

Package leaflet:
Information for the user

MAXALT® 10 mg tablets
Active substance: Rizatriptan

Read the entire package leaflet carefully before you start taking this medicine because it contains important information.

Keep the package leaflet. You may want to read it again later.

If you have any further questions, ask your doctor or pharmacist.

This medicine has been prescribed for you personally. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

If you notice any side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What is MAXALT and what is it used for?
2. What should you consider before taking MAXALT?
3. How to take MAXALT?
4. What are the possible side effects?
5. How to store MAXALT?
6. Contents of the pack and other information

1. What is MAXALT and what is it used for?

MAXALT belongs to a specific class of migraine medications (triptans, also selective serotonin 5-HT_{1B/1D}-receptor agonists).

MAXALT is used to treat headaches during a migraine attack in adults.

Treatment with MAXALT:

Dilated blood vessels surrounding the brain lead to headaches during a migraine attack.

Treatment with MAXALT causes the blood vessels surrounding the brain to constrict.

2. What should you consider before taking MAXALT?

- ▶ MAXALT must not be taken if

you are hypersensitive (allergic) to the active substance rizatriptan or any of the other ingredients of this medicine listed in section 6. you have moderate or severe high blood pressure or untreated mild high blood pressure (as MAXALT can cause blood vessel constriction and thus increase blood pressure).

you have or have had heart disease. This includes, for example, heart attack or chest pain (angina pectoris) or symptoms indicating heart disease.

you have a history of stroke or transient ischemic attack (TIA).

you suffer from conditions with narrowed or blocked blood vessels (peripheral arterial disease).

you have severe liver dysfunction or severely impaired kidney function.

you are taking certain medications for depression (such as moclobemide, phenelzine, tranylcypromine, pargyline) or a certain antibiotic (linezolid) or have stopped taking any

of these medications less than 2 weeks ago. These medications belong to the so-called monoamine oxidase (MAO) inhibitors.

you are taking medications to treat your migraine that are referred to as ergotamine-type medications, such as ergotamine or dihydroergotamine.

you are taking methysergide to prevent migraine.

Take methysergide for the prevention of migraine.

You are taking other medications of the same class as MAXALT, such as Sumatriptan, Naratriptan, or Zolmitriptan, to treat your migraine.

(See under: Taking MAXALT with other medications)

If you are unsure whether any of the above contraindications apply to you, consult your doctor or pharmacist before taking MAXALT.

► Warnings and precautions

Before taking MAXALT, talk to your doctor or pharmacist if:

you have the following risk factors for heart disease:

- high blood pressure,
- diabetes mellitus,
- you smoke or use nicotine replacement therapy,
- you have a family history of heart disease,
- you are a man over 40 years old,
- you are a woman post-menopause.

you have previously experienced short-term symptoms such as pain or tightness in the chest.

you have a heart conduction disorder (bundle branch block).

you suffer from a kidney or liver disease.

your headaches are accompanied by dizziness, difficulty walking, coordination problems, or weakness in the legs and arms.

there is a history of allergies in your medical history.

you have previously had allergic reactions such as swelling of the face, lips, tongue, and/or throat, which can cause breathing and/or swallowing difficulties (angioedema).

You are taking so-called selective serotonin reuptake inhibitors (SSRIs) such as sertraline, escitalopram oxalate, and fluoxetine, or serotonin-norepinephrine reuptake inhibitors (SNRIs) such as venlafaxine and duloxetine for the treatment of depression.

You are taking herbal preparations containing St. John's wort.

If you experience a persistent headache while being treated with MAXALT, it may be that you have taken MAXALT too often. In such cases, you should consult your doctor, as you may need to stop taking MAXALT.

Please describe your symptoms to your doctor or pharmacist (e.g., unilateral, throbbing headaches, nausea, sensitivity to light and sound). Your doctor will determine if you have migraines. MAXALT is intended only for the treatment of a migraine attack. MAXALT should not be used to treat other types of headaches, as these may have other, more serious causes.

