

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sumatriptan 50mg & 100mg Film-coated Tablets

Sumatriptan

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

1. What Sumatriptan is and what it is used for
2. What you need to know before you take Sumatriptan
3. How to take Sumatriptan
4. Possible side effects
5. How to store Sumatriptan
6. Contents of the pack and other information

1. WHAT SUMATRIPTAN IS AND WHAT IT IS USED FOR

Sumatriptan tablet contains the active substance sumatriptan as sumatriptan succinate, which belongs to a group of medicines called triptans (also known as 5-HT₁ receptors agonists). Sumatriptan is used to treat migraine headache.

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 turns help to take away the headache or relieve other symptoms of a migraine attack, such as feeling or being sick (nausea or vomiting) and sensitivity to light and sound.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SUMATRIPTAN

Do not take Sumatriptan if you:

- are allergic to sumatriptan, selective 5-HT₁ receptor agonists, antibiotics called sulphonamides, or to any of the other ingredients of this medicine (listed in section 6).
- have a heart problem such as narrowing of the arteries or chest pains, or have already had a heart attack.
- have circulation problem in your legs that cause cramp-like pains when you walk (peripheral vascular disease).
- have had a stroke or a mini-stroke (also called transient ischaemic attack or TIA).
- have serious liver disease.
- have high blood pressure. You may be able to use Sumatriptan if your high blood pressure is mild and is being treated.
- are taking other migraine medicines, including those which contains ergotamine, or similar medicines such as methysergide maleate; or any triptan or 5-HT₁ agonist (such as naratriptan or zolmitriptan).
- are taking anti-depressants called monoamine oxidase inhibitors (MAIOs), if you

- have taken an MAIO in the last 2 weeks.
- are a child under 18 years of age.

Warnings and Precautions

Sumatriptan should only be used if there is a clear diagnosis of migraine.

Talk to your doctor or pharmacist before taking Sumatriptan if you:

- are a heavy smoker, or using nicotine replacement therapy, and especially if you are a man aged over 40 or a woman who has been through the menopause, tell your doctor so that your heart function can be checked before Sumatriptan is prescribed for you. In very rare cases, people have developed serious heart conditions after using Sumatriptan, even though they had no signs of heart disease before. If any of the above points applies to you, it could mean you have a greater risk of developing heart disease.
- have a history of fits (seizures) or if you have other conditions which might make it more likely that you will have a fit for example, a head injury or alcoholism, tell your doctor so that you can be supervised more closely.
- have had high blood pressure, Sumatriptan may not be suitable for you. Tell your doctor or pharmacist before using Sumatriptan.
- have liver or kidney disease, tell your doctor or pharmacist before using Sumatriptan.
- have an intolerance to some sugars, tell your doctor so that you can be supervised more closely.
- are allergic to antibiotics called sulphonamides, you may also be allergic to Sumatriptan. If you know you are allergic to an antibiotic but you are not sure whether it is a sulphonamide, tell your doctor or pharmacist before taking Sumatriptan.
- are taking antidepressants called SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors), tell your doctor or pharmacist before using Sumatriptan. Also see “Other medicines and Sumatriptan”.
- use Sumatriptan frequently, using Sumatriptan too often may make your headache worse. Tell your doctor if this applies to you. He or she may recommend you stop using Sumatriptan.
- feel pain or tightness in your chest after you see Sumatriptan, these effects may be intense but they usually pass quickly. If they do not pass quickly, or they become severe, get medical help immediately. Section 4 has more information about these possible side effects.

Other medicines and Sumatriptan tablets

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes any herbal products or medicines you have bought without a prescription.

Some medicines must not be taken with Sumatriptan, and others may cause adverse effects if they are taken together with Sumatriptan. You must tell your doctor if you are taking:

- ergotamine also used to treat migraine (see section 2). Do not use Sumatriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan. Do not take any medicines which contain ergotamine or compounds similar to ergotamine again at least 6 hours after using Sumatriptan.
- other triptans/5-HT₁ receptor agonists (such as naratriptan, rizatriptan, zolmitriptan), also used to treat migraine, (see section 2). Do not use Sumatriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before using

Sumatriptan. Do not take another triptans/5-HT1 receptors agonist again for atleast 24 hours after using Sumatriptan. .

- MAOIs used to treat depression. Do not use Sumatriptan if you have taken these in the last 2 weeks.
- SSRIs and SNRIs used to treat depression. Using Sumatriptan with these medicines can cause serotonin syndrome (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms. Shivering, increased heartbeat and shaking).tell your doctor immediately if you are affected in this way.
- St John's wort (*Hypericum perforatum*). Taking herbal remedies That contain ST John's wort together with Sumatriptan may make side effects more likely.

Pregnancy and breast-feeding

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

Pregnancy

There is only limited information about the safety of Sumatriptan for pregnant women, though up till now there is no evidence of any increased risk of birth defects. Your doctor will discuss with you whether or not you should use Sumatriptan while you are pregnant.

Breast-feeding

Do not breast-feed your baby for 12 hours after using Sumatriptan. If you express any breast milk during this time, discard the milk and do not give it to your baby.

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

Either the symptoms of migraine or your medicine may make you drowsy. If you are effected, do not drive or operate machinery.

Sumatriptan 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.

Information about sodium content

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

3. HOW TO TAKE SUMATRIPTAN

Always take Sumatriptan 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.

