

Read all this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

In this leaflet:

1. What MAXALT 10 mg tablets is and what it is used for
2. Before you take MAXALT 10 mg tablets
3. How to take MAXALT 10 mg tablets
4. Possible side effects
5. Storing MAXALT 10 mg tablets

MAXALT® 10 mg tablets
rizatriptan

Each tablet contains as active substance 10 mg of rizatriptan.

The excipients are lactose monohydrate, microcrystalline cellulose, pregelatinized starch, ferric oxide (Red) E172 and magnesium stearate.

License holder:

MERCK SHARP & DOHME DE ESPAÑA, S.A.
C/Josefa Valcárcel, 38
28027 MADRID

Manufacturing responsible:

FROSST IBÉRICA, S.A.
Vía Complutense, 140.
28805 – Alcalá de Henares (Madrid)
ESPAÑA

1. WHAT MAXALT 10 mg IS TABLETS AND WHAT IT IS USED FOR

MAXALT 10 mg is available in packages of 2 or 6 tablets. The tablets are pale pink, capsule-shaped, coded MAXALT on one side and MSD 267 on the other.

MAXALT is a member of a class of drugs called selective 5-HT_{1B/1D} receptor agonists.

MAXALT is indicated for the acute treatment of the headache phase of migraine attacks, with or without aura.

2. BEFORE YOU TAKE MAXALT 10 mg TABLETS

Do not take MAXALT 10 mg if:

- you are allergic to rizatriptan or to any of the ingredients of this medicine;
- you have hypertension (high blood pressure), moderately severe, severe or untreated mild high blood pressure;
- you have basilar or hemiplegic migraine;
- you have “atypical” headaches that might be associated with serious medical conditions;

- you have heart disease or history of heart disease;
- you have severe liver or severe kidney disease;
- you have had a previous cerebrovascular accident (CVA) or transient ischaemic attack (TIA) (poor circulation of the blood);
- you have peripheral vascular disease;
- you 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 (See Taking other medicines);
- you have taken ergotamine-type medications, such as ergotamine or dihydro-ergotamine, methysergide within the last 24 hours (See Taking other medicines);
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- you are taking another 5-HT_{1B/1D} agonist, such as sumatriptan, naratriptan, or zolmitriptan to treat your migraine (See Taking other medicines).

Take special care with MAXALT 10 mg:

MAXALT should not be used to prevent a migraine attack.

Discontinue the treatment and inform your doctor immediately:

- If you have symptoms which include chest pressure and pain, which may be intense and affect the throat.
- If you have angioedema (swelling of the face, tongue and throat).

Use in children and adolescents:

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

Use in patients older than 65 years:

The safety and effectiveness of MAXALT in patients older than 65 years have not been fully studied.

Taking MAXALT 10 mg with food and drink:

It is recommended to take MAXALT in fasting state and with some liquid, to avoid the absorption delay due to the presence of food.

Pregnancy and Breast-feeding:

Consult your doctor or pharmacist before taking a medicine.

It is not known whether the use of MAXALT is safe in pregnant women or during breast-feeding, therefore MAXALT should only be used during pregnancy or breast-feeding when, in opinion of your doctor, the expected therapeutic benefits justify it.

Driving and using machines:

Migraine or treatment with MAXALT may cause sleepiness and dizziness in some patients, therefore try not to perform tasks that require special attention (driving an automobile or operating machinery) until you know how you tolerate the medication.

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken, any other medicine - even those not prescribed.

Certain medicines can interact with MAXALT MAX; in these cases, dosage adjustment or discontinuing the treatment with any of the medicines can be necessary.

It is especially important that you inform your doctor if you are taking some of the following medicines:

- Medicines used to treat heart problems (propranolol)
- Medicines to treat depression (e.g. paroxetine)

The use of MAXALT is contraindicated together with:

- Other drugs in the same class as MAXALT, such as sumatriptan, naratriptan or zolmitriptan.
- Ergotamine-type medications, such as ergotamine or dihydro-ergotamine to treat your migraine; or methysergide to prevent a migraine attack.
- 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.

3. HOW TO TAKE MAXALT 10 mg TABLETS

Follow these instructions unless your doctor has given you different indications.

Remember to take your medicine.

MAXALT should not be used to prevent a migraine attack.

The recommended dose is 10 mg a day.

The tablets should be swallowed whole with liquid.

The absorption of rizatriptan from the tablet is delayed by one hour when taken with food; therefore, the start of headache relief may also be delayed.

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 you do not respond to 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 tablets in a 24-hour period).

If you are receiving propranolol, or if you have mild to moderate liver disease or mild to moderate kidney disease, you should use the 5-mg dose of MAXALT, up to a maximum of 2 doses in a 24-hour period.

If you have the impression that the effect of MAXALT 10 mg is too strong or too weak, talk to your doctor or pharmacist.

If you take more MAXALT 10 mg than you should:

If you take more MAXALT than you should, consult your doctor or pharmacist immediately.

In case of overdose or accidental ingestion consult the Information Service of Toxicology. Telephone: (91) 562 04 20.

4. POSSIBLE SIDE EFFECTS

Like all medicines, MAXALT 10 mg may have side effects.

The reported adverse effects were the following:

- The most common adverse effects reported were dizziness, sleepiness and tiredness.
- Other common adverse effects were: headache, stomach upset or pain, chest pain, diarrhea, feelings of heaviness and tingling in parts of the body, dry mouth, nausea, vomiting, throat discomfort, flushing (redness of the face lasting a short time), hot flushes/flushes, palpitations, rapid heartbeat, decreased mental sharpness, tremor, difficulty breathing, sweating.
- Other less common adverse effects were: reduced ability to coordinate movements (ataxia), disorientation, vertigo, high blood pressure, digestion problems (dyspepsia), itching, hives, tightness in parts of the body, stiffness, neck pain, muscle weakness, thirst, insomnia, nervousness, blurred vision.
- Rarely, there were reports of fainting, heart problems, allergic reactions including swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing, wheezing, rash, and severe sloughing of the skin. Also bad taste and facial pain have been reported.

As with other drugs in this class, there have been very rarely reports of heart attack and stroke generally occurring in patients with risk factors for heart and blood vessel disease (high blood pressure, diabetes, smoking, family history of heart disease or stroke).

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

5. STORING MAXALT 10 mg TABLETS

Keep out of the reach and sight of children.

Store MAXALT at room temperature.

Expiration:

This medicine should not be used after the expiration date indicated on the container.

This leaflet was approved on May 2004.