Product Name: Sumatriptan 100mg Tablets
Size L: 100 x H: 400 mm

400 mm

200 mm

Pharmacode Reading Direction
XXXX

PHARMA CODE

Sumatriptan 100 mg Tablets

P3486T

Sumatriptan

Package leaflet: Information for the patient

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

1. WHAT SUMATRIPTAN TABLETS IS AND WHAT IT IS USED FOR

Each tablet contains a single dose of sumatriptan, which belongs to a group of medicines called triptans (also known as 5-HT_1 receptor agonists).

Sumatriptan Tablets have been developed for the treatment of migraine. The symptoms of migraine which are thought to be due to temporary widening of blood vessels in the head, may include aura (warning sensations of visual distortion such as flashes of light and zigzag lines or waves). Medicines like Sumatriptan Tablets are believed to work by reducing the size of these blood vessels.

If you are not sure why Sumatriptan Tablets have been prescribed for you ask your doctor.

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). You may be allergic if after taking sumatriptan, you suddenly experience feelings of tightness in the throat or chest, swelling of the tongue, lips or eyelids, difficulty in breathing or swallowing, a widespread feeling of warmth, flushing or itching of the skin and/or a rash like 'hives', progressing to feeling faint or loss of consciousness.

Should any of these occur, stop taking the Sumatriptan Tablets and get medical assistance immediately.
- have had a heart attack or suffer from any heart disease such as narrowing of the arteries (ischaemic heart disease).
- have symptoms that might indicate heart disease, such as chest pain or a sensation of pressure of tightness in your chest.
- have high blood pressure, or if your blood pressure is high despite medication.
- have poor blood circulation in your legs that causes cramp-like pain when you walk too far (peripheral vascular disease)
- have a history of stroke or transient ischaemic attach (TIA, a minor form of stroke that lasts less than 24 hrs).
- have severe liver problems.
- are taking any medicines for your migraine which contain ergotamine or ergotamine derivatives, such as ergotamine tartrate or methysergide maleate (in which case, you should stop taking them at least 24 hours before taking Sumatriptan Tablets) or any triptan or 5HT_1 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.

If you think you may have any of these problems contact your doctor before taking sumatriptan.

Before prescribing sumatriptan, your doctor will establish whether your headache is caused by migraine and not by any other condition.

Warnings and precautions
Talk to your doctor or pharmacist before taking Sumatriptan Tablets.
You should tell your doctor before starting sumatriptan if you:
- know that you have problems with your liver or kidneys;
- have been diagnosed with epilepsy or any other disease that reduces the threshold for epileptic fits;
- know that you are allergic to antibacterial medicines that belong to the group of sulphonamides;
- are being treated for high blood pressure as in a small number of cases sumatriptan has been seen to increase blood pressure;
- experience pain and/or tightness in the chest or throat. These effects are usually short lasting. If they however persist and you are concerned, or they become severe, contact your doctor immediately for advice;
- experience chronic daily headaches. Taking sumatriptan too often may result in developing a chronic headache. In such cases you should contact your doctor as you may have to stop taking sumatriptan;
- are taking anti-depressants called SSRIs or SNRIs;
- the use of Buprenorphine together with Sumatriptan tablets can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and Sumatriptan Tablets");
- are considered to be at risk of developing heart disease (e.g. diabetic or a heavy smoker or using nicotine replacement therapy), and particularly if you are a post-menopausal woman or a man over 40 years with these risk factors, your doctor should check your heart function before prescribing sumatriptan. In very rare cases serious heart conditions have occurred after taking sumatriptan, even if no signs of any heart disease were found. Contact your doctor for advice if you have any concerns.

Children and adolescents
Sumatriptan Tablets should not be used in children under 18 years of age.

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

Certain medicines may influence the effectiveness of sumatriptan, and sumatriptan may influence the effectiveness of other medicines. Contact your doctor if you take:
- other medicines for migraine, such as ergotamine or similar medicines. 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.;
- medicines to treat depression (SSRIs or SNRIs). 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;
- buprenorphine / opioids. These medicines may interact with Sumatriptan Tablets and may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.
- medicines to treat depression (MAOIs). Don't use Sumatriptan if you have taken these in the last 2 weeks;
- medicines to treat manic/depressive (bipolar) disorders, such as lithium.

