Package leaflet: Information for the patient
Sumatriptan 50 mg and 100 mg Tablets

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

- Sumatriptan belongs to the group of antimigraine preparations. The active substance of Sumatriptan Film-coated Tablets is sumatriptan, a 5-HT1 receptor agonist.
- Migraine headaches are thought to result from the dilatation of blood vessels. Sumatriptan constricts these blood vessels, thus relieving the migraine headache.
- Sumatriptan is used to treat migraine attacks with or without aura (a warning sensation that usually involves visual distortions, such as light-flashes, zigzag lines, stars, or waves).

2. What you need to know before you take Sumatriptan

Do not take Sumatriptan if you:

- are **allergic** (hypersensitive) to sumatriptan or any of the other ingredients of this medicine (listed in section 6)
- have had a **heart attack**
- have any heart disease
- have **symptoms that might indicate heart disease**, such as temporary chest pain or a sensation of pressure in your chest
- have a **history of stroke** or transient ischaemic attack (TIA, a minor form of stroke that lasts less than 24 hrs)
- have blood circulation problems in your legs that cause cramps like pains when you walk (called peripheral vascular disease)
- have significantly **high blood pressure**, or if your blood pressure is high despite medication
- have severe **liver problems**
- use or have recently used medicines containing **ergotamine** or ergotamine derivatives (including methysergide) or any triptan or 5-HT1 agonist (such as naratriptan or zolmitriptan);
- use or have recently used **medicines to treat depression** that belong to the group known as monoamine oxidase (MAO) inhibitors.

If you think that you may have any of these problems, or if you are in any doubt at all, contact your doctor before taking Sumatriptan.

Warnings and precautions

- Before you are prescribed Sumatriptan your physician will establish whether your headache is caused by migraine and not by any other condition.

Talk to your doctor or pharmacist before taking 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;
- have controlled high blood pressure as is in a small number of cases sumatriptan has been seen to increase blood pressure;
- are taking Selective Serotonin Reuptake Inhibitors (SSRI) or serotonin noradrenalin reuptake inhibitors (SNRI). Hyperreflexia and lack-of coordination has been observed after concomitant use of Selective Serotonin Reuptake Inhibitors and sumatriptan;
- 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 considered to be at risk of developing heart disease (e.g. diabetic, heavy smoker or undergoing 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.
- take herbal preparations containing St. John's Wort (*Hypericum perforatum*) with sumatriptan side effects may become more common.

Other medicines and Sumatriptan

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 against migraine**, such as ergotamine, derivatives of ergotamine or other medicines in the same group as Sumatriptan (such as naratriptan, zolmitriptan, rizatriptan, almotriptan and eletriptan). If you have taken such drugs, it should take 24 hours before you can take Sumatriptan. Conversely, do not take ergotamine, ergotamine derivatives or medicines in the same group as Sumatriptan until 6 hours after taking Sumatriptan
- **medicines to treat depression** (MAO inhibitors, serotonin re-uptake inhibitors or serotonin noradrenaline reuptake inhibitors).

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

Pregnancy and breast-feeding

Pregnancy:

- Ask your doctor or pharmacist for advice before taking this medicine
- There is only limited information regarding the safety of Sumatriptan in human pregnancy. Up to now, these data do not indicate that there is an increased risk for malformations. It is recommended that you do not take Sumatriptan during pregnancy, unless instructed by your doctor to do so.

Breast-feeding:

- Ask your doctor or pharmacist for advice about taking this medicine whilst breast-feeding
- Sumatriptan is excreted into breast milk. You can minimise the exposure of your baby by avoiding breast-feeding for 12 hours after administration of Sumatriptan, during which time any breast milk expressed should be discarded.

Driving and using machines

- Migraine itself or its treatment with Sumatriptan may cause drowsiness. Do not drive or operate machinery if you are affected.

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

Sumatriptan contains sodium.
This medicine contains less than 1 mmol sodium (23 mg) per film-coated 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.

Sumatriptan must not be taken to prevent migraine attacks, because it is intended to treat migraine attacks. Sumatriptan must be taken as soon as possible after the migraine headache appears; however, it is equally effective when taken at a later stage of the attack.

