

HCR: MSD (Pty) Ltd	Dosage form: Tablet
Product name: Maxalt 5, Maxalt 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® TABLETS (rizatriptan benzoate)

SCHEDULING STATUS

S4

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

MAXALT® 5 Tablet

MAXALT® 10 Tablet

(rizatriptan benzoate)

Read all of this leaflet carefully before you start taking MAXALT Tablets

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 CONTAINS

MAXALT (rizatriptan benzoate) is available as a 5- or 10-mg pale pink tablet containing either 5 mg or 10 mg of rizatriptan.

In addition, MAXALT tablets contain the following inactive ingredients:

- corn starch
- lactose
- magnesium stearate
- microcrystalline Cellulose

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- red Ferric Oxide

MAXALT tablets contain sugar (lactose)

2. WHAT MAXALT IS USED FOR

MAXALT 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 to treat your migraine attack.

How does MAXALT work during a migraine attack?

Treatment with MAXALT:

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

Do not take MAXALT:

Do not take MAXALT if you:

- are allergic to rizatriptan or to any of the ingredients of MAXALT (see **What MAXALT contains** section).
- have uncontrolled high blood pressure.
- have heart disease or history of heart disease.

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

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

Take special care with MAXALT:

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 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 Tablets if you are pregnant.

You should not breastfeed if you are taking MAXALT Tablets.

If you are:

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

while taking this MAXALT 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.

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Important information about some of the ingredients of MAXALT Tablet

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Taking other medicines with MAXALT

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

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

Do not take MAXALT 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 if you are now taking propranolol (see **How to take MAXALT?** section) 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 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.

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4. HOW TO TAKE MAXALT

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 for your migraine attack. When you have a migraine headache, take your medication as directed by your doctor.

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

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

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

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

If your condition worsens, seek medical attention.

If you take more MAXALT than you should

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

5. POSSIBLE SIDE EFFECTS

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MAXALT can have side effects.

Not all side effects reported for MAXALT 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 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:

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).

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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 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

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?

Store at or below 30 °C

Store all medicines out of reach and sight of children.

7. PRESENTATION OF MAXALT

MAXALT 5 Tablets are packed in blisters of 3.

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MAXALT 10 Tablets are packed in blisters of 3 and 6. 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 5 Tablet: Pale pink, capsule-shaped, convex tablet embossed with "MSD" on one side and "266" on the other side.

MAXALT 10 Tablet: Pale pink, capsule-shaped, convex tablet embossed with "MAXALT" on one side and "MSD 267" on the other side.

9. REGISTRATION NUMBERS

MAXALT 5 Tablet: 32/7.3/0534

MAXALT 10 Tablet: 32/7.3/0535

10. NAME AND BUSINESS ADDRESS OF THE REGISTRATION HOLDER

MSD (Pty) Ltd

117 16th Road

HALFWAY HOUSE

1685

Telephone number: 011 655 3000

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11. DATE OF PUBLICATION

Date of registration: 17 April 2009

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