.g. driving vehicles or operating machinery. At the beginning of treatment or after a dosage increase, some patients may experience somnolence or other central nervous system (CNS) related symptoms such as headache, fatigue and dizziness.

4.8 Undesirable effects

a. Summary of the safety profile
The most frequently reported adverse reactions were nasopharyngitis, somnolence, headache, fatigue, and dizziness. The safety profile of levetiracetam is generally similar across age groups (adult and paediatric patients) and across the approved epilepsy indications.

b. Tabulated list of adverse reactions

System Organ Class	Frequency	Side effects
Infections and infestations	*Frequent*	Nasopharyngitis
	Less frequent	Infection
Blood and lymphatic system disorders	*Less frequent*	Leucopenia*, neutropenia*, pancytopenia*, thrombocytopenia*, agranulocytosis
Immune system disorders	*Less frequent*	Drug reaction with eosinophilia and systemic symptoms (DRESS), hypersensitivity (including angioedema and anaphylaxis)
Metabolism and nutrition disorders	*Frequent*	Anorexia
	Less frequent	Decreased weight*, increased weight, hyponatraemia
Psychiatric disorders	*Frequent*	Anxiety, depression, hostility, aggression, insomnia, nervousness, irritability
	Less frequent	Psychotic disorders*, mood swings*, agitation, personality disorder, emotional lability, suicide attempt*, suicidal ideation*, completed suicide*, abnormal behaviour*, hallucination*, anger*, confusional state*, panic attack affect/liability mood swings, thinking abnormal*, delirium, obsessive compulsive disorder (OCD)*
Nervous system disorders	*Frequent*	Dizziness, headache, somnolence, convulsion, balance disorder, lethargy, tremor
	Less frequent	Paraesthesia*, amnesia, memory impairment, abnormal coordination, ataxia, disturbance in attention, choreoathetosis, dyskinesia, hyperkinesia, gait disturbance, encephalopathy, seizures aggravated
Eye disorders	*Frequent*	Diplopia, blurred vision
Ear and labyrinth disorders	*Frequent*	Vertigo
Cardiac disorders	*Less frequent*	Electrocardiogram QT prolonged
Respiratory, thoracic, and mediastinal disorders	*Frequent*	Pharyngitis, rhinitis, cough
	Less frequent	Sinusitis
Gastrointestinal disorders	*Frequent*	Diarrhoea, dyspepsia, nausea, vomiting, abdominal pain
	Less frequent	Pancreatitis
Hepatobiliary disorders	*Less frequent*	Abnormal liver function tests*, hepatic failure*, hepatitis*
Skin and subcutaneous tissue disorders	*Frequent*	Rash
	Less frequent	Alopecia, eczema*, pruritus*, toxic epidermal necrolysis*, Stevens-Johnson syndrome*, erythema multiforme*
Musculoskeletal, connective tissue and bone disorders	*Frequent*	Ataxia, muscular weakness, myalgia
	Less frequent	Rhabdomyolysis and blood creatine phosphokinase increased**
Renal and urinary disorders	*Less frequent*	Acute kidney injury
General disorders and administrative site conditions	*Frequent*	Asthenia, fatigue
Investigations	*Less frequent*	Injury

*Post marketing side effects
** Prevalence is significantly higher in Japanese patients when compared to non-Japanese patients

c. Description of selected adverse reactions
The risk of anorexia is higher when levetiracetam is co-administered with topiramate.
In several cases of alopecia, recovery was observed when levetiracetam was discontinued.
Bone marrow suppression was identified in some of the cases of pancytopenia.
Cases of encephalopathy generally occurred at the beginning of the treatment (a few days to a few months) and were reversible after treatment discontinuation.

d. Paediatric population
The adverse reaction profile of levetiracetam is generally similar across age groups and across the approved epilepsy indications. Safety results in paediatric patients in placebo-controlled clinical studies were consistent with the safety profile of levetiracetam in adults except for behavioural and psychiatric adverse reactions which were more common in children than in adults.

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
Experience with levetiracetam overdose is limited. Symptoms that may occur with RASSETOM overdose include drowsiness, aggression, agitation, coma, depressed level of consciousness, respiratory depression, and somnolence.

Management of overdose
There is no specific antidote for RASSETOM overdose. Treatment should be symptomatic and supportive. Emesis should be attempted if indicated.
Standard haemodialysis should be considered, particularly, in selected patients based on clinical state of renal impairment.
The dialyser extraction efficiency is 60 % for levetiracetam and 74 % for the primary metabolite.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiepileptics, other antiepileptics.
ATC code: N03AX14
Pharmacological classification: A 2.5 Anticonvulsants, including antiepileptics.

Mechanism of action
Levetiracetam is an antiepileptic medicine. It is a pyrrolidine derivative, the S-enantiomer of α-ethyl-2-oxo-1-pyrrolidine acetamide, which is chemically unrelated to existing antiepileptic active substances. Levetiracetam inhibits partial and secondarily generalised tonic-clonic seizures in the kindling model of epilepsy. It is ineffective against maximum electroshock and pentylenetetrazol induced seizures. It is found to be more clinically effective against partial and secondarily tonic-clonic seizures. The mechanism by which levetiracetam exerts these anti-seizure effects is unknown. No evidence for an action on voltage-gated sodium Na+ channels or either gamma-aminobutyric acid GABA- or glutamate-mediated synaptic transmission has emerged.