The recommended dose for adults is 50 mg. For some patients 100 mg may be necessary. If Sumatriptan does not bring immediate relief, it is not beneficial to take more tablets for this attack. Sumatriptan 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.

Do not take more than 300 mg (**six 50 mg** tablets, or **three 100 mg** tablets) in 24 hours.

Use in children and adolescents
The use of Sumatriptan in children, adolescents and patients over 65 years is not recommended.
For patients with mild to moderate liver impairment low doses of 25-50 mg should be considered.

Method of administration
Swallow the tablet whole with some water.

If you take more Sumatriptan than you should
Overdose symptoms are the same as those listed in section 4 'Possible side effects'. If you have taken too many tablets, contact a doctor or hospital.

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. **Contact your doctor** if you need to discuss these.

The following side effects are possible with the following frequencies:

Common: may affect up to 1 in 10 people
- Drowsiness, dizziness, tingling
- Temporary increase in blood pressure (arising soon after treatment), flushing
- Feeling sick (nausea) or being sick (vomiting)
- Sensation of tension. This is generally transient (temporary), but may be strong and may appear in any part of the body, including chest and throat, muscle pain
- Pain, sensation of heat or cold, pressure or tightness. These symptoms may be strong and they may appear in any part of the body, including chest and throat
- Shortness of breath
- Feeling of weakness, tiredness

Very rare: may affect up to 1 in 10,000 people

- If you have a blood test to check your liver function, Sumatriptan may affect your results.

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

- Allergic reactions of the skin: A skin rash such as red spots or hives (skin lumps).
  Anaphylaxis (Strong allergic reactions such as swelling of eyelids, face or lips and sudden wheeziness, fluttering or tightness in the chest).
  If any strong allergic reaction appears, stop taking Sumatriptan and contact your doctor immediately.
- Nystagmus (involuntary back- and forth-movement of the eyeball), scotoma (dark spots in the field of vision), tremor and dystonia (involuntary muscle contractions).
  Fits - usually in people with a history of epilepsy.
- Visual disturbances (flickering, dipoplia, reduced vision, loss of vision including permanent defect), although these may be caused by the migraine attack itself.
- Racing heart, slow heartbeat, palpitations, irregular heartbeat, and serious complications of the coronary artery, heart attack, transient ischaemic ECG changes.
- Decrease in blood pressure, which is a disease characterised by signs of paleness or a blue tinge to the skin and/or pain of the fingers, toes, ears, nose or jaw in response to cold or stress (Raynaud's phenomenon).
- Inflammation of the colon (part of the intestine), which may present as lower left-sided stomach-ache and bloody diarrhoea (ischaemic colitis).
- Diarrhoea
- Pain in the joints
- Feeling anxious
- Neck stiffness
- 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
- Serotonin syndrome has been reported (characterized by symptoms such as restlessness, hallucinations, coordination difficulties, rapid heartbeat, rapid changes in blood pressure, increased body temperature, overactive reflexes, nausea, vomiting and diarrhoea).

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects
If you get 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 Yellow Card Scheme Website: 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 Sumatriptan after the expiry date which is stated on the carton. 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 contains

- The active substance is sumatriptan. Each tablet contains 50 mg/100 mg of sumatriptan (as succinate).
- The other ingredients are:
- Tablet core: lactose monohydrate, croscarmellose sodium, colloidal anhydrous silica, microcrystalline cellulose and magnesium stearate
- Tablet coating: hypromellose, lactose monohydrate, titanium dioxide (E171), macrogol 3000 and glycerol triacetate. The 50 mg tablets also contain iron oxides red, yellow and black (E172).

What Sumatriptan looks like and contents of the pack

- Sumatriptan 50 mg Film-coated Tablets are peach to pink, oblong-shaped film-coated tablets debossed "5" and "0" on one side with scoreline on each side.
- The tablet can be divided into equal doses.
- Sumatriptan 100 mg Film-coated Tablets are white to off-white, oblong-shaped film-coated tablets debossed "100" on one side and plain on the other.

The product is available in pack sizes of 2, 3, 4, 6, 12, 18, 24, 30 and 50 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder: Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

The company responsible for manufacture is TEVA Pharmaceutical Works Private Limited Company, H-4042 Debrecen, Pallagi str. 13, Hungary*
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* Only the paragraph containing the details of the current batch release site will be included in the printed version of the PIL