

SUMATRIPTAN 50 mg TABLETS SUMATRIPTAN 100 mg 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 further questions, ask your doctor or your 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 they are used for
2. What you need to know before you take Sumatriptan Tablets
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1. What Sumatriptan Tablets are and what they are used for

Each Sumatriptan Tablet contains a single dose of sumatriptan, which belongs to a group of medicines called triptans (*also known as 5-HT₁ receptor agonists*).

Sumatriptan Tablets are used to treat migraine headache.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Sumatriptan Tablets are 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 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 this medicine 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 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 sertraline
 - **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 do not use Sumatriptan Tablets.

Take special care with Sumatriptan Tablets

Talk to your doctor or pharmacist before using 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 this medicine, 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 this medicine 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 will 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 a 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 (this medicine contains lactose)

If any of these apply to you: **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 this medicine. 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 these tablets.**

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 this medicine.** Also see 'Other medicines and Sumatriptan Tablets', below.

If you use Sumatriptan Tablets frequently: Using Sumatriptan Tablets too often may make your headaches worse. **Tell your doctor if this applies to you.** He or she may recommend you stop using these tablets.

If you feel pain or tightness in your chest after you use Sumatriptan Tablets: These effects may be intense but they usually pass quickly. If they do not 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 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 Tablets and others may cause adverse effects if they are taken with Sumatriptan Tablets. **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 use Sumatriptan Tablets'). Do not use Sumatriptan Tablets at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan Tablets. Do not take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using Sumatriptan Tablets.
- **other triptans/5-HT₁ receptor agonists** (such as naratriptan, rizatriptan, zolmitriptan), also used to treat **migraine**, (see section 2 'Do not use Sumatriptan Tablets'). Do not use Sumatriptan Tablets at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan Tablets. Do not take another triptan/5-HT₁ receptor agonist again for at least 24 hours after using Sumatriptan Tablets.
- **MAOIs** used to treat **depression**. Do not use Sumatriptan Tablets if you have taken these in the last 2 weeks.

- **SSRIs and SNRIs** used to treat **depression**. Using Sumatriptan Tablets 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 Tablets may make side effects more likely.

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 these tablets 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 these tablets while you are pregnant
- **Do not breast-feed your baby for 12 hours after using this medicine**. If you express any breast milk during this time, discard the milk and do not give it to your baby.

Driving and using machines

Either the symptoms of migraine or your medicine may make you drowsy. **If you are affected, do not drive or operate machinery.**

3. How to take Sumatriptan Tablets

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

Swallow each tablet whole with water. Do not chew or crush them.

When to take Sumatriptan Tablets

- It is best to take these tablets **as soon as you feel a migraine coming on**, although-you can take it at any time during an attack
- **Do not use these tablets** to try to prevent an attack-only use it after your migraine symptoms start.

How much to take

Adults aged 18 to 65

- **The usual dose for adults aged 18 to 65** is one 50mg tablet, swallowed whole with water. Some patients may need a 100 mg dose - you should follow your doctor's advice.

Children under 18

- **This medicine** is not recommended for children under 18 years old.

Elderly (aged over 65)

- **This medicine** is not recommended for people aged over 65.

If your symptoms start to come back

- You can take a second tablet if at least 2 hours have passed since the first tablet. **Do not take more than 300 mg in total in 24 hours.**

If the first tablet has no effect

- **Do not take a second tablet** or any other Sumatriptan Tablets preparation for the same attack. Sumatriptan Tablets can still be used for your next attack.

If these tablets do not give you any relief: **Ask your doctor or pharmacist for advice.**

If you take more Sumatriptan Tablets than you should

- **Do not take more than six 50 mg tablets or three 100 mg tablets** (that's 300 mg in total) in 24 hours.

Taking too much Sumatriptan Tablets could make you ill. If you have taken more than 300 mg in 24 hours: **Contact your doctor for advice.**

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 everybody gets them. Some symptoms may be caused by the migraine itself.

Allergic reactions: 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 this medicine:

Do not use any more. Contact a doctor straight

away.

Common side effects (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 common side effects include:

- Feeling sick (*nausea*) or being sick (*vomiting*), although this may be due to the migraine itself
- Tiredness or drowsiness
- Dizziness, feeling of weakness, or getting hot flushes
- Temporary increase in blood pressure
- Shortness of breath
- Aching muscles.

Very rare side effects (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 this medicine.

Some patients may get 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 diarrhoea (*ischaemic colitis*)
- Diarrhoea
- Pain in the joints
- Feeling anxious
- Excessive sweating

Reporting 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 **United Kingdom Yellow Card Scheme**, Website: www.mhra.gov.uk/yellowcard.

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

5. How to store Sumatriptan Tablets

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 (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 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 (as the succinate), 50 mg or 100 mg
- The other ingredients in the tablets are lactose, microcrystalline cellulose, croscarmellose sodium, acesulfame potassium, magnesium stearate and colloidal silicon anhydrous.

What Sumatriptan Tablets look like and contents of the pack

Both the 50mg and 100mg tablets are white and capsule shaped with an embossment on one side of '50' or '100' respectively.

Each pack of Sumatriptan 50mg and 100mg Tablets contains 2, 4, 6 or 12 tablets in blister strips. Not all pack sizes may be marketed.

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