5.2 Pharmacokinetic properties

The pharmacokinetic profile is dose linear with low intra- and inter-subject variability. There is no modification of the clearance after repeated administration. There is no evidence for any relevant gender, race, or circadian variability. The pharmacokinetic profile is comparable in healthy volunteers and in patients with epilepsy.
Due to its complete and linear absorption, plasma levels can be predicted from the oral dose of levetiracetam expressed as mg/kg bodyweight. Therefore, there is no need for plasma level monitoring of levetiracetam.

A significant correlation between saliva and plasma concentrations has been shown in adults and children (ratio of saliva/plasma concentrations ranged from 1 - 1,7 for oral tablet formulation and after 4 hours post-dose for oral solution formulation).

Absorption:
Levetiracetam is rapidly and almost completely absorbed after oral administration, oral bioavailability is 100 %. Peak plasma concentrations (C_{max}) are achieved at 1,3 hours after dosing. Steady-state is achieved after 2 days of a twice daily administration schedule. Plasma protein binding is minimal (< 10 %). Peak concentrations (C_{max}) are typically 31 and 43 µg/mL following a single 1 000 mg dose and repeated 1 000 mg twice daily dose, respectively. The extent of absorption is dose-independent and is not altered by food.
Distribution:
No tissue distribution data are available in humans. Neither levetiracetam nor its primary metabolite are significantly bound to plasma proteins (< 10 %). The volume of distribution of levetiracetam is approximately 0,5 - 0,7 L/kg, a value close to the volume of distribution of intracellular and extracellular water.

Biotransformation:
Levetiracetam is not extensively metabolised in humans.
The major metabolic pathway (24 % of the dose) is an enzymatic hydrolysis of the acetamide group. Production of the primary metabolite, ucb L057, is not supported by liver cytochrome P450 isoforms. Hydrolysis of the acetamide group was measurable in a large number of tissues including blood cells. The metabolite ucb L057 is pharmacologically inactive.
Two minor metabolites were also identified. One was obtained by hydroxylation of the pyrrolidone ring (1,6 % of the dose) and the other one by opening of the pyrrolidone ring (0,9 % of the dose).

Other unidentified components accounted only for 0,6 % of the dose. No enantiomeric interconversion was evidenced *in vivo* for either levetiracetam or its primary metabolite.
In vitro, levetiracetam and its primary metabolite have been shown not to inhibit the major human liver cytochrome P450 isoforms (CYP3A4, 2A6, 2C9, 2C19, 2D6, 2E1 and 1A2), glucuronyl transferase (UGT1A1 and UGT1A6) and epoxide hydroxylase activities. In addition, levetiracetam does not affect the *in vitro* glucuronidation of valproic acid.

In human hepatocytes in culture, levetiracetam had little or no effect on CYP1A2, SULT1E1 or UGT1A1.
Levetiracetam caused mild induction of CYP2B6 and CYP3A4. The *in vitro* data and *in vivo* interaction data on oral contraceptives, digoxin and warfarin indicate that no significant enzyme induction is expected *in vivo*. Therefore, the interaction of levetiracetam with other substances, or vice versa, is unlikely.

Elimination:
The plasma half-life in adults has been reported as 7 ± 1 hours and did not vary with dose, route of administration or repeated administration. The total body clearance was a mean of 0, 96 mL/min/kg.
Approximately 95 % are excreted in the urine, (approximately 93 % of the dose was excreted within 48 hours) 66 % of which is unchanged and 24 % is metabolised by hydrolysis of the acetamide group.
Excretion via faeces accounted for only 0,3 % of the dose.
Levetiracetam neither induces nor is a high-affinity substrate for cytochrome P450 isoforms of glucuronidation enzymes and thus is devoid of known interactions with other anti-seizure medicines, oral contraceptives, or anticoagulants.

Pharmacokinetics in special patient groups
Elderly:
In the elderly, the half-life is increased by about 40 % (10 - 11 hours). This is related to the decrease in renal function in this population (see section 4.2).
Renal impairment:
The apparent body clearance of both levetiracetam and of its primary metabolite is correlated to the creatinine clearance. It is therefore recommended that the maintenance daily dose of levetiracetam be adjusted, based on creatinine clearance in patients with moderate and severe renal impairment (see section 4.2). In anuric end-stage renal disease subjects, the half-life was approximately 25 and 3,1 hours during interdialytic and intradialytic periods, respectively. The fractional removal of levetiracetam was 51 % during a typical 4-hour dialysis session.
Hepatic impairment:
In subjects with mild and moderate hepatic impairment, there was no relevant modification of the clearance of levetiracetam. In most subjects with severe hepatic impairment, the clearance of levetiracetam was reduced by more than 50 % due to a concomitant renal impairment (see section 4.2).

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, genotoxicity, and carcinogenic potential.

Adverse effects, not observed in clinical studies but seen in the rat and to a lesser extent in the mouse, at exposure levels similar to human exposure levels and with possible relevance for clinical use were liver changes, indicating an adaptive response such as increased weight and centrilobular hypertrophy, fatty infiltration, and increased liver enzymes in plasma.

