

Package leaflet: Information for the patient

Sumatran Relief 50 mg Tablets sumatriptan (as succinate)

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

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice
- If you get any side effects, talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after one day (24 hours).

What is in this leaflet

1. What Sumatran Relief is and what it is used for
2. What you need to know before you take Sumatran Relief
3. How to take Sumatran Relief
4. Possible side effects
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1. What Sumatran Relief is and what it is used for

Sumatran Relief contains the active substance sumatriptan, that belongs to a group of medicines called triptans, which are used to treat migraine headache.

Sumatran Relief can be used to relieve acute migraine attacks that happen with or without warning signs (aura), such as sensitivity to light, feeling sick, in patients who have a well established pattern of symptoms and who have previously been diagnosed with migraine.

Sumatran Relief must only be used if a diagnosis of “migraine” has been clearly established by your doctor in your case and other factors have been excluded. Certain forms of migraine cannot be treated with sumatriptan.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Sumatriptan is believed to reduce the widening of these blood vessels. This in turn helps to take away the headache and relieve other symptoms of a migraine attack, such as feeling or being sick (nausea or vomiting) and sensitivity to light and sound.

Sumatran Relief works only when a migraine attack has started. It will not stop you from getting an attack. You must not use sumatriptan to prevent a migraine attack.

You must talk to a doctor if you do not feel better or if you feel worse after one day.

2. What you need to know before you take Sumatran Relief

Do not take Sumatran Relief:

- if you are allergic to sumatriptan or any of the other ingredients of this medicine (listed in section 6) (see also “Warnings and precautions”)
- if you are allergic to certain antibiotics (sulfonamides)
- if you are trying to prevent a migraine attack
- if you are under 18 or over 65

- if you have seizures or a history of seizure or if you have other conditions which might make it more likely that you'll have a fit – for example, a head injury or alcoholism. Sumatriptan might increase the risk of seizures.
- if you have or have ever had heart problems, including a heart attack, angina (chest pain caused by exercise or effort), Prinzmetal's angina (chest pain which happens at rest) or have experienced heart-related symptoms such as shortness of breath or palpitations
- if you have problems with the blood circulation to your hands and feet (peripheral vascular disease)
- if you have had a stroke
- if you have had a mini-stroke (TIA)
- if you have liver or kidney impairment
- if you have high blood pressure or a history of high blood pressure
- if you are taking drugs containing ergotamine or ergotamine derivatives (migraine drugs such as methysergide) or any triptan/5-HT₁ receptor agonist. These must not be taken at the same time as sumatriptan.
- if you are currently taking or have stopped taking MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease) within the last two weeks. See also "Other medicines and Sumatran Relief" below.
- if you have been told by your doctor that you have a rare form of migraine such as hemiplegic, basilar or ophthalmoplegic migraine.

Warnings and precautions

Talk to your doctor or pharmacist or nurse before taking Sumatran Relief if:

- you are a smoker or a heavy user of products containing nicotine (patches or chewing gum), especially if you are a woman past the menopause or a man over 40 years
- you have high cholesterol, diabetes, a family history of early heart disease (father/brother developed heart disease before the age of 55, mother/sister developed heart disease before the age of 65) or are marked obese. The doctor should examine you first.

After taking Sumatran Relief, you may feel pain in your chest and a feeling of pressure for a short time. This can be quite intensive and may radiate up towards your throat. In very rare cases this may be caused by effects on your heart. Therefore, if the symptoms do not disappear, contact your doctor.

Prolonged use of any type of painkiller for headaches can make them worse. Medication-overuse headache is a dull constant headache which is often worse in the morning. It is present on most days or part of every day. If you take Sumatran Relief too often (e.g. on 2 or more days each week) alone or in combination with other painkillers (more than 10 occasions per month), your headache may also become worse. In this case, your doctor or pharmacist might recommend you stop taking Sumatran Relief.

