

Package leaflet: Information for the user

MAXALT® 10 mg Tablets/5 mg Tablets (rizatriptan)

Read all of this leaflet carefully before you start taking this medicine, because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist. See section 4.

What is in this leaflet:

1. What MAXALT is and what it is used for
2. What you need to know before you take MAXALT
3. How to take MAXALT
4. Possible side effects
5. How to store MAXALT
6. Contents of the pack and other information

1. What Maxalt is and what it is used for

MAXALT belongs to a class of medicines called selective serotonin 5-HT_{1B/1D} receptor agonists.

MAXALT is used to treat the headache phase of the migraine attack in adults.

Treatment with MAXALT:

Reduces swelling of blood vessels surrounding the brain. This swelling results in the headache pain of a migraine attack.

2. What you need to know before you take MAXALT

Do not take MAXALT if:

- you are allergic to rizatriptan benzoate or any of the other ingredients of MAXALT
- you have moderately severe or severe high blood pressure or mild high blood pressure that is not controlled by medication
- you have or have ever had heart problems including heart attack or pain on the chest (angina) or you have experienced heart disease related signs
- you have severe liver or severe kidney problems
- you have had a stroke (cerebrovascular accident CVA) or mini stroke (transient ischaemic attack TIA)
- you have blockage problems with your arteries (peripheral vascular disease)
- you are taking monoamine oxidase (MAO) inhibitors such as moclobemide, phenelzine, tranylcypromine, or pargyline (drugs against depression), or linezolid (an antibiotic), or if it has been less than two weeks since you stopped taking MAO inhibitors

- you are now taking ergotamine-type medications, such as ergotamine or dihydro-ergotamine to treat your migraine or methysergide to prevent a migraine attack
- you are taking any other drug in the same class, such as sumatriptan, naratriptan, or zolmitriptan to treat your migraine (see **Other medicines and MAXALT** below).

If you are not sure if any of the above apply to you talk to your doctor or pharmacist before taking MAXALT.

Warnings and precautions:

Before you take MAXALT, tell your doctor or pharmacist, if:

- you have any of the following risk factors for heart disease: high blood pressure, diabetes, you smoke or you are using nicotine substitution, your family has a history of heart disease, you are a man over 40 years of age, or you are a postmenopausal woman
- you have kidney or liver problems
- you have a particular problem with the way your heart beats (bundle branch block)
- you have or have had any allergies
- your headache is associated with dizziness, difficulty in walking, lack of co-ordination or weakness in the leg and arm
- you use herbal preparation containing St. John's wort
- you have had allergic reaction like swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema)
- you are 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
- you have had short lived symptoms including chest pain and tightness.

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

Please tell your doctor or pharmacist about your symptoms. Your doctor will decide if you have migraine. You should take MAXALT only for a migraine attack. MAXALT should not be used to treat headaches that might be caused by other, more serious conditions.

Please tell your doctor if you are taking or have recently taken, or plan to take, any other medicines including medicines obtained without a prescription. This includes herbal medicines and those you normally take for a migraine. This is because MAXALT can affect the way some medicines work. Also, other medicines can affect MAXALT.

Other medicines and MAXALT

Do not take MAXALT

- if you are already taking a 5-HT_{1B/1D} agonist (sometimes referred to as 'triptans'), such as sumatriptan, naratriptan or zolmitriptan.
- 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.
- if you use ergotamine-type medications such as ergotamine or dihydro-ergotamine to treat your migraine.
- if you use methysergide to prevent a migraine attack.

The above listed medicines when taken with MAXALT may increase the risk of side effects.

You should wait at least 6 hours after taking MAXALT before you take ergotamine-type medications such as ergotamine or dihydro-ergotamine or methysergide.

You should wait at least 24 hours after taking ergotamine-type medications before taking MAXALT.

Ask your doctor for instructions and the risks about taking MAXALT

- if you are taking propranolol (see section 3: **How to take MAXALT**).
- if you are taking SSRIs such as sertraline, escitalopram oxalate, and fluoxetine or SNRIs such as venlafaxine, and duloxetine for depression.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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 breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It is not known whether MAXALT is harmful to an unborn baby when taken by a pregnant woman. Breastfeeding should be avoided for 24 hours after treatment.