During concomitant use of sumatriptan and herbal preparations containing St. John's Wort (*Hyperidum perforatum*) side effects may become more common

Pregnancy and breast-feeding
Sumatriptan Tablets should not be taken if you are pregnant, likely to become pregnant or if you are breast-feeding, unless advised to do so by your doctor. Don't breast-feed your baby for 12 hours after taking Sumatriptan Tablets. 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
Sumatriptan Tablets may cause drowsiness. If you are affected do not drive or operate machine.

Sumatriptan Tablets contains lactose monohydrate
Sumatriptan Tablets contains lactose which is a type of sugar. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product

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

3. HOW TO TAKE SUMATRIPTAN TABLETS

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

ONE tablet should be taken at the first sign of a migraine attack, although it will still be effective if taken at a later stage.

If this tablet does not make your migraine better do not take any more tablets for this attack because it is unlikely that a second dose will work. Sumatriptan Tablets can be used for your next attack.

If after your first dose, your migraine goes away but then returns, you may take another tablet, provided it is at least **two hours** since you took the first tablet.

Don't use sumatriptan to try to prevent an attack - only use it after your migraine symptoms start.

The usual dose for adults aged 18 to 65 is one sumatriptan 50 mg tablet, swallowed whole with water. Do not chew or crush them.
Some patients may need a 100 mg dose - you should follow your doctor's advice. **DO NOT TAKE MORE THAN 300 mg of sumatriptan in any 24-hour period**.

There is little experience of Sumatriptan Tablets in those over 65 years of age so it is not usually prescribed for this age group.

If you have the impression that the effect of Sumatriptan Tablets is too strong or too weak, talk to your doctor or pharmacist.

How quickly will the treatment start to work?
It takes Sumatriptan Tablets about 30 minutes to start working. If the tablets do not ease your migraine, then you may take your usual 'pain killers', provided they do not contain ergotamine or its derivatives.

Wait at least six hours after taking a Sumatriptan Tablet before taking any medicines containing ergotamine or its derivatives.

If you take more Sumatriptan Tablets than you should
It is important to keep to the dose on the label or follow the instructions above. Taking more than this could make you ill. If an overdose is taken, **DO NOT DELAY**, ask your doctor what to do or contact your nearest accident and emergency department.

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 Tablets:

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.
- Short-lived/temporary muscle spasm of jaw affecting jaw movement

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) – when not part of migraine attack
- Tiredness or drowsiness
- Dizziness, feeling weak, or getting hot flushes
- Temporary increase in blood pressure
- Shortness of breath
- Aching muscles.

Very rare side effects (may affect up to 1 in 10,000 people):
- Liver function changes. If you have a blood test to check how your liver is working and have taken Sumatriptan tablets, tell your doctor as it may affect the results.

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 attach 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
- 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 TABLETS

Keep this medicine out of the sight and reach of children.

Store in the original package.

Do not use this medicine after the expiry date which is stated on the label after EXP.. 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 contains
- The active substance is sumatriptan. Each tablet contains 100 mg sumatriptan (as the succinate).
- The other ingredients are lactose monohydrate, croscarmellose sodium, anhydrous lactose, microcrystalline cellulose, magnesium stearate, mannitol, titanium dioxide (E171), talc, triacetin (E1518).

What Sumatriptan Tablets looks like and contents of the pack
White, oval, biconvex, 8.2x17mm coated tablets, embossed with 'SN' on one side and "100" on the other side.

PVC/al blister and/or PVC-PVdC/al blister and/or HDPE bottle with LDPE Cap

The following pack sizes are available: 2, 3, 6, 7, 12, 14, 18, 21, 24, 28, 30, 50, 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer
Crescent Pharma Ltd, Key House, Sarum Hill, Basingstoke, RG21 8SR, UK.

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100 mm

100 mm

Crescent PHARMA LIMITED