No adverse reactions on male or female fertility or reproduction performance were observed in rats at doses up to 1800 mg/kg/day (≥ 6 the maximum recommended human dose (MRHD) on a mg/m² or exposure basis) in parents and F1 generation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Tablet cores:
Croscarmellose sodium
Magnesium stearate
Maize starch
Microcrystalline cellulose
Povidone
Silica colloidal
Talc

Tablet coating:
Opadry blue AMB 84F80803: (FD & C blue #2/Indigo carmine aluminium lake)
Opadry pink AMB 84F 84674: (FC & C yellow #6 Sunset yellow FCF aluminium lake, iron oxide red, iron oxide yellow)
Opadry white AMB 84F58775
Opadry yellow AMB 84FB2508: (Iron oxide yellow)

Excipients common to Opadry variants:
Macrogol
Macrogol
Polyvinyl alcohol (part hydrolysed)
Talc
Titanium dioxide

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store at or below 30 °C. Keep blisters in carton until required for use.

6.5 Nature and contents of container

RASSETOM tablets are available in clear PVC/Aluminium blister strips, in pack sizes of 30 or 60 tablets, packed in an outer cardboard box.
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

RASSETOM 250 mg: A44/2.5/0368
RASSETOM 500 mg: A44/2.5/0369
RASSETOM 750 mg: A44/2.5/0370

9. DATE OF FIRST AUTHORISATION

Date of registration: 01 March 2013

10. DATE OF REVISION OF THE TEXT

28 February 2025

NAMIBIA:
RASSETOM 250 mg: NAM/NS2 13/2.5/0178
RASSETOM 500 mg: NAM/NS2 13/2.5/0179
RASSETOM 750 mg: NAM/NS2 13/2.5/0180

pharma dynamics

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: S3

RASSETOM 250 mg film coated tablets
RASSETOM 500 mg film coated tablets
RASSETOM 750 mg film coated tablets
Levetiracetam
RASSETOM tablets are sugar free.
Essentially 'sodium free'.

Read all of this leaflet carefully before you start taking RASSETOM
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist, nurse or other healthcare provider.
- RASSETOM 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 RASSETOM is and what it is used for

RASSETOM contains levetiracetam, an antiepileptic medicine.

RASSETOM is used for
- seizures in adults and children over the age of 16 years, when epilepsy is diagnosed for the first time.

RASSETOM can also be used as an additional medicine to treat:
- seizures in adults and children over the age of 16 years, when epilepsy is diagnosed
- myoclonic seizures (short, shock-like jerks of a muscle or group of muscles) in adults and adolescents from 12 years of age with juvenile myoclonic epilepsy
- primary generalised tonic-clonic seizures (major fits, including loss of consciousness) in adults and adolescents from 16 years of age with idiopathic generalised epilepsy (the type of epilepsy that is thought to have a genetic cause).

2. What you need to know before you take RASSETOM
Do not take RASSETOM:
- if you are hypersensitive (allergic) to levetiracetam or any of the other ingredients of RASSETOM (see section 6)
- if you are pregnant, suspect you are pregnant or breastfeeding.

Warnings and precautions

Take special care with RASSETOM:
- If you have thoughts of harming or killing yourself. If you have any symptoms of depression and/or suicidal ideation, please contact your doctor immediately
- if you suffer from kidney problems, or receive dialysis, follow your doctor's instructions. He/she may decide that your dose should be adjusted
- if you have a severe liver disease
- If you suffer from high fever or recurring infections, or bleeding disorders, as the doctor may want to do blood tests and monitor your condition
- if you have abnormal thoughts, feel irritable or react more aggressively than usual, or if you or your family and friends notice important changes in mood or behaviour
- if you experience a serious untoward reaction, DRESS (drug reaction with eosinophilia and systemic symptoms) also known as HSS (hypersensitivity syndrome), contact your doctor immediately or go to the casualty department at your nearest hospital. It clinically manifests as a feeling of discomfort, severe itching of the skin, fever, facial oedema and swollen lymph nodes. Early symptoms of DRESS, such as fever or swollen lymph nodes can be present even when a rash cannot be seen
- If you experience worsening of your seizures, especially at the start of therapy or when your dose is increased, contact your doctor immediately
- If you have a family or medical history of irregular heart rhythm (visible on an electrocardiogram), or if you have a disease and/or take a treatment that make(s) you prone to heartbeat irregularities or salt imbalances
- If you stop taking RASSETOM suddenly, you may have increased seizures. Tell your doctor if you have new or worsening seizures. Do not stop taking RASSETOM without first talking to your doctor, even if you feel better (see section 3, If you stop taking).

Children and adolescents

RASSETOM should not be given to infants and children under the age of 12 years.
If you notice any slowdown in the growth or unexpected puberty development of your child, please contact your doctor.