Children and adolescents

The use of MAXALT tablets in children under 18 years of age is not recommended.

Use in patients older than 65 years

There have been no full studies to look at how safe and effective MAXALT is amongst patients older than 65 years.

Driving or using machines

You may feel sleepy or dizzy while taking MAXALT. If this happens, do not drive or use any tools or machines.

MAXALT contains lactose monohydrate

The 5-mg tablet contains 30.25 mg of lactose monohydrate and the 10-mg tablet contains 60.50 mg of lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take MAXALT

MAXALT is used to treat migraine attacks. Take MAXALT as soon as possible after your migraine headache has started. Do not use it to prevent an attack.

Always take MAXALT exactly as your doctor has told you. You should check with your doctor or your pharmacist if you are not sure.

The usual dose is 10 mg.

If you are currently taking propranolol or have kidney or liver problems you should use the 5-mg dose of MAXALT. You should leave at least 2 hours between taking propranolol and MAXALT up to a maximum of 2 doses in a 24-hour period.

MAXALT (rizatriptan benzoate) tablets should be taken by mouth and swallowed whole with liquid.

MAXALT is also available as a 10-mg oral lyophilisate that dissolves in the mouth. The oral lyophilisate 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 migraine returns within 24 hours

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

If after 2 hours you still have a migraine

If you do not respond to the first dose of MAXALT during an attack, you should not take a second 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 2 doses of MAXALT in a 24-hour period, (for example, do not take more than two 10 mg or 5 mg tablets or oral lyophilisate in a 24-hour period). You should always wait at least 2 hours between doses.

If your condition worsens, seek medical attention.

If you take more MAXALT than you should:

If you take more MAXALT than you should, talk to your doctor or pharmacist straight away. Take the medicine pack with you.

Signs of overdosage can include dizziness, drowsiness, vomiting, fainting and slow heart rate.

If you have any further questions on the use of this product ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, MAXALT can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

In adult studies, the most common side effects reported were dizziness, sleepiness and tiredness.

Common (affects 1 to 10 users in 100)

- tingling (paraesthesia), headache, decreased sensitivity of skin (hypoesthesia), decreased mental sharpness, insomnia.
- fast or irregular heart beat (palpitation).
- flushing (redness of the face lasting a short time).
- throat discomfort
- feeling sick (nausea), dry mouth, vomiting, diarrhea, indigestion (dyspepsia)
- feeling of heaviness in parts of the body, neck pain, stiffness.

- pain in abdomen or chest.

Uncommon (affects 1 to 10 users in 1000)

- bad taste in your mouth.
- unsteadiness when walking (ataxia), dizziness (vertigo), blurred vision, tremor, fainting (syncope).
- confusion, nervousness.
- high blood pressure (hypertension); thirst, hot flushes, sweating
- rash, itching and lumpy rash (hives),; swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema), difficulty breathing (dyspnoea)
- feeling of tightness in parts of the body, muscle weakness.
- changes in the rhythm or rate of the heartbeat (arrhythmia); abnormalities of the electrocardiogram (a test that records the electrical activity of your heart), very fast heartbeat (tachycardia)
- facial pain; muscle pain.

Rare (affects 1 to 10 users in 10,000)

- wheezing.
- allergic reaction (hypersensitivity); sudden life-threatening allergic reaction (anaphylaxis).
- stroke (this generally occurs in patients with risk factors for heart and blood vessel disease (high blood pressure, diabetes, smoking, use of nicotine substitution, family history of heart disease or stroke, man over 40 years of age, postmenopausal women, particular problem with the way your heart beats [bundle branch block]).
- Slow heartbeat (bradycardia).

Not known (frequency cannot be estimated from the available data):

- heart attack, spasm of the blood vessels of the heart (these generally occur in patients with risk factors for heart and blood vessel disease (high blood pressure, diabetes, smoking, use of nicotine substitution, family history of heart disease or stroke, man over 40 years of age, postmenopausal women, particular problem with the way your heart beats (bundle branch block)).
- a syndrome called "serotonin syndrome" that may cause side effects like coma, unstable blood pressure, extremely high body temperature, lack of muscle coordination, agitation, and hallucinations.
- severe shedding of the skin with or without fever (toxic epidermal necrolysis).
- seizure (convulsions/fits).
- spasm of blood vessels of the extremities including coldness and numbness of the hands or feet.
- spasm of the blood vessels of the colon (large bowel), which can cause abdominal pain.

