

HCR: MSD (Pty) Ltd	Dosage form: RPD Wafer
Product name: Maxalt RPD 5/Maxalt RPD 10	Strength: 5/10 mg
Date of submission to MCC: 18 May 2017	Approved 20.03.2018

SAHPRA APPROVED PATIENT INFORMATION LEAFLET
INFORMATION FOR THE PATIENT ABOUT MAXALT RPD® WAFERS
(rizatriptan benzoate)

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MAXALT RPD® 5 Wafer

MAXALT RPD® 10 Wafer

(rizatriptan benzoate)

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 or your pharmacist.

MAXALT 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.

1. WHAT MAXALT RPD CONTAINS

MAXALT RPD (rizatriptan benzoate) is available as a 5 or 10mg white to off-white rapidly dissolving wafer. The wafer contains 5 or 10 mg of rizatriptan.

In addition, MAXALT RPD wafers contain the following inactive ingredients:

- Aspartame
- Gelatin

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- Glycine
- Mannitol
- Peppermint Flavour

MAXALT RPD Wafers contain sugar alcohol (mannitol)

2. WHAT MAXALT RPD 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.

3. 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 (see **What MAXALT RPD contains** section).
- have uncontrolled high blood pressure.

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- 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.

Take special care with MAXALT RPD:

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 you 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.

Taking MAXALT with food and drink

MAXALT can take longer to work if it is taken after food. Although it is better to take it on an empty stomach, you can still take it if you have eaten.

Pregnancy and Breastfeeding

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

Driving and using machinery

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

Important information about some of the ingredients of MAXALT RPD

Phenylketonuric patients: You should be aware that MAXALT RPD contains

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phenylalanine (a component of aspartame).

Taking other medicines with MAXALT RPD

Always tell your healthcare professional 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 **How should adults take MAXALT RPD?** sections) 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.

4. 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.

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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 maximum of 3 doses in a 24-hour period.

If your condition worsens, seek medical attention.

If you take more MAXALT RPD than you should

In case of an overdose, contact your doctor or poison information centre immediately so that medical attention may be given promptly.

MAXALT 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, muscle weakness, 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 of stroke).

If you take MAXALT 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.

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

6. STORING AND DISPOSING OF MAXALT

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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 aluminum sachet until you are ready to take the medicine inside.

Store all medicines out of reach and sight of children.

7. PRESENTATION OF MAXALT RPD

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.

8. IDENTIFICATION OF MAXALT

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.

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9. REGISTRATION NUMBERS

MAXALT RPD 5 Wafer: 32/7.3/0536

MAXALT RPD 10 Wafer: 32/7.3/0537

10. NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

MSD (Pty) Ltd

117 16th Road

HALFWAY HOUSE

1685

Telephone number: 011 655 3000

11. DATE OF PUBLICATION

Date of registration: 17 April 2009

Date of the most recently revised package insert: 20 March 2018

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