

Patient Information about
MAXALT® (max-awlt) and MAXALT-MLT®
for Migraine
Generic name: rizatriptan benzoate

Please read this information before you start taking MAXALT*. Also, read the leaflet each time you renew your prescription, just in case anything has changed. Remember, this leaflet does not take the place of careful discussions with your doctor. You and your doctor should discuss MAXALT when you start taking your medication and at regular checkups.

What is MAXALT and what is it used for?

MAXALT is a medication used for the treatment of migraine attacks in adults. MAXALT is a member of a class of drugs called selective 5-HT_{1B/1D} receptor agonists.

It is available as a traditional tablet (MAXALT) and as an orally disintegrating tablet (MAXALT-MLT*). Unless otherwise stated, the information contained in this leaflet applies both to MAXALT Tablets and to MAXALT-MLT Orally Disintegrating Tablets.

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

You will find more information about migraine at the end of this leaflet.

How should I take MAXALT?

Your doctor has prescribed either a 5-mg or 10-mg dosage of MAXALT or MAXALT-MLT for your migraine attack. When you have a migraine headache, take your medication as directed by your doctor.

MAXALT Tablets

If you are using MAXALT Tablets, swallow the tablet whole with liquid.

MAXALT-MLT Orally Disintegrating Tablets

If you are using MAXALT-MLT, leave the orally disintegrating tablet in its package until you are ready to take it. Remove the blister from the foil pouch. Do not push the tablet through the blister; rather, peel open the blister pack with dry hands and place the tablet on your tongue. The tablet will dissolve rapidly and be swallowed with your saliva. No liquid is needed to take the orally disintegrating tablet.

If your headache comes back after your initial dose, a second dose may be taken anytime after 2 hours of administering the first dose. For any attack where you have no response to the first dose, do not take a second dose without first consulting with your doctor. 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).

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If you are receiving propranolol, you should use the 5-mg dose of MAXALT or MAXALT-MLT, up to a maximum of 3 doses (15 mg total) in a 24-hour period.

If your condition worsens, seek medical attention.

Who should not take MAXALT?

Do not take MAXALT if you:

- have had a serious allergic reaction to MAXALT or any of its ingredients
- have uncontrolled high blood pressure
- have heart disease or history of heart disease
- are currently taking monoamine oxidase (MAO) inhibitors** such as phenelzine sulfate (NARDIL®) or tranylcypromine sulfate (PARNATE®) for mental depression, or have taken MAO inhibitors within the last two weeks.

MAXALT should not be used within 24 hours of treatment with another 5-HT₁ agonist** such as sumatriptan (IMITREX®), naratriptan (AMERGE™) or zolmitriptan (ZOMIG™); or ergotamine-type medications such as ergotamine (BELLERGA-S®, CAFERGOT®, ERGOMAR®, WIGRAINE®), dihydro-ergotamine (D.H.E. 45®), or methysergide (SANSERT®).

What should I tell my doctor before and during treatment with MAXALT?

Tell your doctor:

- about any past or present medical problems
- about any history of high blood pressure, chest pain, shortness of breath, heart disease, or stroke
- about any risk factors for heart disease or blood vessel disease
 - high blood pressure or diabetes
 - high cholesterol
 - obesity
 - smoking
 - family history of heart disease or blood vessel disease
 - post menopausal
 - male over 40
- about any allergies you have or have had
- if you are pregnant or plan to become pregnant
- if you are breast-feeding or plan to breast-feed
- about all drugs you are taking or plan to take, including those obtained without a prescription, and those you normally take for a migraine.

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MAXALT® (Rizatriptan Benzoate) Tablets

MAXALT-MLT® (Rizatriptan Benzoate) Orally Disintegrating Tablets

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- if you take selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs), two types of drugs for depression or other disorders. Common SSRIs** are CELEXA® (citalopram HBr), LEXAPRO® (escitalopram oxalate), PAXIL® (paroxetine), PROZAC®/SARAFEM® (fluoxetine), SYMBYAX® (olanzapine/fluoxetine), ZOLOFT® (sertraline), and fluvoxamine. Common SNRIs** are CYMBALTA® (duloxetine) and EFFEXOR® (venlafaxine).

MAXALT-MLT orally disintegrating tablets contain aspartame, a source of phenylalanine.

Phenylketonurics: MAXALT-MLT 5-mg and 10-mg orally disintegrating tablets contain 1.05 and 2.10 mg phenylalanine, respectively.

What if I am pregnant?

Do not use MAXALT if you are pregnant, think you might be pregnant, are trying to become pregnant, or are not using adequate contraception, unless you have discussed this with your doctor.

Can I take MAXALT with other medications?**

Do not take MAXALT with any other drug in the same class within 24 hours, such as sumatriptan (IMITREX®), naratriptan (AMERGE™) or zolmitriptan (ZOMIG™).

Do not take MAXALT within 24 hours of taking ergotamine-type medications such as ergotamine (BELLERGAL-S®, CAFERGOT®, ERGOMAR®, WIGRAINE®), dihydro-ergotamine (D.H.E. 45®) or methysergide (SANSERT®) to treat your migraine.

Do not take MAXALT when you are taking monoamine oxidase (MAO) inhibitors, such as phenelzine sulfate (NARDIL®) or tranylcypromine sulfate (PARNATE®) for mental depression, 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 (INDERAL®). (See **How should I take MAXALT?** section.)

Ask your doctor for instructions about taking MAXALT if you are now taking selective serotonin reuptake inhibitors (SSRIs) or serotonin norepinephrine reuptake inhibitors (SNRIs), two types of drugs for depression or other disorders. (See **What should I tell my doctor before and during treatment with MAXALT?** section.)