Tell your doctor right away if you have symptoms of allergic reactions, serotonin syndrome, heart attack or stroke.

In addition, tell your doctor if you experience any symptoms that suggest an allergic reaction (such as a rash or itching) after taking MAXALT.

Reporting of side effects

If you get any side effects, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card

Scheme Website: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store MAXALT

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton/blister after "EXP". The expiry date refers to the last day of the month.

Do not store MAXALT above 30°C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What MAXALT contains

The active substance of MAXALT is rizatriptan. One tablet contains 5/10 mg rizatriptan as 7.265 or 14.53 mg of rizatriptan benzoate.

The other ingredients of MAXALT tablets are lactose monohydrate, microcrystalline cellulose (E460a), starch, pregelatinised; iron oxide red (E172) and magnesium stearate (E572).

What MAXALT looks like and contents of pack

5 mg tablets are pale pink, capsule shaped, coded MSD on one side and 266 on the other.
10 mg tablets are pale pink, capsule-shaped, coded MAXALT on one side and MSD 267 on the other.

Pack sizes: Packs with 2, 3, 6, 12 or 18 tablets.

Not all pack sizes may be marketed.

Marketing Authorization Holder and Manufacturer

Marketing Authorization Holder

Merck Sharp & Dohme Limited
Hertford Road, Hoddesdon,
Hertfordshire
EN11 9BU, UK.

Manufacturer

MERCK SHARP & DOHME B.V.
Waarderweg 39
2031 BN Haarlem
The Netherlands

This medicinal product is authorised in the Member States of the EEA under the following names:

Maxalt 5 mg Tablets

Austria , Cyprus, Estonia, Finland, France, Greece, Iceland, Latvia, Malta, The Netherlands, Norway, Poland, Portugal, Sweden, The United Kingdom	MAXALT
Belgium and Luxemburg	MAXALT 5 mg
Bulgaria	Максалт 5 mg таблетки
Czech Republic	MAXALT 5mg, tablety
Denmark	MAXALT, tabletter
Germany	MAXALT 5 mg Tabletten
Hungary	MAXALT 5 mg tableta
Ireland	Rizatriptan 5 mg Tablets
Italy	MAXALT 5 mg compresse
Lithuania	MAXALT 5 mg tabletės
Romania	MAXALT 5 mg comprimate
Slovakia	MAXALT 5 mg
Slovenia	Maxalt 5 mg tablete

Maxalt 10 mg Tablets

Austria , Cyprus, Estonia, Finland, France, Greece, Iceland, Latvia, Malta, The Netherlands, Norway, Poland, Portugal, Sweden, The United Kingdom	MAXALT
Belgium, Luxemburg and Spain	MAXALT 10 mg
Bulgaria	Максалт 10 mg таблетки
Czech Republic	MAXALT 10 mg, tablety
Denmark	MAXALT, tabletter
Germany	MAXALT 10 mg Tabletten
Hungary	MAXALT 10 mg tableta
Ireland	Rizatriptan 10 mg Tablets
Italy	MAXALT 10 mg compresse
Lithuania	MAXALT 10 mg tabletės
Romania	MAXALT 10 mg comprimate
Slovakia	MAXALT 10 mg
Slovenia	Maxalt 10 mg tablete

This leaflet was last revised in March 2014.

How can you obtain more information about MAXALT?

This leaflet gives you some of the most important information about MAXALT. If you have any questions after you have read it, ask your doctor or pharmacist who can give you further information.

Further information about migraine is available from the following organisations:

Migraine Action Association
4th Floor, 27 East Street
Leicester
LE1 6NB
Tel: 0116 275 8317
Fax: 0116 254 2023

and

The Migraine Trust
52-53 Russell Square
London
WC1B 4HP
Tel: 020 7631 6970
Fax: 020 7436 2886
Email: info@migrainetrust.org

(Migraine Action Association and The Migraine Trust are independent organizations and are not associated with Merck Sharp & Dohme Limited.)

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Merck Sharp & Dohme Limited.
Hertford Road, Hoddesdon, Hertfordshire, EN11 9BU, UK.

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