Patient Information Leaflet

SCHEDULING STATUS: S4

PROPRIETARY NAMES AND PHARMACEUTICAL FORMS:

Rizagran Melt 5 (orodispersible tablets)

Rizagran Melt 10 (orodispersible tablets)

Read all of this leaflet carefully before you start taking Rizagran Melt orodispersible tablets:

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or pharmacist.
- RIZAGRAN MELT orodispersible tablets have 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.

1. WHAT RIZAGRAN MELT CONTAINS:

Active ingredient:

Each RIZAGRAN MELT 5 orodispersible tablet contains 7,267 mg of rizatriptan benzoate equivalent to 5 mg of rizatriptan.

Each RIZAGRAN MELT 10 orodispersible tablet contains 14,534 mg of rizatriptan benzoate equivalent to 10 mg of rizatriptan.

Inactive ingredients:

Aspartame, calcium silicate (FM 1 000), crospovidone (Polyplasdone XL) Type A, magnesium stearate, mannitol (Pearlitol SD 200), silica colloidal anhydrous (Aerosil 200), silicified microcrystalline cellulose (Prosolv SMCC50), sweet orange flavour.

Each RIZAGRAN MELT 5 orodispersible tablet contains sugar alcohol (mannitol 35,373 mg).

Each RIZAGRAN MELT 10 orodispersible tablet contains sugar alcohol (mannitol 70,746 mg).

Each RIZAGRAN MELT 5 orodispersible tablet contains an artificial sweetener (aspartame 2,800 mg).

Each RIZAGRAN MELT 10 orodispersible tablet contains an artificial sweetener (aspartame 5,600 mg).

2. WHAT RIZAGRAN MELT IS USED FOR:

RIZAGRAN MELT is a member of the group of medicines called serotonin agonists. Your doctor has prescribed RIZAGRAN MELT to treat your migraine attack.

3. BEFORE YOU TAKE RIZAGRAN MELT:

Do not take RIZAGRAN MELT:

- If you are allergic (hypersensitive) to rizatriptan or any of the other ingredients of RIZAGRAN MELT (see "WHAT RIZAGRAN MELT CONTAINS").
- If you are currently taking monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine, tranylcypromine (used to treat depression) or linezolid (medicine used to treat bacterial infections), or have taken MAO inhibitors within the last two weeks.
- If you have high blood pressure that is not controlled by medication.
- If you have had a stroke (cerebrovascular accident or CVA) or mini stroke (transient ischaemic attack TIA).
- If you have ever had heart problems including heart attack or pain on the chest (angina) or you have experienced heart disease related signs.
- If you have severe liver or kidney disease.
- If you are taking ergotamine-type medications, such as ergotamine or dihydro-ergotamine to treat your migraine or methysergide to prevent a migraine attack.
- If you have peripheral vascular disease, (a problem in which narrowed arteries reduce blood flow to your limbs).
- If you are pregnant or breastfeeding (see "Pregnancy or breastfeeding").
- If you are less than 18 years of age.

If you are not sure whether you should take RIZAGRAN MELT, contact your doctor.

Take special care with RIZAGRAN MELT:

- If you have not been diagnosed with migraine, you should not take RIZAGRAN MELT.
- If you have “atypical” headaches, i.e. headaches that might be associated with potentially serious medical conditions (e.g. stroke, ruptured aneurism) as use of RIZAGRAN MELT could be harmful.
- If you are at risk for coronary artery disease (CAD), you should have a cardiovascular assessment before taking RIZAGRAN MELT. You should not take RIZAGRAN MELT if you have established CAD.
- If you have signs of angioedema (e.g. facial oedema, tongue swelling and pharyngeal oedema) which may occur in patients treated with triptans, including RIZAGRAN MELT, stop taking RIZAGRAN MELT and tell your doctor immediately or go to the casualty department of your nearest hospital.
- If you are taking pain medication for headaches over a prolonged period of time, this may make the headaches worse. If you have experienced this, please stop treatment and consult your doctor.
- RIZAGRAN MELT contains mannitol and may have a laxative effect.

