PATIENT INFORMATION LEAFLET

RASSETOM RANGE

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
2. What you need to know before you take RASSETOM
3. How to take RASSETOM
4. Possible side effects
5. How to store RASSETOM
6. Contents of the pack and other information

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 50kg*:*

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

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

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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