► Taking MAXALT with other medicines

Inform your doctor or pharmacist if you are taking/using, have recently taken/used, or intend to take/use other medicines. This applies to both prescription and non-prescription medicines, as well as herbal or homeopathic preparations.

Also inform your doctor about all medicines you normally take for the treatment of your migraines. This is important because MAXALT can affect the way some other medicines work, and the effect of MAXALT can also be influenced by other medicines.

Do not take MAXALT:

if you are taking other medicines to treat or prevent migraines at the same time:

- other triptans such as sumatriptan, naratriptan, or zolmitriptan
- ergotamine-type medicines such as ergotamine or dihydroergotamine
- methysergide

if you are taking medicines for the treatment of depression, such as moclobemide, phenelzine, tranylcypromine, or pargyline, or if you are taking a certain antibiotic (linezolid) or have stopped taking any of these medicines less than 2 weeks ago. These medicines belong to the so-called monoamine oxidase (MAO) inhibitors.

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

You should wait at least 6 hours after taking MAXALT before taking ergotamine-type medicines for the treatment of migraines (such as ergotamine, dihydroergotamine, or methysergide).

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

Ask your treating doctor for instructions and the risks of taking MAXALT,

if you are taking the beta-blocker propranolol for the prevention of migraines (see 3. How to take MAXALT?).

if you are taking so-called SSRIs such as sertraline, escitalopram oxalate, and fluoxetine, or SNRIs such as venlafaxine and duloxetine due to depression.

► Taking MAXALT with food

Taking it on an empty stomach is preferable, as the effect of MAXALT may be delayed after a meal. However, you can also take it after eating.

► Pregnancy and breastfeeding

If you are pregnant or breastfeeding, or if you suspect you are pregnant or intend to become pregnant, ask your doctor or pharmacist for advice before taking this medicine.

It is not known whether MAXALT harms the unborn child if the medicine is taken by a pregnant woman.

Breastfeeding should be avoided for 24 hours after treatment.

► Children and adolescents

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

► Treatment of elderly people

The tolerability and effectiveness of MAXALT in patients over 65 years have not been extensively studied.

► Driving and using machines

You may feel drowsy or dizzy after taking MAXALT. In this case, you should not drive or operate machinery until you feel better.

► MAXALT contains milk sugar (lactose monohydrate)

One tablet contains 60.50 mg of milk sugar (lactose monohydrate). Please only take this medication after consulting your doctor if you know that you suffer from an intolerance to milk sugar (lactose intolerance).

3. How should MAXALT be taken?

MAXALT is used to treat migraine attacks. Take MAXALT as early as possible when the headache of an attack begins. Do not take it to prevent an attack.

Always take this medication exactly as agreed with your doctor. Ask your doctor or pharmacist if you are unsure.

The recommended dose is 1 tablet of MAXALT 10 mg (10 mg rizatriptan).

If you suffer from impaired kidney or liver function, you should receive the lower single dose of MAXALT, 1 tablet of MAXALT 5 mg (5 mg rizatriptan).

If you are being treated with the beta-blocker propranolol, you should also receive the lower single dose of MAXALT, 1 tablet of MAXALT 5 mg (5 mg rizatriptan).

There should be at least 2 hours between taking MAXALT and propranolol.

Do not take more than 2 single doses of MAXALT within 24 hours.

MAXALT tablets should be taken whole and swallowed with liquid.

MAXALT is also available as 5 mg or 10 mg orally disintegrating tablets (the technical term is oral lyophilisate), which dissolve in the mouth. The orally disintegrating tablet can also be taken when no liquid is available or to prevent nausea and vomiting that can occur when taking the tablets with liquid.

► If the migraine recurs within 24 hours

In some patients, the migraine headache recurs within 24 hours. If your migraine returns, you can take another dose of MAXALT. You should wait at least 2 hours between the first and second dose.

