Sumatriptan 50mg Tablets
Sumatriptan 100mg Tablets

(sumatriptan succinate)

Your medicine is known by the above names, but will be referred to as Sumatriptan throughout this leaflet.

Patient Information Leaflet

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 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 belongs to a group of medicines called triptans (*also known as 5-HT1 receptor agonists*), which are 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.

Sumatriptan 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 Sumatriptan

Do not take Sumatriptan
- 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 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, which contain ergotamine, or similar medicines such as methysergide or any triptan/5-HT receptor agonist (medicines which are also used for treating migraine).
- With anti-depressants called MAOIs (monoamine oxidase inhibitors), or if you have taken these medicines in the last 2 weeks.

For children under 18 years of age

If any of these apply to you:

→ Tell your doctor, and don't take Sumatriptan.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sumatriptan

If you have any extra risk factors
- If you are a heavy smoker, 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, 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.

If you have liver or kidney disease

→ 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 you use 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 of this leaflet has more information about these possible side effects.

Other medicines and Sumatriptan

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other 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 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-HT_1 receptor agonists (such as naratriptan, rizatriptan, zolmitriptan) also used to treat migraine, (see section 2). 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
- SSRIs (Selective Serotonin Reuptake inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake inhibitors) 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.
- MAOIs (monoamine oxidase inhibitors) used to treat depression. Don't use Sumatriptan if you have taken these in the last 2 weeks.
- St John's Wort (*Hypericum perforatum*). Taking herbal remedies that contain St John's Wort while you are using Sumatriptan may make side effects more likely.

Pregnancy, breast-feeding and fertility
- If you are pregnant or breast-feeding, 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.
Using sumatriptan can cause symptoms such as dizziness and weakness, which may adversely affect your speed of reaction. Wait until you have found out how you react to sumatriptan before you drive or use machines.

Sumatriptan contain sodium:

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

3) How to take Sumatriptan

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

The recommended dose is:
Adults:
The recommended dose is 50 mg Sumatriptan in the event of a migraine attack. Some patients may need to take a dose of 100 mg Sumatriptan.

Children and adolescents (under 18 years of age)
Sumatriptan is not recommended in children and adolescents.

Elderly (patients above 65 years of age)
Sumatriptan is not recommended for this age group.

Patients with liver impairment
Your doctor may prescribe you Sumatriptan 50 mg.

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.

If you find the effect of Sumatriptan to be too strong or not strong enough, tell your doctor or pharmacist.

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, Sumatriptan can be taken again.

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

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

The recommended dose must not be exceeded.

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

If you forget to take Sumatriptan
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 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:
→ Don't use any more. Contact a doctor straight away.

Common (may affect up to 1 in 10 people):
- Short-lived/temporary muscle spasms of the jaw affecting jaw movement.
- Heaviness, pressure, tightness or pain in the chest, throat or other parts of the body, or feeling of 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 common side effects include:
- Feeling sick (nausea) or being sick (vomiting),
- Tiredness or drowsiness.
- Dizziness, feeling weak, or getting hot flushes.
- Temporary increase in blood pressure.
- Shortness of breath.
- Aching muscles

Rare (may affect up to 1 in 1000 people):
- Breast pain

Very rare (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.

Some patients may have 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 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 diarrhea (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, 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 App Store**. By reporting side effects you can help provide more information on the safety of this medicine.

5) How to store Sumatriptan
- **Keep out of the sight and reach of children.**
- Do not use after the expiry date printed on the carton or blister label after 'EXP'. The expiry date refers to the last day of that month.
- This medicinal product does not require any special storage conditions.
- If the medicine becomes discoloured or shows any other signs of deterioration, you should seek the advice of your pharmacist who will tell you what to do.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6) Contents of the pack and other information
What Sumatriptan contains
The active substance is sumatriptan.
- Each tablet contains 50mg sumatriptan (as sumatriptan succinate).
- Each tablet contains 100mg sumatriptan (as sumatriptan succinate).

The other ingredients are:
croscarmellose sodium (E468), polysorbate 80 (E433), calcium hydrogen phosphate anhydrous (E450), microcrystalline cellulose (E460), sodium hydrogen carbonate (E500) and magnesium stearate (E470b).

What Sumatriptan look like and contents of the pack
- **Sumatriptan 50mg Tablets** are white to off-while, capsule shaped, biconvex, uncoated tablets, debossed with 'C' on one side and '33' on the other side.
- **Sumatriptan 100 mg tablets** are white to off-white, capsule, shaped, biconvex, uncoated tablets, debossed with 'C' on one side and '34' on the other side.

They are available in blister packs containing 6 tablets.

PL 46420/0041	Sumatriptan 50mg Tablets	**POM**
PL 46420/0042	Sumatriptan 100mg Tablets	**POM**

Who makes and repackages your medicine?
Your medicine is manufactured by Milpharm Limited, Ares, Odyssey Business Park, West End Road, South Ruislip HA4 6QD United Kingdom
or APL Swift Services (Malta) Limited, HF26, Hal Far Industrial Estate, Hal Far, Birzebbugia, BBG 3000, Malta.
Procured from within the EU and repackaged by the Product Licence holder: Suerte Pharma Ltd, 4/5 Northolt Trading Estate, Belvue Road, Northolt, Middlesex, UB5 5QS.

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