

Package Leaflet: Information for the user

Sumatriptan 50 mg film-coated tablets Sumatriptan 100 mg film-coated tablets

sumatriptan

Read all of this leaflet carefully before you start using 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 tablet is and what it is used for
2. What you need to know before you use Sumatriptan tablet
3. How to use Sumatriptan tablet
4. Possible side effects
5. How to store Sumatriptan tablet
6. Contents of the pack and other information

1. What Sumatriptan tablet is and what it is used for

Sumatriptan belongs to a group of medicines called serotonin receptor (5-HT₁) agonists.

Migraine headaches are thought to result from the dilatation of blood vessels. Sumatriptan constricts these blood vessels, thus relieving the migraine headache.

Sumatriptan tablet is used to treat migraine attacks with or without aura (aura is a premonition usually connected with flashes of light, serrated images, stars or waves).

2. What you need to know before you use Sumatriptan tablet

Do not use Sumatriptan tablet:

- 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 chest pains (angina), or have already had a heart attack.
- if you have had a stroke or a mini-stroke (TIA or a transient ischaemic attack).
- if you have blood circulation problems in the legs causing cramp-type pain when you walk (peripheral vascular disease, PVD).
- if you have high blood pressure or if your blood pressure remains high despite medication.
- if you have severely reduced liver function.
- if you use, or have recently used, medication containing ergotamine or similar medicines such as methysergide maleate (for the treatment of migraine).

- if you use, or have recently used, the so called MAO inhibitors (for instance moclobemide for the treatment of depression or selegiline for the treatment of Parkinson's disease).

Warnings and precautions

Before you will be prescribed Sumatriptan tablet your physician will establish whether your headache is caused by migraine and not by any other condition. Talk to your doctor before using Sumatriptan tablet, if any of the following applies to you:

- If you have symptoms indicating cardiac disease, such as chest pain or a feeling of pressure in the chest area which may be radiating to your neck.
- If you are taking anti-depressants called selective serotonin reuptake inhibitor (SSRI) or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors).
- If you have an intolerance to some sugars.
- If you have reduced liver or kidney function.
- 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.
- If you are allergic to sulfonamide. 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 this medicine.
- If you are a heavy smokers or are 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 the patients have developed serious cardiac disease after taking sumatriptan even though they have no sign of cardiac disease before. Tell your doctor so that your heart function can be checked before sumatriptan is prescribed for you.

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.

If you **use sumatriptan frequently**. Using sumatriptan too often may make your headaches worse. Your doctor may recommend you stop using sumatriptan.

Other medicines and Sumatriptan tablet

Some medicines may influence the effects of Sumatriptan tablet and Sumatriptan tablet may influence the effects of other medicines. Tell your doctor or pharmacist if you are taking or have recently taken or might take any other medicines. This includes any herbal products, dietary supplements such as vitamins, iron or calcium or medicines you've bought without a prescription. This is especially important when using medicines that contain:

- ergotamine or its derivatives (for migraine). If you have taken a product containing ergotamine, wait for at least 24 hours before taking sumatriptan tablet. Equally wait for at least six hours after taking sumatriptan tablet before taking a product containing ergotamine.
- MAO inhibitors (for example moclobemide for depression or selegiline for the treatment of Parkinson's disease). Sumatriptan tablet must not be used if you have taken these in the last 2 weeks.
- SSRIs and SNRIs used to treat depression.) Using Sumatriptan tablet 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 containing St. John's Wort with Sumatriptan tablet, may make side effects more likely.

Pregnancy and breast-feeding

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

Pregnancy:

There is 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 tablet while you are pregnant.

Breast-feeding:

Ask your doctor or pharmacist for advice before taking any drugs. Sumatriptan is secreted in the mother's milk. Therefore breast-feeding should be avoided for 24 hours after taking Sumatriptan tablet.

Driving and using machines

A migraine patient may feel sleepy due to the migraine attack or treatment with Sumatriptan tablet. This should be taken into consideration in circumstances that require more careful concentration than usual, such as driving and use of machinery.

Sumatriptan tablet contains lactose

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

3. How to use Sumatriptan tablet

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure. It's best to take Sumatriptan tablet as soon as you feel a migraine coming on, although you can take it at any time during an attack. Do not use Sumatriptan tablet to try to prevent an attack – only use it after your migraine symptoms start.

Adults (aged 18 to 65 years):

The recommended dose is one 50 mg tablet of Sumatriptan tablet for a migraine attack. Some patients may require 100 mg. You should follow your doctor's advice.

Children (below 18 years):

Use of Sumatriptan tablet is not recommended for children under 18 years old.

Elderly (over 65 years):

Use of Sumatriptan tablet is not recommended for people aged over 65.

Method of administration:

Swallow the tablet whole with water. Preferably take as soon as possible after starting a migraine attack. Do not chew or crush the tablets.

If you experience that the effect of Sumatriptan tablet is too strong or weak, contact your doctor or pharmacist.