Phenylketonuric patients:

- Please be aware if you have phenylketonuria (an inherited inability to metabolise phenylalanine that causes brain and nerve damage if untreated) as RIZAGRAN MELT contains aspartame, a source of phenylalanine (see “Important information about some of the ingredients of RIZAGRAN MELT”).

Pregnancy and breastfeeding:

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist or other healthcare professional for advice before taking RIZAGRAN MELT.

It is not known whether RIZAGRAN MELT is harmful to an unborn baby when taken by a pregnant woman or to a breastfed infant.

If you plan to become pregnant, or are of childbearing age, please consult your doctor, pharmacist or other healthcare professional for advice before taking RIZAGRAN MELT.

Driving and using machinery:

Migraine or treatment with RIZAGRAN MELT may cause sleepiness in some patients. Dizziness has also been reported in some patients receiving RIZAGRAN MELT. Do not drive or operate machinery before you know how RIZAGRAN MELT affects you.

Important information about some of the ingredients of RIZAGRAN MELT:

RIZAGRAN MELT contains aspartame. If you have a condition called phenylketonuria, you must not take RIZAGRAN MELT (see “Take special care with RIZAGRAN MELT - “Phenylketonuria patients”).

RIZAGRAN MELT contains mannitol and may have a laxative effect (see “Take special care with RIZAGRAN MELT”).

Taking other medicines with RIZAGRAN MELT:

Always tell your healthcare professional if you are taking any other medicine. (This includes complementary or traditional medicines.)

- Do not take RIZAGRAN MELT if you are taking the antibiotic linezolid or monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine and tranylcypromine, or if it has been less than two weeks since you stopped taking a MAO inhibitor.
- Ask your doctor for instructions on taking RIZAGRAN MELT if you are currently taking selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram oxalate and fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine and duloxetine for depression. Cases of serotonin syndrome have been reported during combined use of SSRIs/SNRIs and triptans including RIZAGRAN MELT. Symptoms of serotonin syndrome include restlessness, unconsciousness, rapid heart rate, high blood pressure, loss of muscle coordination or muscle twitching, nausea, vomiting and diarrhoea.
- Do not take RIZAGRAN MELT with any other medicine in the same class, such as sumatriptan.
- Ask your doctor for instructions on taking RIZAGRAN MELT if you are now taking propranolol (see “How to take RIZAGRAN MELT”) or ergotamine type medicines such as ergotamine or dihydroergotamine to treat your migraine, or methysergide to prevent a migraine attack. If you are taking ergotamine-type medication and RIZAGRAN MELT, it is not recommended to take them within 6 hours of each other.

- If you are taking herbal medicines containing St John's Wort (*Hypericum perforatum*). The adverse effects of RIZAGRAN MELT may be more frequent if used together with these medicines.

4. HOW TO TAKE RIZAGRAN MELT:

Do not share medicines prescribed for you with any other person.

Always take RIZAGRAN MELT exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure.

RIZAGRAN MELT tablets are used to treat migraine attacks. Take RIZAGRAN MELT tablets as soon as possible after your migraine headache has started. Do not use it to prevent an attack.

The usual dose is 5 mg or 10 mg of RIZAGRAN MELT for your migraine attack. When you have a migraine, take your medication exactly as your doctor has instructed.

Do not take more than 30 mg of RIZAGRAN MELT orodispersible tablets in a 24-hour period, (e.g. do not take more than three 10 mg or six 5 mg orodispersible tablets in a 24-hour period). You should always wait at least 2 hours between doses.

RIZAGRAN MELT orodispersible tablets dissolve in the mouth:

- Open the RIZAGRAN MELT orodispersible tablets blister pack with dry hands.
- The orodispersible tablet should be placed on your tongue, where it dissolves and can be swallowed with the saliva.
- The orodispersible tablets can be used in situations in which liquids are not available, or to avoid the nausea and vomiting that may accompany the ingestion of tablets with liquids.

If you are receiving propranolol, you should use the 5 mg dose of RIZAGRAN MELT orodispersible tablets, up to a maximum of 3 doses in a 24-hour period.

In some people, migraine symptoms can return within 24-hours. If your migraine does return, you can take additional doses of RIZAGRAN MELT. You should always wait at least 2 hours between doses.

