

FLAT DIMENSION = 260 x 430mm
FOLDED DIMENSION = 130 x 27mm

30 mm

10 mm

PACKAGE LEAFLET: INFORMATION FOR THE USER

Sumatriptan 50 mg Film-coated Tablets
Sumatriptan 100 mg Film-coated Tablets
(sumatriptan succinate)

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

1. What Sumatriptan tablets are and what are they used for

The name of your medicine is Sumatriptan 50 mg and 100 mg Film coated Tablets. The active substance present in these tablets is Sumatriptan Succinate. Sumatriptan tablets belong to a group medicine called 5-hydroxytryptamine (5HT1), receptor 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 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.

2. What you need to know before you take Sumatriptan tablets

Do not take Sumatriptan tablets:

- if you are allergic to Sumatriptan, or any of the other ingredients of this medicine listed in section 6)
- if you have a heart problem such as narrowing of the arteries (Ischaemic heart disease) or chestpains (angina), or have already had a heart attack
- If you have circulation problems in your legs that cause cramp-like pains when you walk (peripheralvascular disease)
- if you have had a stroke or a mini-stroke (also known as transient ischaemic attack or TIA)
- if you have high blood pressure. You may be able to use Sumatriptan if your high blood pressureis mild and is being treated
- if you have serious liver disease
- **With other migraine medicines**, including those which contain ergotamine, or similar medicines such as methysergide maleate; or anytriptan or 5-HT1 agonist (such as naratriptan or zolmitriptan)

With any of the following anti-depressants:

- **MAOIs** (*monoamine oxidase inhibitors*) or if you have taken an MAOI in the last 2 weeks
- **SSRIs** (*selective serotonin reuptake inhibitors*) including citalopram, fluoxetine, fluvoxamine, paroxetine and sertaline
- **SNRIs** (*serotonin noradrenaline reuptake inhibitors*) including venlafaxine and duloxetine
- **For children under 18 years of age.**

If any of these apply to you: **Tell your doctor, and don’t use Sumatriptan tablets.**

Warnings and precautions

Talk to your doctor or pharmacist before taking this medicine:

If you have any extra risk factors

- **If you are a heavy smoker, or using nicotine replacement therapy**, and especially
- **If you are a man aged over 40**, or
- **If you are a woman who has been through the menopause.**

In very rare cases, people have developed serious heart conditions after using Sumatriptan tablets, even though they had no signs of heart disease before. If any of the points above applies to you it could mean you have a greater risk of developing heart disease – so: **tell your doctor** so that your heart function can be checked before Sumatriptan is prescribed for you.

- **If you have a history of fits** (*seizures*) 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: tell your doctor so that you can be supervised more closely.
- **If you have had high blood pressure Sumatriptan may not be suitable for you:** tell your doctor or pharmacist before using Sumatriptan.
- **If you have liver or kidney disease: If either of these apply to you:** tell your doctor or pharmacist before using Sumatriptan.
- **If you have an intolerance to some sugars:** tell your doctor so that you can be supervised more closely.
- **If you are allergic to antibiotics called sulphonamides.** If so, 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 using sumatriptan.
- **If you are taking anti-depressants called SSRIs** (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors). Tell your doctor or pharmacist before taking Sumatriptan. Also see Other medicines and Sumatriptan Tablets, below.
- **If you use Sumatriptan frequently:** Using Sumatriptan too often may make your headaches worse. Tell your doctor if this applies to you. He or she may recommend you stop using Sumatriptan.
- **If you feel pain or tightness in your chest after you use sumatriptan.** These effects may be intense but they usually pass quickly. If they don’t pass quickly, or they become severe: get medical help immediately. Section 4 (overleaf) has more information about these possible side effects.

The use of buprenorphine together with sumatriptan can lead to serotonin syndrome, a potentially life-threatening condition (see “Other medicines and Sumatriptan Tablets”).

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’re taken with Sumatriptan. **You must tell your doctor if you are taking:**
- **ergotamine** also used to treat **migraine**, or similar medicines such as methysergide (see section 2 Do not take Sumatriptan tablets). Don’t use Sumatriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan. Don’t take any medicines which contain ergotamine or compounds similar to ergotamine again for 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 take Sumatriptan tablets). Don’t use Sumatriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan. Don’t take another triptan/5-HT1 receptor agonist again for at least 24 hours after using Sumatriptan.
 - **MAOIs** used to treat **depression**. Don’t 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** (*Hypericumperforatum*). Taking herbal remedies that contain St John’s Wort together with Sumatriptan may make side effects more likely.
- Buprenorphine/ opioids (used to treat opioid overdose). These medicines may interact with Sumatriptan and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

Pregnancy, breast-feeding and fertility

Pregnancy

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

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

Don’t breast-feed your baby for 12 hours after using Sumatriptan.

If you express any breast milk during this time, discard the milk and don’t 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 affected, don’t drive or operate machinery.**

Sumatriptan Tablets contain Lactose

Sumatriptan tablets contain lactose monohydrate. If you have been told by your doctor that you have intolerance to some sugars, speak to your doctor before taking this medicinal product.

Information on 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 tablets

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

When to take Sumatriptan tablets

- It’s best to take sumatriptan as **soon as you feel a migraine coming on**, although you can take it at any time during an attack
- **Don’t use sumatriptan** to try to prevent an attack – only use it after your migraine symptoms start.

The recommended dose is:

- **Adults (18 to 65 years of age): The usual dose for adults aged 18 to 65** is one Sumatriptan 50 mg tablet, swallowed whole with water. Some patients may need a 100 mg dose - you should follow your doctor’s advice.
- **Children and adolescents (under 18 years of age): Sumatriptan** is not recommended for children under 18 years old.
- **Elderly (over 65 years of age): Sumatriptan** is not recommended for people aged over 65.

