

PACKAGE LEAFLET: INFORMATION FOR THE USER
MAXALT[®] MELT 10 mg Oral Lyophilisate
(rizatriptan)

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

- 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. Do not pass it on to others. It may harm them, even if their symptoms 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.

In this leaflet:

1. What MAXALT MELT is and what it is used for
2. Before you take MAXALT MELT
3. How to take MAXALT MELT
4. Possible side effects
5. How to store MAXALT MELT
6. Further information

1. WHAT MAXALT MELT IS AND WHAT IT IS USED FOR

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

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

Treatment with MAXALT MELT:

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

2. BEFORE YOU TAKE MAXALT MELT

Do not take MAXALT MELT if:

- you are allergic (hypersensitive) to rizatriptan benzoate or any of the other ingredients of MAXALT MELT
- 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 **Taking with other medicines** below).

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

Take special care with MAXALT MELT if you:

Before you take MAXALT MELT, 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 post-menopausal 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 MELT 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 MELT.

Please tell your doctor or pharmacist about your symptoms. Your doctor will decide if you have migraine. You should take MAXALT MELT only for a migraine attack. MAXALT MELT 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 MELT can affect the way some medicines work. Also, other medicines can affect MAXALT MELT.

Taking with other medicines

Do not take MAXALT MELT:

- 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 MELT may increase the risk of side effects.

You should wait at least 6 hours after taking MAXALT MELT 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 MELT.

Ask your doctor for instructions and the risks about taking MAXALT MELT

- if you are taking propranolol (see section 3: **How to take MAXALT MELT**).
- 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.

Taking MAXALT MELT with food and drink:

MAXALT MELT 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

It is not known whether MAXALT MELT is harmful to an unborn baby when taken by a pregnant woman.

Talk to your doctor before taking this medicine if you are pregnant, planning to get pregnant or are breastfeeding. Breastfeeding should be avoided for 24 hours after treatment.

Ask your doctor or pharmacist for advice before taking any medicine.

Use in children

The use of MAXALT MELT oral lyophilisates 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 MELT is amongst patients older than 65 years.

Driving or using machines

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

Important information about some of the ingredients of MAXALT MELT

Phenylketonuric patients: Contains a source of phenylalanine. May be harmful for people with phenylketonuria. Each MAXALT MELT oral lyophilisate contains 3.75 mg of aspartame (which contains phenylalanine).

3. HOW TO TAKE MAXALT MELT

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

Always take MAXALT MELT 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 MELT up to a maximum of 2 doses in a 24-hour period.

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 MELT. 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 MELT during an attack, you should not take a second dose of MAXALT MELT for treatment of the same attack. It is still likely, however, that you will respond to MAXALT MELT during the next attack.

Do not take more than 2 doses of MAXALT MELT in a 24-hour period, (for example, do not take more than two 10 mg oral lyophilisates or more than two 10 mg or 5 mg tablets in a 24-hour period). You should always wait at least 2 hours between doses.

If your condition worsens, seek medical attention.

How to administer MAXALT oral lyophilisates

- MAXALT (rizatriptan benzoate) is available as a 5 or 10 mg oral lyophilisate that dissolves in the mouth.
- Open the MAXALT MELT oral lyophilisate blister pack with dry hands.
- The oral lyophilisate should be placed on your tongue, where it dissolves and can be swallowed with the saliva.
- 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.

MAXALT is also available as a tablet to be taken with liquids.

If you take more MAXALT MELT than you should:

If you take more MAXALT MELT 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 MELT 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, tremor,
- fast or irregular heart beat (palpitation), very fast heartbeat (tachycardia),
- flushing (redness of the face lasting a short time), hot flushes, sweating,
- throat discomfort, difficulty breathing (dyspnoea),
- feeling sick (nausea), dry mouth, vomiting, diarrhoea,
- feeling of heaviness in parts of the body,
- 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.
- confusion, insomnia, nervousness.
- high blood pressure (hypertension); thirst, indigestion (dyspepsia).
- rash, itching and lumpy rash (hives); swelling of face, lips, tongue and/or throat which may cause difficulty breathing and/or swallowing (angioedema).
- neck pain, feeling of tightness in parts of the body, stiffness, 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).
- facial pain; muscle pain.

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

- fainting (syncope).
- 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 MELT.

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.

5. HOW TO STORE MAXALT MELT

Keep MAXALT MELT out of the reach and sight of children.

Do not use MAXALT MELT after the expiry date which is stated on the carton/carry case/sachet/blister after "EXP". The expiry date refers to the last day of the month.

Do not store MAXALT MELT oral lyophilisate above 30°C.

Store in the original packaging in order to protect from moisture.

Do not remove the oral lyophilisate blister from the outer aluminium sachet until you are ready to take the medicine inside. Do not use the medicine if the aluminium sachet is damaged.

Always keep the aluminium sachets in the carrying case.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What MAXALT MELT contains

The active substance of the MAXALT MELT is rizatriptan. One oral lyophilisate contains 10 mg rizatriptan as 14.53 mg of rizatriptan benzoate.

The other ingredients of MAXALT MELT oral lyophilisates are: gelatin, mannitol (E421), glycine, aspartame (E951) and peppermint flavour (composed of peppermint oil, maltodextrin and dextrin).

What MAXALT MELT looks like and contents of pack

10 mg oral lyophilisates are white to off-white, round with a modified square on one side, with a peppermint flavour.

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

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 Melt 10 mg Oral Lyophilisate

| | |
|--------------------------|---|
| Austria, Finland, Sweden | MAXALT RAPITAB |
| Belgium, Luxemburg | MAXALT LYO 10 mg |
| Bulgaria | Максалт RPD 10 mg перорален лиофилизат |
| Cyprus, Estonia, Latvia | MAXALT |
| Czech Republic | MAXALT 10 mg perorální lyofilizát |
| Denmark | MAXALT Smelt, smeltetabletter |
| France | MAXALTLYO |
| Germany | MAXALT lingua 10 mg Schmelztabletten |
| Greece | MAXALT Rapid Sol. Tab. |
| Hungary | MAXALT RAPIDISC 10 mg belsőleges iofilizátum |
| Iceland | MAXALT SMELT 10 mg frostþurrkaðar töflur |
| Ireland | Rizatriptan 10 mg oral lyophilisates |
| Italy | MAXALT RPD 10 mg liofilizzato orale |
| Lithuania | MAXALT 10 mg geriamieji liofilizatai |
| Malta, United Kingdom | MAXALT MELT |
| The Netherlands | MAXALT SMELT |
| Norway | Maxalt Rapitab |
| Poland, Portugal | MAXALT RPD |
| Romania | Maxalt 10mg liofilizat oral |
| Slovakia | MAXALT 10 mg perorálny |
| Slovenia | Maxalt 10 mg peroralni liofilizati |
| Spain | MAXALT MAX 10mg |

This leaflet was revised in April 2013.

How can you obtain more information about MAXALT MELT?

This leaflet gives you some of the most important information about MAXALT MELT. 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 organisations and are not associated with Merck Sharp & Dohme Limited.)

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