If you do not respond to the first dose of RIZAGRAN MELT orodispersible tablets during an attack, you should not take a second dose of RIZAGRAN MELT orodispersible tablets for treatment of the same

attack.

It is still likely, however, that you will respond to RIZAGRAN MELT orodispersible tablets during the next attack.

Your doctor will tell you how long your treatment with RIZAGRAN MELT will last.

If you have the impression that the effect of RIZAGRAN MELT is too strong or too weak, tell your doctor or pharmacist.

If you take more RIZAGRAN MELT 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.

5. POSSIBLE SIDE EFFECTS:

RIZAGRAN MELT can have side effects.

Not all side effects reported for RIZAGRAN MELT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking RIZAGRAN MELT, please consult your doctor, pharmacist or other healthcare professional for advice.

If any of the following happens, stop taking RIZAGRAN MELT and tell your doctor immediately or go to the casualty department of your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth, tongue and/or throat, which may cause difficulty in swallowing or breathing or severe skin rashes.
- Severe skin reactions which starts with painful red areas, then large blisters and ends with peeling of layers of skin. This is accompanied by fever and chills, aching muscles and generally feeling unwell.

These are all very serious side effects. If you have them, you may have had a very serious allergic reaction to RIZAGRAN MELT. 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:

- Serotonin syndrome that may cause side effects like coma, unstable blood pressure, very high body temperature, agitation, hallucinations.
- Throat discomfort, difficulty breathing (dyspnoea).
- Fast, slow or irregular heart beat (palpitation); very fast heart beat (tachycardia); very slow heartbeat (bradycardia).
- Changes in the rhythm of the heartbeat.
- Seizures.
- Spasm of blood vessels of the fingers and toes including coldness and numbness of hands and feet.

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

Tell your doctor if you notice any of the following side effects that have been reported frequently:

- Tingling (paraesthesia), headache, decreased sensitivity of skin (hypoaesthesia), decreased mental sharpness, dizziness, sleepiness, insomnia.
- Electrocardiogram abnormalities (a test that records the electrical activity of your heart).
- Nausea, dry mouth, vomiting, diarrhoea, indigestion (dyspepsia).
- Flushing (redness of the face lasting a short time), sweating.
- Feeling of heaviness in parts of the body.
- Pain in the stomach or chest, tiredness or, muscle pain.

Tell your doctor if you notice any of the following side effects that have been reported less frequently:

- Unsteadiness when walking (ataxia), disorientation, nervousness, dizziness (vertigo), tremor, fainting (syncope) and confusion.
- Blurred vision.
- Stroke.
- Hot flushes.

- High blood pressure (hypertension).
- Thirst, bad taste in your mouth.
- Itching.
- Muscle weakness, neck pain, stiffness.

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

6. STORING AND DISPOSING OF RIZAGRAN MELT:

Store at or below 25 ºC.

Keep blister strips in the outer carton until required for use.

RIZAGRAN MELT tablets should not be removed from the blister strips in order to protect from moisture.

Do not use after the expiry date stated on the label.

STORE ALL MEDICINES OUT OF THE REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF RIZAGRAN MELT:

RIZAGRAN MELT 5: Alu/Alu hard aluminium foil blister or Alu/Alu silver soft aluminium peel-off foil: 2, 3, 6, 18 orodispersible tablets.

RIZAGRAN MELT 10: Alu/Alu hard aluminium foil blister or Alu/Alu silver soft aluminium peel-off foil: 2, 3, 6, 18 orodispersible tablets.

Blisters are packed in cartons.

Not all pack sizes may be marketed.

8. IDENTIFICATION:

RIZAGRAN MELT 5: White to grey-white, round, flat tablet, debossed with “RZT” on one side, and “5” on the other side.

RIZAGRAN MELT 10: White to grey-white, round, flat tablet, debossed with “RZT” on one side, and “10” on the other side.

9. REGISTRATION NUMBERS:

Rizagran Melt 5: 45/7.3/0237

Rizagran Melt 10: 45/7.3/0238

10. NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER:

Sandoz SA (Pty) Ltd[1]

72 Steel Road

Spartan

Kempton Park

1619

11. DATE OF PUBLICATION:

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[1]Company Reg. No: 1990/001979/07