► If you still have migraine headaches after 2 hours

If you do not experience relief from the first dose of MAXALT during a migraine attack, you should not take another dose for the same attack. However, it is possible that you may respond to MAXALT during the next attack.

Do not take more than two single doses within 24 hours (for example, do not take more than two 10 mg tablets or 5 mg tablets or orally disintegrating tablets within 24 hours). You should wait at least 2 hours between taking the first and second dose.

If your migraine worsens, you should contact your doctor.

- ▶ If you have taken more MAXALT than you should have

In case of overdose, you should seek medical attention immediately. Take the medicine packaging with you.

Signs of an overdose may include dizziness, drowsiness, vomiting, fainting, and slow heartbeat.

If you have further questions about taking this medicine, ask your doctor or pharmacist.

4. What side effects are possible?

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

The most common side effects in clinical studies in adults were dizziness, drowsiness, and weakness/fatigue.

Common: (affect 1 to 10 users in 100)

Paresthesia, headache, decreased (touch) sensitivity of the skin (hypoesthesia), decreased attention, insomnia.
Palpitations or irregular heartbeat.
Feeling of warmth with temporary skin redness (flush).
Throat discomfort.
Nausea, dry mouth, vomiting, diarrhea, indigestion (dyspepsia).
Heaviness in certain parts of the body, neck pain, stiffness.
Abdominal pain or chest pain.

Occasionally: (affect 1 to 10 users out of 1,000)

Taste disturbance/bad taste in the mouth.
Movement disorders when walking (ataxia), dizziness (vertigo), blurred vision, tremor, unconsciousness (syncope).
Disorientation, nervousness.
High blood pressure, thirst, hot flashes, sweating.
Rash, itchy and weeping rash (urticaria); swelling of the face, lips, tongue, and/or throat, which can lead to difficulty breathing and/or swallowing (angioedema), shortness of breath (dyspnea).
Tension in certain body regions, muscle weakness.

Heart rhythm disturbances or changes in heart rate (arrhythmias); changes in the electrocardiogram (a test that records the electrical activity of the heart), palpitations (tachycardia).

Facial pain; muscle pain.

Rare: (affect 1 to 10 users out of 10,000)

Wheezing.

Allergic reactions (hypersensitivity); sudden life-threatening allergic reactions (anaphylaxis).

Stroke (predominantly affects patients with risk factors for heart and vascular disease [high blood pressure, diabetes, smoking, use of nicotine replacement products, heart disease or stroke in family history, men over 40 years, women after menopause, heart conduction disorder [bundle branch block]]).

Slowed heartbeat (bradycardia).

Unknown: (the frequency of occurrence of the following events cannot be precisely determined based on the available data)

Heart attack, arterial circulatory disorder of the heart (this predominantly affects patients with risk factors for heart and vascular disease [high blood pressure, diabetes, smoking, use of nicotine replacement products, heart disease or stroke in family medical history, men over 40 years, women after menopause, cardiac conduction disorder [bundle branch block]]).

A condition known as "serotonin syndrome" with side effects such as coma, unstable blood pressure, significantly increased body temperature, muscle coordination disorders, restlessness, and hallucinations.

Severe skin detachment reactions with or without fever (toxic epidermal necrolysis [Lyell syndrome]).

Seizures (twitching/seizures).

Paroxysmal narrowing of blood vessels in the hands or feet, which may be accompanied by coldness or numbness (peripheral vascular ischemia).

Paroxysmal narrowing of blood vessels in the colon, which can lead to abdominal pain.

Seek medical attention immediately if you experience symptoms that may indicate the following:

an allergic reaction,

a heart attack (e.g., sudden severe chest pain that may radiate to the left arm, feeling of tightness or anxiety, sudden severe shortness of breath or dizziness) or

a stroke (e.g., numbness or paralysis in certain body areas, balance disorders, visual disturbances, hearing loss, difficulty speaking).