- These tablets are to be taken orally.
- Swallow the tablets whole with a glass of water.
- Sumatriptan has a bitter taste. The bitter taste is masked with aid of a grapefruit flavour.
- This medicine is intended to treat short-lived (acute) migraine attacks and should not be used to prevent migraine attacks.
- The score line is only to facilitate breaking for the ease of swallowing and not to divide into equal doses.

- Sumatriptan should be taken as soon as possible after the onset of the migraine headache. However, Sumatriptan is equally effective when used at a later time during the migraine attack.

Adults

- The recommended dose is 50 mg. In some cases, a 100 mg dose may be needed.

Use in children and adolescents

Sumatriptan is not recommended for use in children under 18 years of age.

Elderly

Sumatriptan is not recommended.

Hepatic impairment

If you have mild to moderate liver problems, your doctor may start you on a lower dose (25-50 mg).

If your symptoms start to come back

- You can take a second Sumatriptan tablet if at least 2 hours have passed since the first tablet. Do not take more than 300 mg in total in 24 hours.

If the first tablet has no effect

- Do not take a second tablet or any other Sumatriptan preparation for the same attack. Sumatriptan can still be used for your next attack.

If Sumatriptan does not give you any relief, ask your doctor or pharmacist for advice.

If you take more Sumatriptan than you should:

If you accidentally take too many tablets, contact your doctor or nearest hospital emergency department **immediately** for advice. Remember to take this leaflet or any remaining tablets with you.

If you forget to take Sumatriptan

Take as soon as you remember, unless it is nearly time for your next dose. If you miss a dose, do **not** take a double dose to make up for a forgotten dose.

If you stop taking Sumatriptan

It is important that you keep taking Sumatriptan for as long as your doctor has told you to.

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Sumatriptan can cause side effects, although not everybody gets them. Some symptoms may be caused by the migraine itself.

Allergic reaction: get doctor's help straight away

The following side effects have occurred but their exact frequency is not known.

- The signs of allergy include rash, hives, (itchy rash); wheezing; swollen eyelids, face or lips; complete collapse.

If you get any of these symptoms soon after using Sumatriptan, **do not use any more. Contact a doctor straight away.**

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

- Pain, heaviness, pressure, or tightness in the chest, throat or other parts of the body, or unusual sensations, including numbness, tingling, and warmth or cold. These effects may be intense but generally pass quickly. If these effects continue or become severe (especially the chest pain, get medical help urgently. In a very small number of people these symptoms can be caused by a heart attack.
- Short-lived/temporary muscle spasms of the jaw affecting jaw movement.

Other common side effects include:

- Feeling sick (nausea) or being sick (vomiting), although this may be due to the migraine itself.
- Tiredness or drowsiness.
- Dizziness, feeling weak, or getting hot flushes.
- Temporary increase in blood pressure.
- Shortness of breath.
- Aching muscles.

Other rare side effects include:

- Breast pain

Very rare side effects (may affect less than 1 in 10,000 people)

- Liver function changes. If you have a blood test to check your liver function, tell your doctor or nurse that you are taking Sumatriptan.

Some patients may get the following side effects but it is not known how often they occur

- Seizures/fits, tremors, muscle spasm, neck stiffness.
- Visual disturbances such as flickering, reduced vision, double vision, loss of vision, and in some cases even permanent defects (although these may be due to migraine attack itself).
- Heart problems, where your heartbeat may go faster, slower or change rhythm, chest pain (angina) or heart attack.
- Pale, blue-tinged skin, or pain in fingers, toes, ears, nose or jaw in response to cold or stress (Raynaud's phenomenon).
- Feeling faint (blood pressure may go down).
- Pain in the lower left side of the stomach and bloody diarrhoea (ischaemic colitis).
- Diarrhoea.
- Pain in the joints.
- 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, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

the Yellow Card Scheme at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google play or Apple Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE SUMATRIPTAN TABLETS

- 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 carbon/blister after EXP. The expiry date refers to the last day of that month.
- 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 to protect the environment.

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Sumatriptan contains

- The active substance is sumatriptan, as sumatriptan succinate.
- Each 50 mg tablet contains 50 mg of sumatriptan as sumatriptan succinate.
- Each 100 mg tablet contains 100 mg of sumatriptan as sumatriptan succinate.

The other ingredients are: ammonium methacrylate copolymer type A, carmellose sodium, microcrystalline cellulose, croscarmellose sodium, lactose monohydrate, magnesium stearate, flavouring (grapefruit).

Sumatriptan 50 mg tablets also contain colouring: red iron oxide (E172) and yellow iron oxide (E172).

What Sumatriptan tablets looks like and content of the pack

- Sumatriptan 50 mg are pink with partly pink dots, oblong tablets of width 6.8–7.2 mm and length 11.8–12.2 mm, with a break-line on both sides.
- Sumatriptan 100 mg are white to slightly yellow, oblong tablets of width 6.8–7.2 mm and length 11.8–12.2 mm with a break-line on both sides.
- Not all pack sizes may be marketed.

Sumatriptan Tablets are available in:

- Sumatriptan 50mg Tablets are available in blister pack of 2,3,4,6,8,12,18,20,30,50 or 100 tablets.
 - Sumatriptan 100 mg Tablets are available in blister packs of 2,3,4,6,12,18,19,20 or 30 tablets.
- Not all pack size may be marketed.

Marketing Authorization Holder

Activase Pharmaceuticals Limited
11 Boumpoulinas, 3rd Floor,
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Manufacturer

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

Product Licence Numbers:

Sumatriptan 50 mg Tablets: PL 28444/0221

Sumatriptan 100 mg Tablets: PL 28444/0222

HARD to READ? Phone 0800 970 6115 for help

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