Other medicines and RASSETOM

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional medicines.)
- other antiepileptic medicines (such as phenytoin, carbamazepine, valproic acid, phenobarbital, lamotrigine, gabapentin, and primidone), as they may affect the way RASSETOM works
- probenecid (a medicine used to increase uric acid excretion by the kidneys in patients with gout), as this may affect the way RASSETOM works
- methotrexate (a medicine used to treat certain types of cancer), as the use of RASSETOM may increase your blood levels of methotrexate
- do not take macrogol (a medicine used as a laxative) for one hour before and one hour after taking RASSETOM, as this may result in a loss of its effect.

RASSETOM with food and drink

RASSETOM should be taken by mouth, swallowed with liquid and may be taken with or without food.

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 taking this medicine.

Do not take RASSETOM if you are pregnant or suspect that you are pregnant. Contact you doctor immediately.

Do not take RASSETOM if you are breastfeeding your baby (see Do not take RASSETOM).

Driving and using machines

RASSETOM has minor or moderate influence on the ability to drive and use machines.
RASSETOM may make you feel sleepy or dizzy. It is not always possible to predict to what extent RASSETOM may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which RASSETOM affects them.

RASSETOM contains sodium

RASSETOM contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium free'.

3. How to take RASSETOM

Do not share medicines prescribed for you with any other person.
Always take RASSETOM exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

When RASSETOM is used alone:
Adults and children from 16 years of age:
The recommended starting dose is 250 mg twice daily which should be increased to an initial dose of 500 mg twice daily after two weeks. The dose can be further increased by 250 mg twice daily every two weeks depending upon the clinical response as determined by your doctor. The maximum daily dose is 1 500 mg twice daily.

When RASSETOM is taken in combination with other antiepileptic medicines:
Adults and children older than 12 years of age (weighing 50 kg or more):
The recommended dose is 500 mg twice daily. Depending upon the response and tolerance the daily dose can be increased up to 1 500 mg twice daily. The maximum daily dose is 3 000 mg.

Your doctor may occasionally change your dose to make sure you get the best results from this medicine.

Children:
Children 12 - 17 years of age weighing less than 50 kg:
The recommended dose is 10 mg/kg twice daily.
Depending upon response and tolerability the dose can be increased up to 30 mg/kg twice daily.

RASSETOM should not be given to children under the age of 12 years.

Your doctor will tell you how long your treatment with RASSETOM will last. Do not stop treatment early because this could increase your seizures. If you have the impression that the effect of RASSETOM is too strong or too weak, tell your doctor or pharmacist.

If you take more RASSETOM 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:
- sleepiness, agitation, aggression, decrease of alertness, inhibition of breathing and coma.

If you forget to take RASSETOM

If you forget to take RASSETOM, take as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at the next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

If you stop taking RASSETOM

It is important that you continue the course of treatment. Do not stop treatment early because your seizures can increase. Do not stop taking RASSETOM unless your doctor tells you to do so.

4. Possible side effects

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

If any of the following happens, stop using RASSETOM 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.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to RASSETOM. 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:
- signs of serious mental changes or if someone around you notices signs of confusion, somnolence (sleepiness), amnesia (loss of memory), memory impairment (forgetfulness), abnormal behaviour, worsening or increase in frequency of seizures
- psychological problems, mood or mental changes, agitation, lack of interest in life, depersonalisation, personality problems, excessively emotional, suicide, suicide attempt, suicidal ideas, abnormal behaviour, hallucination, anger, state of confusion, panic attack, mood swings, abnormal thinking, delirium, obsessive compulsive disorder (OCD)
- Stevens-Johnson syndrome (a life-threatening skin disorder with symptoms such as a red-purplish rash and blisters) or any other blisters with a dark ring around the edge or a severe rash with skin peeling
- symptoms such as low urine volume, tiredness, nausea, vomiting, confusion and swelling in the legs, ankles, or feet, as this may be a sign of sudden decrease of kidney function
- a more severe form of rash causing skin peeling in more than 30 % of the body surface (toxic epidermal necrolysis)
- a skin rash which may form blisters and look like small targets (central dark spots surrounded by a paler area, with a dark ring around the edge) – (erythema multiforme)
- pancreatitis (symptoms may include) pain in the upper abdomen that radiates to the back, tenderness when touching the upper abdomen, fever, rapid pulse, upset stomach, vomiting
- intense muscle aching or swelling, muscle weakness or stiffness, destruction of striated muscle cells, muscle tissue damage feeling exhausted, dark red or brown urine, or very little or no urine, fever as these may be signs of rhabdomyolysis (a serious medical condition that can be fatal or result in permanent disability).

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:
- loss of appetite, anorexia
- irritability, anxiety, depression, hostility, problem getting to sleep, nervousness, aggression
- dizziness (sensation of spinning), headache, sleeping problems, convulsions, balance disorder, involuntary trembling, lack of energy or enthusiasm
- double vision, blurred vision
- vertigo (sensation of rotation)
- diarrhoea, indigestion, nausea, vomiting, abdominal pain
- runny nose, inflammation of nasal passages, sore throat, cough, common cold
- skin rash
- muscle pain, muscle weakness, loss of full control of bodily movement
- unusual weakness or tiredness.