Contact your doctor if:

- ◆ your typical headaches persist for longer than 24 h
- ◆ you experience four or more migraine attacks per month
- ◆ you do not recover completely between attacks
- ◆ your attacks have worsened or become more frequent, more persistent, or their symptoms have changed
- ◆ you have any unusual symptoms suggestive of a stroke or TIA (transient ischaemic attack) such as muscle weakness, clumsiness, visual disturbances, confusion.

If you are using sumatriptan intermittently over a longer term, it is advisable to see your doctor for regular check-ups as your risk for heart disease and stroke might change.

Children and adolescents

Sumatran Relief is not recommended in children and adolescents below the age of 18 years or in older people over 65 years of age.

Other medicines and Sumatran Relief

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines including any herbal products, dietary supplements such as vitamins, iron or calcium or medicines that you bought without a prescription.

Certain medicines can cause side effects if taken together with Sumatran Relief:

You must tell your pharmacist if you are taking:

- any medicines containing a triptan (including other sumatriptan containing products, zolmitriptan, rizatriptan, naratriptan) or
- any medicines containing ergotamine or methysergide
- MAO inhibitors (e.g. moclobemide) to treat depression or selegiline to treat Parkinson's disease. Sumatran Relief must not be taken at the same time as or within two weeks after stopping use of MAO inhibitors.
- SSRIs (e.g. citalopram, fluoxetine, paroxetine) and SNRIs (e.g. duloxetine, venlafaxine) used to treat depression. Using [Nationally completed name] with these medicines can cause serotonin syndrome (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heart beat and shaking). Tell your doctor immediately if you are affected in this way.
- lithium (for manic/depressive [bipolar] disorders). Can also cause serotonin syndrome as described above.
- herbal products containing St John's wort (*Hypericum perforatum*). Side effects may occur with greater frequency.
- with concomitant use of oral contraceptives, due to an increased risk of stroke.

Pregnancy, breast-feeding and fertility

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

Don't breast-feed your baby for 12 hours after using Sumatran Relief.

Some breastfeeding women report breast and/or nipple pain after use of sumatriptan. The pain is usually temporary and disappears in 3 to 12 hours.

Driving and using machines

Migraine itself as well as using sumatriptan can cause drowsiness, dizziness and weakness which may adversely affect your speed of reaction. Wait until you have found out how you react to Sumatran Relief. You should not drive or use machines until you are sure you are not affected.

Sumatran Relief contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

Sumatran Relief contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially "sodium free"

Sumatran Relief contains sulphites

The grapefruit flavouring contains sulphites that may rarely cause severe hypersensitivity reactions and bronchospasm.

3. How to take Sumatran Relief

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Take it as early as possible during a migraine attack, but it can also be taken during an ongoing attack.

The recommended dose is:

Adults (18 to 65 years):

The recommended dose is 50 mg sumatriptan once the migraine has started.

If your migraine improves after the first dose (50 mg) but the symptoms reappear an additional 50 mg can be taken. You must wait at least 2 hours after taking the first dose before you can take the second dose. You must not take more than 100 mg of sumatriptan in any 24-hour period.

If the first tablet has no effect:

Do not take a second tablet for the same attack. If the first tablet has no effect, you can take other painkillers such as paracetamol, acetylsalicylic acid, or non-steroidal anti-inflammatory drugs, such as ibuprofen medicines.

Method of administration

Take the tablet with water, preferably as soon as possible after onset of the migraine attack.

The recommended dose must not be exceeded.

The tablet can be divided into equal doses.

Children under 18 and adults over 65

Sumatran Relief is not recommended for these age groups. Talk to your doctor if you have migraine symptoms.

If you take more Sumatran Relief than you should

When you take too much of Sumatran Relief, immediately contact your doctor or pharmacist. Side effects such as those mentioned under “Possible side effects” may occur.

If you forget to take Sumatran Relief Do not take a double dose to make up for a forgotten dose.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of the symptoms reported as undesirable effects may be associated symptoms of migraine.

