

<b>Product name: MAXALT RPD 5 /MAXALT RPD 10 (5/10 mg)</b>	<b>AMENDED PROPOSED PATIENT INFORMATION LEAFLET INFORMATION ANNOTATED COPY</b>
Date of Submission to SAHPRA:	

**PROPOSED PATIENT INFORMATION LEAFLET**

**SCHEDULING STATUS**

**S4**

**MAXALT RPD® 5 Wafer**

**MAXALT RPD® 10 Wafer**

Rizatriptan benzoate

**Contains sugar alcohol:**

Each 5 mg RPD contains 7,5 mg of mannitol.

Each 10 mg RPD contains 15,0 mg of mannitol.

**Contains sweetener:**

Each 5 mg RPD contains 1,875 mg of aspartame.

Each 10 mg RPD contains 3,75 mg of aspartame.

**Read all of this leaflet carefully before you start taking MAXALT RPD**

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- MAXALT RPD 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 MAXALT RPD is and what it is used for**

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

**1. What MAXALT RPD is and what it is used for**

MAXALT RPD is used to treat migraine attacks in adults and is a member of a class of medicines also called tryptans.

Your doctor has prescribed MAXALT RPD to treat your migraine attack.

**How does MAXALT RPD work during a migraine attack?**

Treatment with MAXALT RPD:

1. Reduces widening of blood vessels surrounding the brain. This widening results in the headache pain of a migraine attack.
2. Blocks the release of substances from nerve endings that cause more pain and other symptoms of migraine.
3. Interrupts the sending of specific pain signals to your brain.

**2. What you need to know before you take MAXALT RPD**

**Do not take MAXALT RPD:**

Do not take MAXALT RPD if you:

- are allergic to rizatriptan or to any of the ingredients of MAXALT RPD (see section 6).

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- have uncontrolled high blood pressure.
- have heart disease or history of heart disease.
- are currently taking monoamine oxidase (MAO) inhibitors such as
- moclobemide, phenelzine, tranylcypromine, linezolid, or pargyline, or have taken MAO inhibitors within the last two weeks.
- are pregnant or breastfeeding.
- need to treat a headache that might be caused by other, more serious condition
- have or have had a stroke or transient ischaemic attack (TIA)
- have or have had blood vessel problems, including ischaemic bowel disease

### Use in children

Effectiveness of MAXALT RPD has not been established in children under 18 years of age, therefore MAXALT RPD is not recommended for use in these patients.

If you are not sure whether you should take MAXALT RPD, contact your doctor.

### Warnings and precautions

Tell your doctor if you have:

- any past or present medical problems
- any risk factors for heart disease
- high blood pressure or diabetes
- family history of heart disease

Also tell your doctor about:

- smoking
- any allergies you have or have had
- your symptoms.

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- all medicines you are taking, including those obtained without a prescription, and those you normally take for a migraine.
- MAXALT RPD should not be used to treat headaches that might be caused by other, more serious conditions.

### Other medicines and MAXALT RPD

Always tell your health care provider if you are taking any other medicine. (This includes complementary or traditional medicines.)

Do not take MAXALT RPD with any other tryptan in the same class, such as sumatriptan.

Do not take MAXALT RPD if you are taking a monoamine oxidase (MAO) inhibitor such as moclobemide, phenelzine, tranylcypromine, linezolid, or pargyline, or if it has been less than two weeks since you stopped taking an MAO inhibitor.

Ask your doctor for instructions about taking MAXALT RPD if you are now taking propranolol (see section 3) or ergotamine-type medications such as ergotamine or dihydro-ergotamine to treat your migraine, or methysergide to prevent a migraine attack.

Ask your doctor for instructions about taking MAXALT RPD if you are now taking selective serotonin reuptake inhibitors (SSRIs) such as sertraline, citalopram, escitalopram, and fluoxetine or serotonin norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine, and duloxetine for depression.

### Pregnancy and breastfeeding

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You should not take MAXALT RPD if you are pregnant.

You should not breastfeed if you are taking MAXALT RPD.

If you are:

- pregnant or plan to become pregnant,
- breastfeeding or plan to breastfeed your baby,

while taking this MAXALT RPD please consult your doctor, pharmacist, or other healthcare professional for advice.

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 health care provider for advice before taking this medicine.

### **Driving and using machines**

Migraine or treatment with MAXALT RPD may cause sleepiness in some patients. Dizziness has also been reported in some patients receiving MAXALT RPD. If you experience these, you should evaluate your ability to drive or to operate machinery.

It is not always possible to predict to what extent MAXALT RPD may interfere with the daily activities of a patient. Patients should always ensure that they do not engage in the above activities until they are aware of the measure to which MAXALT RPD affects them.

### **MAXALT RPD contains aspartame**

MAXALT RPD contains aspartame.

Phenylketonuric patients: You should be aware that MAXALT RPD contains phenylalanine (a component of aspartame).

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### 3. How to take MAXALT RPD

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

Your doctor has prescribed either a 5-mg or 10-mg dosage of MAXALT RPD for your migraine attack. When you have a migraine headache, take your medication as directed by your doctor.