Less frequent side effects:
- infection
- decreased number of red blood cells and/or white blood cells and/or platelets (as seen in blood test results)
- weight loss, weight gain, decreased blood sodium concentration
- inflammation of the liver, liver failure, abnormal liver test results
- burning and pricking sensation (pins and needles), memory loss, memory impairment, disturbance in attention, abnormal involuntary body movements, impairment of voluntary movement, increased muscular movement
- palpitations (irregular heartbeat)
- inflammation of the sinuses (sinusitis)
- eczema, itching, hair loss
- injury.

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 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 RASSETOM. You can also send an email directly to the company, pharmacovigilance@pharmadynamics.co.za, to ensure safety of the product.

5. How to store RASSETOM

Store all medicines out of reach of children.
Store at or below 30 °C. 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 RASSETOM contains:
The active substance in each RASSETOM 250 mg tablet contains levetiracetam 250 mg.
The active substance in each RASSETOM 500 mg tablet contains levetiracetam 500 mg.
The active substance in each RASSETOM 750 mg tablet contains levetiracetam 750 mg.
The other ingredients are:
Tablet cores:
Croscarmellose sodium, magnesium stearate, maize starch, microcrystalline cellulose, povidone, silica colloidal, talc.
Tablet coating:
Opadry blue AMB 84F80803: (FD & C blue #2/Indigo carmine aluminium lake)
Opadry pink AMB 84F 84674: (FC & C yellow #6 Sunset yellow FCF aluminium lake, iron oxide red, iron oxide yellow)
Opadry white AMB 84F58775
Opadry yellow AMB 84F82508: (iron oxide yellow)
Excipients common to Opadry variants:
Macrogol, macrogol, polyvinyl alcohol (part hydrolysed), talc, titanium dioxide.

What RASSETOM looks like and contents of the pack
RASSETOM 250 mg:
Blue, oblong-shaped, biconvex film coated tablets debossed with "250" on one side and a score line on the other side.

RASSETOM 500 mg:
Yellow, oblong-shaped, biconvex film coated tablets debossed with "500" on one side and a score line on the other side.

RASSETOM 750 mg:
Peach coloured, oblong-shaped, biconvex film coated tablets debossed with "750" on one side and a score line on the other side.

RASSETOM tablets are available in clear PVC/Aluminium blister strips, in pack sizes of 30 or 60 tablets, packed in an outer cardboard box.

Not all pack sizes may be marketed

Holder of Certificate of Registration
Pharma Dynamics (Pty) Ltd
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Registration numbers
RASSETOM 250 mg: A44/2.5/0368
RASSETOM 500 mg: A44/2.5/0369
RASSETOM 750 mg: A44/2.5/0370

NAMIBIA:
RASSETOM 250 mg: NAM NS2 13/2.5/0178
RASSETOM 500 mg: NAM NS2 13/2.5/0179
RASSETOM 750 mg: NAM NS2 13/2.5/0180

pharma dynamics

G6177

PASIËNTINLIGTINGSBLAD

SKEDULERINGSTATUS: S3

RASSETOM 250 mg filmbedekte tablette
RASSETOM 500 mg filmbedekte tablette
RASSETOM 750 mg filmbedekte tablette
Levetirasetam
RASSETOM tablette is suikervry.
Wesenlik 'natriumvry'.

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

Inhoud van hierdie inligtingsblad

1. Wat RASSETOM is en waarvoor dit gebruik word

RASSETOM bevat levetiracetam, 'n antiepileptiese medisyne.

RASSETOM word gebruik vir die behandeling van:
- aanvalle by volwassenes en kinders ouer as 16 jaar oud, wanneer epilepsie vir die eerste maal gediagnoseer is.

RASSETOM kan ook gebruik word as 'n bykomende medisyne om die volgende te behandel:
- aanvalle by volwassenes en kinders ouer as 16 jaar oud, wanneer epilepsie gediagnoseer is
- miokloniese aanvalle (kort, skok-soortige rukkings van 'n spiergroep, of spiere) by volwassenes en adolessente vanaf 12 jaar oud met jeug-miokloniese epilepsie
- primêre, algemene tonies-kloniese aanvalle (major stuipe, insluitend gehoueverlies) by volwassenes en adolessente vanaf 16 jaar oud, met idiopatiese algemene epilepsie (die tipe epilepsie wat vermoedelik van genetiese oorsprong is).

2. Wat u nodig het om te weet, voordat u RASSETOM neem
Moet nie RASSETOM neem:
- indien u hipersensitief (allergies) is vir levetiracetam, of enige van die bestanddele van RASSETOM nie (sien afdeling 6)
- indien u swanger is, vermoed dat u swanger is, of u baba borsvoed nie.

