



Package leaflet: Information for the patient

Sumatriptan 50mg Film-coated Tablets
Sumatriptan 100mg 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. 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 of the side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- The product names are Sumatriptan 50mg Film-coated Tablets and Sumatriptan 100mg Film-coated Tablets but will be referred to as Sumatriptan throughout the leaflet.

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

Each Sumatriptan triangular shaped tablet contains a single dose of sumatriptan, which belongs to a group of medicines called triptans (also known as 5-HT1 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

Do not take Sumatriptan

- **If you're 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 *chest pains (angina)*, or have already had a heart attack
- **If you have circulation problems in your legs** that cause cramp-like pains when you walk (*peripheral vascular disease*)
- **If you have had a stroke** or a mini stroke (*also called a transient ischaemic attack or TIA*)
- **If you have high blood pressure.** You may be able to use Sumatriptan if your high blood pressure is 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 any triptan or 5HT1 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
 - **For children under 18 years of age.**

Do not take sumatriptan if any of these apply to you and tell your doctor.

Warnings and precautions

Talk to your doctor or pharmacist before taking sumatriptan if:

- **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, 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 using sumatriptan.** Also see 'Other medicines and Sumatriptan', 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.

Other medicines and Sumatriptan

Tell your doctor or pharmacist if you are taking or have recently taken any other medicines. This includes medicines that you buy without a prescription and herbal medicines.

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 Don't use Sumatriptan). 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 Don't use Sumatriptan). 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 (Hypericum perforatum)**. Taking herbal remedies that contain St John's Wort together with Sumatriptan may make side effects more likely.

Fertility, pregnancy and breast-feeding

- **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
- **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 contains lactose

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

Sumatriptan contains sodium

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

When to take Sumatriptan

- 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 aged 18 to 65

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 under 18

Sumatriptan is not recommended for children under 18 years old.

Elderly (aged over 65)

Sumatriptan is not recommended for people aged over 65.

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. **Don't take more than 300 mg in total in 24 hours.**

If the first tablet has no effect

Don't take a second tablet or any other Sumatriptan preparation for the same attack. Sumatriptan can still be used for your next attack.

If Sumatriptan doesn't give you any relief: Ask your doctor or pharmacist for advice.

If you take more Sumatriptan than you should

Don't take more than six 50 mg tablets or three 100 mg tablets (300 mg in total) in any 24 hours.

Taking too much Sumatriptan could make you ill. If you have taken more than 300 mg in 24 hours than you should, talk to a doctor or go to a hospital straight away. Take the medicine pack with you.

If you have any further questions about 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 everyone will get them. Some symptoms may be caused by the migraine itself.

Within the system organ classes, adverse reactions are listed under headings of frequency (number of patients expected to experience the reaction), using the following categories:

Very common: may affect more than 1 in 10 people

Common: may affect up to 1 in 10 people

Uncommon: may affect up to 1 in 100 people

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

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

Not known: frequency cannot be estimated from the available data

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: **Don't 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.

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

- 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.

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

- Breast pain

Very rare side effects (may affect up to 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.
- **Not known:** frequency cannot be estimated from the available data
- 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 the migraine attack itself)
- Heart problems, where your heartbeat may go faster, slower or change rhythm, chest pains (*angina*) or heart attack
- Pale, blue-tinged skin and/or pain in your 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
- 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.
- Pain in the joints
- Feeling anxious
- Difficulty swallowing
- Excessive sweating

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: United Kingdom Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store'.

5. How to store Sumatriptan

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

This medicinal product does not require any special storage condition.

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 Sumatriptan tablets contain**

The active substance is sumatriptan succinate.

The other ingredients are microcrystalline cellulose, lactose monohydrate, croscarmellose sodium, magnesium stearate, titanium dioxide, polydextrose, hypromellose, triacetin, macrogol. The 100mg tablet also contains iron oxide red and iron oxide yellow.

What Sumatriptan tablets looks like and contents of the pack

Sumatriptan 50mg tablets are white, triangular shaped, biconvex, film-coated tablet, debossed with "SUM" on one side and "50" on the other side.

Sumatriptan 100mg tablets are pink, triangular shaped, biconvex, film-coated tablet, debossed with "SUM" on one side and "100" on the other side.

Sumatriptan 50mg tablets are available in ALU-PVC/PVDC blister packs of 2, 3, 6, 12, 18 or 24 tablets.

Sumatriptan 100 mg tablets are available in ALU-PVC/PVDC blister packs of 2, 3, 6, or 12 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

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POM

Manufacturer:

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To listen to or request a copy of this leaflet in Braille, large print or audio please call, 01293827819 (UK only)

Please be ready to give the following information:

Product name	Reference number
Sumatriptan 50mg Film-coated Tablets	PL 49565/0115
Sumatriptan 100mg Film-coated Tablets	PL 49565/0116

This leaflet was last revised in September 2025.

Sumatriptan 50mg/100mg FC Tablets -POM- PIL
Dimensions: 210 x 354 mm (Open Size)

Sumatriptan Tablets

Font type: Times New Roman

Headings: 12pt (Bold)

Sub-Heading: 9pt (Bold)

Normal Text: 9pt (Regular)

COLOURS



Black



Pantone 368 C



Pantone 715 C