*Taking MAXALT RPD:*

Leave MAXALT RPD wafer in the aluminum pouch it comes in until you are ready to take it.

When you are ready to take it:

Remove the “blister pack” from the aluminum pouch. Do not push the MAXALT RPD wafer through the blister.

Peel open the “blister pack” with dry hands and place the MAXALT RPD wafer on your tongue. The wafer will dissolve and be swallowed with your saliva. No drink is needed to take the wafers.

In some patients, migraine symptoms can return within a 24-hour period. If your migraine does return you can take additional doses of MAXALT RPD. You should always wait at least 2 hours between doses.

If you do not respond to MAXALT RPD during an attack, it is recommended that you do not take another dose of MAXALT RPD for treatment of the same attack. It is still likely, however, that you will respond to MAXALT RPD during the next attack.

Do not take more than 30 mg of MAXALT RPD in a 24-hour period, (for example, do not take more than three 10-mg wafers in a 24-hour period).

If you are receiving propranolol, you should use the 5-mg dose of MAXALT RPD, up to a

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maximum of 3 doses in a 24-hour period.

If your condition worsens, seek medical attention.

Always take MAXALT RPD exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how long your treatment with MAXALT RPD will last.

If you have an impression that the effect of MAXALT RPD is too strong or too weak, tell your doctor or pharmacist.

#### **If you take more MAXALT RPD than you should**

In case of an overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

#### **If you forget to take MAXALT RPD**

Do not take a double dose to make up for forgotten individual doses.

#### **4. Possible side effects**

MAXALT RPD can have side effects.

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

**If any of the following happens, stop taking MAXALT RPD and tell your doctor immediately or go to the casualty department at your nearest hospital. These are serious side effects, and you may need urgent medical attention:**

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Feelings of heaviness or tightness in parts of the body, chest pain, seizure, neck pain, throat discomfort, spasm of blood vessels (large bowel) of the colon, spasm of blood vessels of the extremities including coldness and numbness of the hands or feet, changes in the rhythm or rate of the heartbeat (slow heart rate); mental status changes (e.g. agitation, hallucinations, coma), autonomic instability (e.g. increased heart rate, unstable blood pressure, fever), headache, neuromuscular changes (e.g. increased reflexes, incoordination, tremor), gastrointestinal symptoms (e.g. nausea, vomiting, diarrhoea); allergic reactions including swelling of face, lips, tongue and/or throat which may cause difficulty in breathing and/or swallowing, wheezing, hives, rash, itching, and severe sloughing of the skin.

Also tell your doctor if you notice any of the following:

Thirst, insomnia, nervousness, decreased mental sharpness, fainting, high blood pressure, bad taste, facial pain, tingling, hot flashes, dizziness, sleepiness, tiredness, stomach upset or pain, muscle pain, dry mouth, blurred vision, sweating, flushing (redness of the face lasting a short time).

Abnormalities of the electrocardiogram (a test that records the electrical activity of your heart) have also been reported.

There have been reports of heart attack and stroke generally occurring in patients with risk factors of heart and blood vessel disease (high blood pressure, diabetes, smoking, family history of heart disease or stroke).

If you take MAXALT RPD too often, this may result in you getting chronic headaches. In such cases, you should contact your doctor, as you may have to stop taking MAXALT RPD.

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

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### Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reaction Reporting Form**”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of MAXALT RPD.

## 5. How to store MAXALT RPD

### How long should I keep my medicine?

- Do not use this medicine after the month and year following EXPIRES/VERVAL on the carton.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or the sewerage system (e.g. toilets).

### How should I store MAXALT RPD?


- Store at or below 30 °C
- Do not remove the blister from the outer aluminium sachet until you are ready to take the medicine inside.
- Store all medicines out of reach of children.

## 6 Contents of the pack and other information

### What MAXALT RPD contains:

The active substance is rizatriptan benzoate and is available as a 5 or 10 mg white to off-white rapidly dissolving wafer. The wafer contains 5 mg or 10 mg of rizatriptan.

The other ingredients are:

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- Aspartame
- Gelatin
- Glycine
- Mannitol
- Peppermint Flavour

**What MAXALT RPD looks like and contents of the pack**

MAXALT RPD 5 Wafer:

White to off-white round RAPIDISC with a flat or slightly irregular surface debossed with a modified (rounded) triangle on one side and a diameter of 10 – 11,5 mm.

MAXALT RPD 10 Wafer:

White to off-white round RAPIDISC with a flat or slightly irregular surface debossed with a modified (rounded) square on one side and a diameter of 12 - 13,8 mm.

MAXALT RPD 5 wafers are supplied in blister packs of 2, 3 or 6.

MAXALT RPD 10 wafers are supplied in blister packs of 2, 3 or 6. Not all pack sizes may be marketed. Pack 2 blister strips of three tablets each with a package insert into a unit carton overcoded with lot number and expiry date

**Holder of Certificate of Registration**

MSD (Pty) Ltd

117 16<sup>th</sup> Road

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