Waarskuwings en voorsorgmaatreëls
Neem spesiale sorg met RASSETOM:
- indien u selfbeserings-, of selfmoordgedagtes het. Indien u enige simptome van depressie en/of selfmoordneigings ervaar, kontak asseblief u dokter onmiddellik.
- indien u aan nierprobleme lei, of dialise ontvang, volg u dokter se instruksies. Hy/sy mag besluit om u dosis aan te pas
- indien u enige lewersiekte het
- indien u hoë koors het, of herhalende infeksies opdoen, of bloedversteurings ervaar, aangesien u dokter bloedtoetse mag aanvra en u toestand monitor
- indien u abnormale gedagtes ervaar, prikkelbaar voel, of meer aggressief as gewoonlik reageer, of indien u of u familie en vriende belangrike veranderinge in u buie of optrede, opmerk
- indien u 'n ernstige ongunstige reaksie, GRESS (geneesmiddelreaksie met eosinofilie en sistemiese simptome), ook bekend as RSS (hipersensitiwiteitsindroom) ervaar, kontak u dokter onmiddellik, of gaan na die ongevalle afdeling by u naaste hospitaal. Dit manifesteer klinies as 'n gevoel van ongemak, erge gejeuk van die vel, koors, geslagsdeeltes en geswelde limfnode. Vroeë simptome van GRESS, soos koors of geswelde limfnode, kan teenwoordig wees, sonder dat 'n uitslag opgemerk word
- indien u aanvalle vererger, veral tydens die aanvang van behandeling, of wanneer die dosis verhoog word, kontak u dokter onmiddellik.
- indien u 'n familie of mediese geskiedenis van onreëlmatige hartritme het (sigbaar op 'n elektrokardiogram), of u 'n siekte het en/of behandeling ondergaan wat u geneig maak tot hartklop onreëlmatighede, of soutwanbalans
- indien u RASSETOM skielik staak, mag u aanvalle toeneem. Vertel u dokter indien u nuwe aanvalle, of aanvalle wat vererger, ondervind. Moet nie RASSETOM ophou gebruik, sonder om dit eers met u dokter te bespreek nie, selfs al voel u beter (sien afdeling 3, Indien u die gebruik staak).

Kinders en adolessente

RASSETOM moet nie aan babas of kinders jonger as 12 jaar oud, gegee word nie.
Indien u enige groeivertraging, of onverwagte puberteitontwikkeling by u kind opmerk, raadpleeg asseblief u dokter.

Ander medisyne en RASSETOM

Vertel altyd u gesondheidsorgverskaffer indien u enige ander medikasie neem (Dit sluit aanvullende, of tradisionele medisyne in).
- ander antiepileptiese medisyne (soos fenitoïen, karbamasepien, valproïensuur, fenobarbitaal, lamotrigien, gabapentien en primidoon), aangesien dit die werking van RASSETOM mag beïnvloed
- probenesied ('n medisyne wat gebruik word om uriensuuruitskeiding deur die niere, by pasiente met jig, te verhoog), aangesien dit die werking van RASSETOM mag beïnvloed
- metotreksaat ('n medisyne wat gebruik word om sekere tipes kankers te behandel), aangesien die gebruik van RASSETOM, u bloedvlakke van metotreksaat, mag verhoog
- moet nie makrogol ('n medisyne wat as 'n laksaermiddel gebruik word) neem, vir een uur voordat en een uur nadat u RASSETOM geneem het nie, aangesien dit 'n verlies van doeltreffendheid tot gevolg mag hê.

RASSETOM saam met kos en drinkgoed

RASSETOM moet mondelings, met vloeistof gesluk word en mag saam met, of sonder kos geneem word.

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 hierdie medisyne neem.

Moet nie RASSETOM neem indien u swanger is, of vermoed dat u swanger is nie. Kontak u dokter onmiddellik.

Moet nie RASSETOM neem indien u u baba borsvoed nie (sien Moet nie RASSETOM neem).

Bestuur en die hantering van maasjiene

RASSETOM het geringe of matige invloed op die vermoë om te bestuur en masjiene te gebruik.
RASSETOM mag u slaperig of duiselig laat voel. Dit is nie altyd moontlik om te voorspel tot watter mate RASSETOM met die daaglikse aktiwiteite van 'n pasient sal inmeng nie. Pasiente moet verseker dat hulle nie by bogenoemde aktiwiteite betrokke raak, totdat hulle bewus is tot watter mate RASSETOM hulle beïnvloed nie.

RASSETOM bevat natrium

RASSETOM bevat minder as 1 mmol (23 mg) natrium per tablet, dit wil sê wesenlik 'natriumvry'.

3. Hoe om RASSETOM te neem

Moet nie medisyne wat vir u voorgeskryf is met enige ander persoon deel nie. Neem RASSETOM altyd presies soos deur u dokter aangedui word.
Raadpleeg u dokter of apteker indien u onseker is.

Wanneer RASSETOM alleen gebruik word:
Volwassenes en kinders vanaf die ouderdom van 16 jaar:
Die aanbevole aanvangsdosis is 250 mg twee keer daagliks, wat verhoog kan word na 'n aanvangsdosis van 500 mg twee keer daagliks, na twee weke. Die dosis mag verder verhoog word met 250 mg twee keer daagliks, elke twee weke, in ooreenstemming met die kliniese reaksie, soos deur u dokter bepaal word. Die maksimum daaglikse dosis is 1 500 mg twee keer daagliks.

Wanneer RASSETOM in kombinasie met ander anti-epileptiese medisyne geneem word:
Volwassenes en kinders ouer as 12 jaar oud (wat 50 kg of meer weeg):
Die aanbevole dosis is 500 mg twee keer daagliks. Afhangende van die reaksie en verdraagsaamheid, mag die daaglikse dosis verhoog word tot 1 500 mg twee keer daagliks. Die maksimum daaglikse dosis is 3 000 mg.