What are the possible side effects of MAXALT?

Like all prescription drugs, MAXALT can cause side effects. In studies, MAXALT was generally well-tolerated. The side effects were usually mild and temporary. The following is **not** a complete list of side effects reported with MAXALT. Do not rely on this leaflet alone for information about side effects. Ask your doctor to discuss with you the more complete list of side effects.

In studies, the **most common** side effects reported were:

- **dizziness**
- **sleepiness, tiredness, fatigue**
- **pain or pressure sensation (e.g., in the chest or throat)**

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If you experience dizziness, sleepiness, tiredness or fatigue, you should evaluate your ability to perform complex tasks such as driving or operating heavy machinery.

Other, **less common** side effects reported in studies or general use were related to the:

Heart and blood vessels - Alterations in heartbeat, increased blood pressure and spasm of blood vessels of the extremities including coldness and numbness of the hands or feet.

Muscles - Muscle weakness, stiffness, and spasm; and muscle and bone pain.

Nervous system - Nervousness, decreased mental sharpness, tremor, headache, abnormal sensation, vertigo, sleep disturbance, mood and personality changes, alterations in speech and movement, memory impairment, confusion, dream abnormality and seizure.

Digestive system - Stomach upset, diarrhea, dry mouth, constipation, gas, thirst, acid reflux, difficulty swallowing, changes in appetite, burping and inability of the tongue to move.

Skin - Flushing (redness of the face lasting a short time), hot flashes, sweating, itching, rash, acne and skin reaction to sunlight.

Respiratory - Difficult or rapid breathing, dryness or discomfort of the throat or nose, nosebleed, yawning and sinus disorder, cold-like symptoms, cough, and hiccups.

Special Senses - Visual disturbances, ringing in the ears, ear pain, eye discomfort, swelling or tearing, alterations in hearing and smelling, visual intolerance to light, and bad taste.

Miscellaneous - Allergic reactions including swelling of face, lips, tongue and/or throat which may cause difficulty in breathing and/or swallowing, wheezing, hives, rash, and severe sloughing of the skin. Also chills, heat sensitivity, swelling, bloating, hangover effect, fever, fainting, dizziness on standing up, warm/cold sensations, dehydration and changes in urination and menstruation.

As with other drugs in this class, there have been very rare reports of heart attack and stroke generally occurring in patients with risk factors for heart and blood vessel disease (see **What should I tell my doctor before and during treatment with MAXALT?**).

Tell your doctor about these or any other symptoms. If the symptoms persist or worsen, seek medical attention promptly. In addition, tell your doctor if you experience any symptoms that suggest an allergic reaction (see **Miscellaneous** above) after taking MAXALT.

What should I do if I take an overdose?

If you take more medication than you have been told to take, you should contact your doctor, hospital emergency department, or nearest poison control center immediately.

What is migraine and how does it differ from other headaches?

Migraine is an intense, throbbing, typically one-sided headache that often includes nausea, vomiting, sensitivity to light, and sensitivity to sound. According to many migraine sufferers, the pain and symptoms from a migraine headache are more intense than the pain and symptoms of a common headache.

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Some people may have visual symptoms before the headache, such as flashing lights or wavy lines, called an aura.

Migraine attacks typically last for hours or, rarely, for more than a day, and they can return frequently. The severity and frequency of migraine attacks may vary.

Based on your symptoms, your doctor will decide whether you have migraine.

Who gets migraine?

Migraine headaches tend to occur in members of the same family. Both men and women get migraine, but it is more common in women.

What may trigger a migraine attack?

Certain things are thought to trigger migraine attacks in some people. Some of these triggers are:

- certain foods or beverages (e.g., cheese, chocolate, citrus fruit, caffeine, alcohol)
- stress
- change in a behavior (e.g., under/oversleeping; missing a meal; change in diet)
- hormonal changes in women (e.g., menstruation)

You may be able to prevent migraine attacks or diminish their frequency if you understand what specifically triggers your attacks. Keeping a headache diary may help you identify and monitor the possible migraine triggers you encounter. Once the triggers are identified, you and your doctor can modify your treatment and lifestyle appropriately.

How does MAXALT work during a migraine attack?

Treatment with MAXALT:

1. Reduces swelling of blood vessels surrounding the brain. This swelling 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.

It is thought that each of these actions contributes to relief of your symptoms by MAXALT.

How should I store MAXALT?

Keep your medicine in a safe place where children cannot reach it. It may be harmful to children. Store your medication away from heat, light, moisture, and at a controlled room temperature 59°-86°F (15°-30°C). If your medication has expired, throw it away as instructed. If your doctor decides to stop your

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treatment, do not keep any leftover medicine unless your doctor tells you to do so. Throw away your medicine as instructed. Be sure that the discarded tablets are out of the reach of children.

If you are storing MAXALT-MLT, do not remove the blister from the outer aluminum pouch until you are ready to take the medication inside.

This leaflet provides a summary of information about MAXALT. If you have any questions or concerns about either MAXALT or migraine, talk to your doctor. In addition, talk to your pharmacist or other health care provider.

MAXALT Tablets are manufactured for:

 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

By:

MSD, Ltd. Cramlington
Northumberland, NE23 3JU, UK

MAXALT-MLT Orally Disintegrating Tablets are manufactured for:

 **MERCK & CO., INC.**, Whitehouse Station, NJ 08889, USA

By:

Catalent UK Swindon, Zydys Ltd.
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