If the first tablet has no effect

Do not take a second dose for treatment of the same migraine attack even if the first dose would not alleviate the symptoms. Sumatriptan tablet can still be used for your next attack. If Sumatriptan tablet doesn't give you any relief, ask your doctor for advice.

If your symptoms start to come back

If the symptoms are reduced after the first dose but later return, the dose may be repeated once, in rare cases a maximum of twice, during 24 hours. But at least two hours has to be waited between the doses. A daily dose of 300 mg must not be exceeded.

If you use more Sumatriptan tablet than you should

If you have taken too many tablets of Sumatriptan tablet, contact your doctor or hospital immediately. Overdose symptoms are the same as those listed in section 4 'Possible side effects'

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 listed in the following may have been caused by the migraine attack itself.

Allergic reaction:

Not known (cannot be estimated from the available data):

- Allergic reaction of the skin: skin rash such as red spots or hives (skin lumps).
- Anaphylaxis (strong allergic reactions such as swollen eyelids, face or lips and sudden wheeziness, fluttering, tightness in the chest or total collapse).

If any allergic reactions appear, **stop taking Sumatriptan tablet**. Contact your doctor **immediately**.

Other possible side effects:

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

- Drowsiness, dizziness, sensory disturbances
- Difficulty in breathing
- Muscle pain
- Temporary increase in blood pressure (arising soon after treatment), flushing
- Feeling of weakness, tiredness
- Feeling sick (nausea) or being sick (vomiting)
- Pain, sensation of heat or cold, pressure, tightness or heaviness. These symptoms are generally transient (temporary) and may appear in any part of the body, including chest and throat.

Not known (cannot be estimated from the available data):

- Seizures (epileptic fits), involuntary movements (dystonia), tremor, nystagmus
- Visual disorders such as flickering, reduced vision, loss of vision (these may also be due to a migraine attack itself)
- Heart problems where your heartbeat may go faster, slower or change rhythm, chest pains (angina) or a heart attack
- Low blood pressure, Raynaud's phenomenon (a condition where the fingers and toes become white and numb)
- Inflammation of the colon (symptoms include pain in the lower left side of your belly and bloody diarrhoea)
- Neck stiffness

- Minor disturbances in liver function tests have occasionally been observed.
- Diarrhoea
- Anxiety
- Excessive sweating
- Joint pain.
- 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. By reporting side effects you can help provide more information on the safety of this medicine.

You can also report side effects directly via
HPRA Pharmacovigilance
Website: www.hpra.ie

5. How to store Sumatriptan tablet

- This medicinal product does not require any particular storage conditions.
- 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. 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 protect the environment.

6. Contents of the pack and other information

What Sumatriptan tablets contain

50 mg film-coated tablet

Active ingredient:

Sumatriptan. Each tablet contains 70 mg sumatriptan succinate equivalent to 50 mg of sumatriptan.

Other ingredients:

Tablet core: lactose monohydrate, hypromellose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate

Film-coating: hypromellose, titanium dioxide (E 171), triacetin, red iron oxide (E 172)

100 mg film-coated tablets

Active ingredient

Sumatriptan. Each tablet contains 140 mg sumatriptan succinate equivalent to 100 mg of sumatriptan.

Other ingredients:

Tablet core: lactose monohydrate, hypromellose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate
Film-coating: hypromellose, titanium dioxide (E 171)

What Sumatriptan tablets looks like and contents of the pack

Description of the 50 mg film-coated tablet: pink coloured, capsule shaped, biconvex, film-coated tablet, plain on both sides.

Description of the 100 mg film-coated tablet: white or off-white, capsule shaped, biconvex, film-coated tablet, plain on both sides.

Sumatriptan 50 mg film-coated tablets are available in blister packs containing 4,6,12 and 18 tablets.
Sumatriptan 100 mg film-coated tablets are available in blister packs containing 4,6,12 and 18 tablets

Not all package sizes may be marketed.

Marketing Authorisation Holder:

Accord Healthcare Ireland Ltd,
Euro House,
Euro Business Park,
Little Island,
Cork T45 K857,
Ireland

Manufacturer:

Accord Healthcare Polska Sp.z o.o.,
ul. Lutomierska 50,95-200 Pabianice, Poland

Accord Healthcare B.V.
Winthontlaan 200 3526 KV at Utrecht, Netherland

The medicinal product is authorized in the Member States of the EEA under the following names:

Name of the member state	Name of the medicinal product
Czech Republic	Sumatriptan Accord 50 mg/ 100 mg potahované tablety
Finland	Sumatriptan Accord 50 mg/ 100 mg tabletti, kalvopäällysteinen
Denmark	Sumatriptan Accord 50 mg/ 100 mg filmovertrukne tabletter
Ireland	Sumatriptan 50 mg/ 100 mg film-coated tablets
Italy	Sumatriptan Accord
The Netherlands	Sumatriptan Accord 50 mg/ 100 mg filmomhulde tabletten
Sweden	Sumatriptan Accord 50 mg/ 100 mg filmdragerad tablett
United Kingdom	Sumatriptan 50 mg/ 100 mg film-coated tablets

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