U dokter mag van tyd tot tyd u dosis aanpas om seker te maak u kry die beste resultate met hierdie medisyne.

Kinders:
Kinders 12 - 17 jaar oud, wie minder as 50 kg weeg:
Die aanbevole dosis is 10 mg/kg twee keer daagliks.
Afhangende van die reaksie en verdraagsaamheid, mag die dosis na 30 mg/kg, twee keer daagliks verhoog word.

RASSETOM moet nie aan kinders jonger as 12 jaar oud gegee word nie.

U dokter sal u vertel vir hoe lank u behandeling met RASSETOM sal duur. Moet nie behandeling vroegtydig staak nie, aangesien u aanvalle mag toeneem. Indien u onder die indruk is dat die werking van RASSETOM te sterk of te swak is, vertel u dokter of apteker.

Indien u meer RASSETOM neem as wat u behoort

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:
- slaperigheid, agitasie, aggressie, vermindering in waaksaamheid, moeilike asemhaling en koma.

Indien u vergeet om RASSETOM te neem

Indien u vergeet om RASSETOM te neem, neem dit so gou as wat u onthou. Indien dit egter amper tyd is vir u volgende dosis, slaan die vergete dosis oor en neem die medisyne op die volgende geskeduleerde tydstip. Moet nie 'n dubbeldosis neem, om op te maak vir die vergete, individuele doserings nie.

Indien u die gebruik van RASSETOM staak

Dit is belangrik dat u voortgaan met die behandelingskursus. Moet nie behandeling vroegtydig staak nie, aangesien u aanvalle mag toeneem. Moet nie die gebruik van RASSETOM staak, tensy u dokter so aanbeveel nie.

4. Moontlike newe-effekte

RASSETOM kan newe-effekte hê.
Nie alle newe-effekte wat vir RASSETOM aangemeld is, word in hierdie inligtingsblad genoem nie. Sou u algemene gesondheid versleg, of u enige ongunstige effekte ervaar terwyl u RASSETOM gebruik, raadpleeg asseblief u dokter, apteker of gesondheidsorgverskaffer vir advies.

Indien enige van die volgende gebeur, staak die gebruik van RASSETOM 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 of asemhaling bemoeilik
- uitslag of gejeuk.

Hierdie is alles baie ernstige newe-effekte. Indien u dit ervaar, kon u 'n ernstige allergiese reaksie teenoor RASSETOM ervaar het. U mag dringende mediese aandag, of hospitaalsorg benodig.

Vertel u dokter onmiddellik, of gaan na die ongevalle-afdeling by u naaste hospitaal indien u enige van die volgende opmerk:
- tekens van ernstige gemoedsveranderinge, of indien iemand naby u, tekens van verwarring, slaperigheid, amnesie (geheueverlies), geheuebelemmering (vergeetagtigheid), abnormale gedrag, vergergering of toename van aanvalle, opmerk.
- psigologiese probleme, gemoeds-, of sielkundige veranderinge, agitasie, gebrek aan belangstelling in die lewe, depersonalisasie, persoonlikheidsprobleme, uitermatig emosioneel, selfmoord, selfmoordpoging, selfmoordgedagtes, abnormale optrede, hallusinasie, woede, toestand van verwarring, paniekaanval, buierigheid, abnormale denke, delirium, obsessief kompulsiewe steuring (OKS)
- Stevens-Johnson-sindroom ('n lewensbedreigende velsiandoening, met simptome soos 'n rooi-pers uitslag en blase) of enige ander blase met 'n donker ring rondom die rand, of 'n erge uitslag met velafskilfering
- simptome soos 'n lae urienvolume, moegheid, naarheid, braking, verwarring en swelling van die bene, enkels of voete, aangesien dit 'n teken van 'n skielike afname in nierfunksie mag wees
- 'n erger vorm van uitslag wat velafskilfering op meer as 30 % van die liggaamsoppervlak veroorsaak (toksiese epidermale nekrolise)
- 'n veluitslag wat blase kan vorm en soos klein teikens lyk (sentrale donker kolle omring deur 'n ligter area, met 'n donker ring rondom die rand) – (erythema multiforme)
- pankreatitis (simptome mag pyn in die bo-buik wat uitstraal na die rug, gevoeligheid wanner die bo-buik aangeraak word, koors, vinnige polsslag, omgekrapte mag en braking, insluit)
- erge spierpyne en swelling, spierswakheid of -styfheid, vernietiging van gestreepte spierselle, spierweefselbeskadiging, voel uitgeput, donker rooi of bruin urine, of baie min of geen urine, koors, aangesien dit tekens kan wees van rabdomiolise ('n ernstige mediese toestand wat noodlottig mag wees, of tot permanente gestremdheid mag lei).

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

Vertel u dokter indien u enige van die volgende opmerk:
Algemene newe-effekte:
- aptyterlies, anoreksie
- prikkelbaarheid, angstigheid, depressie, vyandigheid, sukkel om aan die slaap te raak, senuweeagtigheid, aggressie
- duiseligheid (draaigevoel) hoofpyn, slaapprobleme, konvulsies, balansversteuring, onwillekeurige bewing, energieverlies of gebrek aan entoesiasme
- dubbelsien, waasige visie
- vertigo (draaisensasie)
- diarree, slegte spysvertering, naarheid, braking, buikpyn
- loopneus, inflammasie van die neuskanale, seer keel, hoes, algemene verkoue
- veluitslag
- spierpyn, spierswakheid, verlies van algehele beheer van liggaamsbeweging
- ongewone swakheid of moegheid.