This also applies if a combination of symptoms occurs, such as coma, unstable blood pressure, significantly increased body temperature, muscle coordination disorders, restlessness, and hallucinations, which are caused by an accumulation of serotonin and are often a result of a drug interaction (serotonin syndrome).

Also contact your doctor and inform them if you experience symptoms after taking MAXALT that indicate an allergic reaction (such as rash or itching).

Reporting side effects

If you notice side effects, contact your doctor or pharmacist. This also applies to side effects not listed in this leaflet.

You can also report side effects directly to the Federal Institute for Drugs and Medical Devices, Dept. Pharmacovigilance, Kurt-Georg-Kiesinger-Allee 3, D-53175 Bonn, Website: www.bfarm.de. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How should MAXALT be stored?

Keep this medicine out of the reach of children.

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

Do not store MAXALT above 30 °C.

Do not dispose of medicines in wastewater. Ask your pharmacist or local waste disposal company how to dispose of the medicine when you no longer use it. This helps protect the environment.

6. Contents of the pack and other information

► What MAXALT contains

The active substance of MAXALT is rizatriptan.

One tablet contains 10 mg rizatriptan (equivalent to 14.53 mg rizatriptan benzoate).

The other ingredients are:

Lactose monohydrate, microcrystalline cellulose (E 460a), modified starch, iron(III) oxide red (E 172), and magnesium stearate (E 572).

► What MAXALT looks like and contents of the pack

MAXALT 10 mg tablets are light pink, capsule-shaped with the inscription "MAXALT" on one side and "MSD 267" on the other side.

Pack sizes:

MAXALT 10 mg tablets are available in blister packs of 3, 6, 12, or 18 tablets. Not all pack sizes may be marketed.

► Marketing authorization holder and manufacturer

Marketing authorization holder

MSD SHARP & DOHME GMBH

Lindenplatz 1 85540 Haar

Postal address:

P.O. Box 1202

85530 Haar

Tel.: 0800/673 673 673
Fax: 0800/673 673 329
E-Mail: e-mail@msd.de

Co-distribution
MSD CHIBROPHARM GMBH, 85530 Haar
DIECKMANN ARZNEIMITTEL GMBH, 85530 Haar
CHIBRET PHARMACEUTICAL GMBH, 85530 Haar
VARIPHARM PHARMACEUTICALS GMBH, 85530 Haar

Manufacturer
Merck Sharp & Dohme BV
Waarderweg 39
2031 BN, Haarlem, Netherlands

This medicinal product is authorized in the Member States of the European Economic Area (EEA) under the following names:

Austria, Cyprus, Estonia, Finland, France, Greece, Iceland, Latvia, Malta, Netherlands, Norway, Poland, Portugal, Sweden and United Kingdom	MAXALT
Belgium, Luxembourg and Spain	MAXALT 10 mg
Bulgaria	MAXALT 10 mg tablets
Czech Republic	MAXALT 10 mg, tablets
Denmark	MAXALT, tablets
Germany	MAXALT 10 mg tablets
Hungary	MAXALT 10 mg tablet
Ireland	Rizatriptan MSD 10 mg Tablets
Italy	MAXALT 10 mg tablets
Lithuania	MAXALT 10 mg tablets
Romania	MAXALT 10 mg tablets
Slovakia	Rizalief 10 mg
Slovenia	Maxalt 10 mg tablets

This package leaflet was last revised in April 2014.

Do you have any further questions?

Please contact:

MSD Infocenter:
Tel.: 0800/673 673 673
Fax: 0800/673 673 329
E-Mail: infocenter@msd.de

In Germany, there are self-help groups and patient organizations for many health problems.

There, affected individuals and relatives can find information, advice, exchange, and help in dealing with the illness. If groups or organizations for this illness exist, you can find the contact addresses through:

BAG-SELBSTHILFE
Kirchfeldstraße 149
40215 Düsseldorf
Phone: 0211-31006-0
Telefax: 0211-31006-48
E-Mail: info@bag-selbsthilfe.de
Internet: www.bag-selbsthilfe.de

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