

Package leaflet: Information for the user

Sumore 50 mg 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 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 Sumore is and what it is used for
2. What you need to know before you take Sumore
3. How to take Sumore
4. Possible side effects
5. How to store Sumore
6. Contents of the pack and other information

1. What Sumore is and what it is used for

Sumore belongs to a group of medicines called triptanes, which are used to treat migraine headache.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Sumore 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.

Sumore 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.

2. What you need to know before you take Sumore

Do not take Sumore

- if you are allergic to sumatriptan or any of the other ingredients of this medicine (listed in section 6).
- 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 pressure over the chest
- if you have problems with the blood circulation to your hands and feet (peripheral vascular disease).
- if you have had a stroke/cerebral infarction, also described as an "attack" or cerebral haemorrhage (CVA; cerebrovascular accident).
- if you have had a temporary disturbance of the blood supply to the brain that left little or no residual symptoms (TIA).
- if you have severe liver function impairment.
- if you have high blood pressure.
- if you are taking drugs containing ergotamine or ergotamine derivatives (migraine drugs such as methysergide) or other triptans (5 hydroxytryptamine (5HT₁) receptor agonists, such as almotriptan, eletriptan, frovatriptan, naratriptan, rizatriptan or zolmitriptan etc.). These must not be taken at the same time as Sumore (see also "Other medicines and Sumore").

- if you are currently taking MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease). Sumatriptan must not be used within two weeks of discontinuation of therapy with MAO inhibitors. See also "Other medicines and Sumore" below.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sumore if:

- you are diabetic, especially if you are a woman past the menopause or a man over 40 years. The doctor should examine you first.
- you are a heavy user of tobacco or products containing nicotine (patches or chewing gum), especially if you are a woman past the menopause or a man over 40 years. The doctor should examine you first.
- you have liver or kidney impairment. The doctor might adjust the dose.
- you have ever suffered seizures/fits (convulsions) or have a predisposition to seizures/fits (convulsions); sumatriptan can cause seizures/fits. Sumore might increase the risk of seizures.
- you are hypersensitive to certain antibiotics (sulphonamides). You may experience an allergic reaction after taking sumatriptan. Caution is advisable.
- you use herbal products containing St John's Wort (*Hypericum perforatum*). Side effects may occur with greater frequency.

Sumore must only be used if a diagnosis of "migraine" has been clearly established in your case and other factors have been excluded. Certain forms of migraine cannot be treated with sumatriptan.

After taking Sumore 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.

Overuse of Sumore may cause chronic, daily headache or worsened headache. Ask your doctor if you think that this is the case for you. It may be necessary to discontinue the treatment with Sumore in order to correct the problem.

Children and adolescents

Sumore is not recommended in children and adolescents under 18 years of age.

Other medicines and Sumore

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

An interaction means that medicines used at the same time can influence the effect(s) and/or side effect(s) of each other. The following comments may also apply to medicines that you have used any time in the past or are to use in the near future.

- medicines containing ergotamine (migraine drugs) or other triptans. These must not be taken at the same time as Sumore (see "Do not take Sumore").
After taking medicines containing ergotamine, you are advised to wait at least 24 hours before taking Sumore. After taking Sumore you are advised to wait at least 6 hours before taking medicines containing ergotamine and at least 24 hours before taking medicines containing other triptans.
- MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease). Sumore must not be taken within two weeks after stopping use of MAO inhibitors.
- Use of triptans with antidepressant drugs like Selective serotonin reuptake inhibitors (SSRI) and Serotonin – nor epinephrine reuptake inhibitors (SNRI) may cause serotonin syndrome (a combination of symptoms that may include confusion, hallucination, restlessness, sweating, muscle spasms, and tremors). If you experience these symptoms please tell your doctor.
- There is a risk that concomitant use of sumatriptan and lithium (for manic/depressive (bipolar) disorders) may cause serotonin syndrome.

Please note that the above medicines may be known to you by other names, often the brand names. In this section only the active ingredient or therapeutic group of the medicine is given, and not the brand name.