Minder algemene newe-effekte:
- infeksie
- vermindering in die hoeveelheid rooibloedselle en/of witbloedselle en/of bloedplatjies (soos opgemerk met bloedtoetsresultate)
- gewigsverlies, gewigstoename, verminderde natriumkonsentrasie in die bloed
- inflammasie van die lewer, lewerversaking, abnormale lewertoetsresultate
- brandende en prikkelende sensasie (speldе en naalde), geheueverlies, geheuebelemmering, aandagsteuring, abnormale onwillekeurige liggaambewegings, belemmering van onwillekeurige liggaambewegings, toename in spierbeweging
- palpitasies (onreëlmatige hartklop)
- inflammasie van die sinusse (sinusitus)
- ekseem, gejeuk, haarverlies
- besering.

Indien u enige newe-effekte opmerk wat nie in hierdie inligtingsblad genoem is nie, raadpleeg asseblief u dokter, of apteker.

Aanmelding van newe-effekte

Indien u newe-effekte ervaar, praat met u dokter, apteker of verpleegkundige. U kan ook newe-effekte aanmeld by SAHPRA via die Med Safety toepassing (Medsafety X SAHPRA) en eReporting platform (who-umc.org), wat op SAHPRA se webtuiste gevind kan word.
Deur die aanmelding van newe-effekte, kan u help om meer inligting aangaande die veiligheid van RASSETOM in te win. U kan ook 'n epos direk na die maatskappy stuur, pharmacovigilance@pharmadynamics.co.za om veiligheid van die produk te verseker.

5. Hoe om RASSETOM te bewaar

Bewaar alle medisyne buite die bereik van kinders.
Bewaar teen of benede 30 °C. Hou die sluitpstroke in die kartonhouer, totdat dit benodig word, vir gebruik.
Moet nie na die vervaldatum wat op die kartonhouer aangedui word, gebruik nie.
Neem alle ongebruikte medisyne na u apteker terug.
Moet nie ongebruikte medisyne in afvoerpype, of rioolstelsels (bv. toilette) weggooi nie.

6. Verpakkingsinhoud en ander inligting
Wat RASSETOM bevat:
Die aktiewe bestanddeel in elke RASSETOM 250 mg tablet bevat levetirasetam 250 mg.
Die aktiewe bestanddeel in elke RASSETOM 500 mg tablet bevat levetirasetam 500 mg.
Die aktiewe bestanddeel in elke RASSETOM 750 mg tablet bevat levetirasetam 750 mg.
Die ander bestanddele is:
Tabletkorrelle:
Kruisgekoppelde natriumkarmellose, magnesiumstearaat, mieliestysel, mikrokristallyne sellulose, povidoon, kolloïdale silika, talkum.
Tabletbedekking:
Opadry blou AMB 84F80803: (FD & C blou #2/Indigo karmyn aluminiumlak)
Opadry pienk AMB 84F 84674: (FC & C geel #6 Sunset yellow FCF aluminiumlak, rooi ysteroksied, geel ysteroksied)
Opadry wit AMB 84F58775
Opadry geel AMB 84F82508: (geel ysteroksied)
Algemene eksipiënte van Opadry variante:
Makrogol, makrogol, polivinielalkohol (gedeeltelik gehidroliseer), talkum, titaandioksied.

Hoe RASSETOM lyk en die verpakkingsinhoud
RASSETOM 250 mg:
Blou, langwerpige, bikonvekse filmbedekte tablette, gedebosseleer met "250" aan een kant en gegroef aan die teenoorgestelde kant.

RASSETOM 500 mg:
Geel, langwerpige, bikonvekse filmbedekte tablette, gedebosseleer met "500" aan een kant en gegroef aan die teenoorgestelde kant.

RASSETOM 750 mg:
Perske-kleurige, langwerpige, bikonvekse filmbedekte tablette, gedebosseleer met "750" aan een kant en gegroef aan die teenoorgestelde kant.

RASSETOM tablette is beskikbaar in deursigtige PVC/aluminium stulpstroke, in pakgroottes van 30 of 60 tablette, verpak in 'n buiterste kartonhouer.

Alle verpakkingsgroottes word nie noodwendig bemark nie.

Eienaar van die Registrasiesertifikaat
Pharma Dynamics (Edms.) Bpk.
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Westlake, 7945
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Hierdie inligtingsblad was voorheen hersien
28 Februarie 2025

Registrasienommers
RASSETOM 250 mg: A44/2.5/0368
RASSETOM 500 mg: A44/2.5/0369
RASSETOM 750 mg: A44/2.5/0370

NAMIBIË:
RASSETOM 250 mg: NAM NS2 13/2.5/0178
RASSETOM 500 mg: NAM NS2 13/2.5/0179
RASSETOM 750 mg: NAM NS2 13/2.5/0180

Code No. GD/DRUGS/604

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