Stop taking the medicine and seek urgent medical advice if you experience

- Allergic reactions: The signs of allergy include rash, hives (itchy rash); wheezing; swollen eyelids, face or lips; complete collapse.
- Fits or seizures
- Heart problems including palpitations or chest pain that does not resolve shortly after taking Sumatran Relief.

The side effects are listed by the following frequency:

Common: (may affect up to 1 in 10 people):

- Feeling dizzy
- Feeling sleepy
- Feeling of unusual sensations, including numbness or tingling
- Temporary increase in blood pressure, soon after intake
- Hot flushes
- Breathlessness
- Feeling sick and vomiting. This may be due to the migraine itself.
- Feeling of pain, heaviness or sensations of heat or cold, pressure or tightness. These effects may be intense, affect any part of the body including the chest and throat but generally pass quickly.
- Aching muscles
- Feeling of weakness or tiredness. These effects are mostly mild to moderate in intensity and pass quickly.

Uncommon: (may affect up to 1 in 100 people):

- Drowsiness

Rare: (may affect up to 1 in 1,000 people)

- Breast pain

Very rare: (may affect up to 1 in 10,000 people):

- Disturbances in liver function tests

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

- Allergic reactions of all degrees of severity varying from skin reactions to allergic shock
- Fits/seizures
- Tremor, tremor of the eyes
- Visual field disturbances
- Uncontrolled/abnormal muscle movement
- Impaired vision, e.g. double vision, flickering and sometimes loss of vision with permanent impairment. Visual disturbances can also occur as a result of the migraine attack itself.
- Slow heart beat, fast heart beat, irregular heart beat, palpitations
- Temporary disturbances of the blood circulation of the heart, spasms of the blood vessels of the heart, chest pain, heart attack
- Fall in blood pressure, reduced blood flow to the arms and legs and consequent pallor and blue tinge to the fingers and toes
- Pain in the lower left side of the stomach and bloody diarrhoea (ischaemic colitis)
- Diarrhoea
- Stiff neck, pain in the joints
- Minor disturbances in liver function tests
- Feeling anxious
- Excessive sweating
- If you had a recent injury or if you have inflammation (like rheumatism or inflammation of the colon) you may experience pain or pain worsening at the site of injury or inflammation
- Difficulty swallowing.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sumatran Relief

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 and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Sumatran Relief contains

- The active substance is sumatriptan (as succinate).
Each tablet contains 50 mg sumatriptan (as succinate).

- The other ingredients are: ammonium methacrylate copolymer type A, carmellose sodium (E 466), microcrystalline cellulose (E 450), croscarmellose sodium (E 468), lactose monohydrate, magnesium stearate (E 470b), flavouring (grapefruit) (contains sulphites), red iron oxide (E 172), yellow iron oxide (E 172).

What Sumatran Relief looks like and contents of the pack

Sumatran Relief 50 mg Tablets are pink, oblong tablets with a break-notch on both sides.

Sumatran Relief 50 mg tablets: Pack size of 2 tablets.

Marketing Authorisation Holder

Rowex Ltd., Bantry, Co. Cork, Ireland.

Manufacturers

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany.

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Information on migraine:

Migraine attacks can occur for no apparent reason, but some people find that their migraines are triggered by something.

Triggers might include:**Diet** (food and drink):

Chocolate, cheese, red wine, citrus fruits, irregular meals, coffee, tea or cutting down on caffeine.

Environmental:

Smoking, smoky rooms, glaring light, flashing lights, flickering TV sets, strong smells, loud noises.

Psychological:

Stress, anxiety, anger, tiredness

Other:

Different sleep patterns (too much or too little), periods (menstruation), some medicines e.g. the Pill, menopause.

It may help to keep a migraine diary. Note down when and where each migraine attack started, what you were doing and what you had eaten that day. You may see a pattern and it may be possible to avoid one or more things that are triggering your attacks.

Cutting out triggers does not always prevent a migraine. Most migraines are not caused by a single, identifiable trigger but by a combination of factors.