Always thoroughly check the pack and information leaflet of the medicines you are already using for the active ingredient or therapeutic group of that medicine.

Pregnancy and breast-feeding

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

Pregnancy

During pregnancy, sumatriptan must only be taken following consultation with your doctor. Sumatriptan should be used during the pregnancy only if the potential benefit to the mother outweighs the potential risk to the unborn child and no other appropriate treatment option is available.

Breast-feeding

Sumore passes into breast milk. Don't breast-feed your baby for 12 hours after taking Sumore. If you express any breast milk during this time, discard the milk and don't give it to your baby.

Some breast-feeding 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

No studies on the effects on the ability to drive and use machines have been performed.

Drowsiness may occur as a result of migraine or its treatment with Sumatriptan and this may influence the ability to drive and to operate machinery.

3. How to take Sumore

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

Dosage:

Adults:

The recommended dose is 50 mg Sumore. Some patients may need to take a dose of 100 mg Sumatriptan.

Elderly (patients above 65 years of age)

Sumore is not recommended for this age group.

Method of administration:

Take the tablet with water, preferably as soon as possible after onset of the migraine attack. Do not chew or crush the tablets.

Duration of treatment:

If symptoms are not reduced after the first dose, you must not take a second dose for the same attack. In the event of a subsequent attack, Sumore can be taken again.

If, after the first dose, your symptoms are reduced, but then return, you may take a second dose within 24 hours, provided you wait at least 2 hours between doses.

You must not take more than 300 mg of Sumore in any 24-hour period.

The recommended dose must not be exceeded.

If you take more Sumore than you should

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

If you forget to take Sumore

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 given below can be caused by a migraine attack itself.

If you get any of the following side effects, you should stop taking Sumore and contact your doctor immediately:

- Allergic/hypersensitivity reactions, with symptoms like swelling of the lips-, face, or throat, rash and difficulty breathing or anaphylaxis with symptoms like sharp fall in blood pressure, pallor, agitation, weak and rapid pulse, clammy skin, impaired consciousness.
- Angina (pain in the chest, often brought on by exercise), heart attack or spasm of the blood vessels of the heart. Symptoms may be chest pain or shortness of breath.
- Spasm of the blood vessels of the gut, which can cause damage to your gut. You may notice stomach pain or bloody diarrhoea.

The frequency of the above side effects is not known (cannot be estimated from the available data). Other side effects are:

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

- Feeling dizzy, drowsy or warm, sensory disturbance
- Transient increase in blood pressure soon after treatment, Flushing
- Breathlessness
- Feeling sick, Vomiting
- Feeling of heaviness, tightness, pain or pressure in any part of the body including throat or chest, Myalgia
- Feeling pain, sensation of heat or cold
- Feeling of weak and fatigue

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

- Somnolence

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

Not Known (frequency cannot be estimated from the available data):

- Fits/seizures
- Tremor
- Dystonia
- 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 heartbeat, palpitations
- Reduced blood flow to the arms and legs and consequent pallor or blur tinge to the fingers and toes
- Diarrhoea
- Fall in blood pressure
- Stiff neck □ Joint pain
- Anxiety

- Increased perspiration
- 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. This includes any possible side effects not listed in this leaflet. You can also report side effects **directly via the national reporting** [Appendix V](#) system listed in *.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sumore

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 medicinal product 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 any medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Sumore contains

- The active substance is sumatriptan.
Each tablet contains 50 mg sumatriptan (as sumatriptan succinate).
- The other ingredients are: Croscarmellose sodium, polysorbate 80, calcium hydrogen phosphate, microcrystalline cellulose, sodium hydrogen carbonate and magnesium stearate.

What Sumore looks like and contents of the pack

Sumore 50 mg tablets are white to off-white, capsule shaped, biconvex, uncoated tablets, debossed with 'C' on one side and '33' on the other side. The size is 11 X 5 mm.

Sumore 50 mg tablets are available in packs of 2, 3, 4, 6, 8, 12, 18, 20, 30, 50 or 100 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

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