PACKAGE LEAFLET

Package leaflet: Information for the patient

Sumatriptan 50 mg film-coated tablets
Sumatriptan 100 mg film-coated 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 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
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1. What Sumatriptan is and what it is used for

This medicine contains the active ingredient sumatriptan succinate. Sumatriptan succinate is one of a group of medicines called 5-HT1 receptor agonists that are used to treat migraine attacks. A migraine causes attacks of headache, sometimes with sickness or other symptoms e.g. some people become sensitive to light or noise. 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.

Sumatriptan should not be used where migraine has not been diagnosed and it cannot prevent an attack of migraine.

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 heart problems such as reduced blood flow to your heart muscles with signs of chest pain, including heart attack (ischaemic heart disease) or cardiac chest pain due to contraction of the vessel walls (Prinzmetal's angina) or suffer from hardened arteries, circulation problems in your legs that cause cramp-like pain when walking (peripheral vascular disease),
- if you have ever had a heart attack (myocardial infarction),
- if you have had a stroke (cerebrovascular accident) in the past or if you have had the symptoms of a stroke, which only lasted a short time and from which you made a complete recovery (transient ischaemic attack),
- if you have severe liver problems,
- if your blood pressure is not controlled or you are being treated for moderately high or very high blood pressure (hypertension),
- if you are taking, or have taken in the last 24 hours, medicines used to treat migraine containing ergotamine or methysergide: or any triptan or 5-HT_1 agonist such as naratriptan or zolmitriptan (see "Other medicines and Sumatriptan" for further information),
- if you are taking or have recently taken any medicines to treat depression or Parkinson's disease called Monoamine Oxidase Inhibitors (MAOIs) in the last 2 weeks,

• if you are taking lithium (normally used to treat mental health conditions such as severe depression, mania or severe types of headache known as cluster headaches).

Warnings and precautions
Sumatriptan should not be used for unusual forms of migraine caused by brain or eye problems (e.g. hemiplegic, basilar or opthalmoplegic migraine).
Talk to your doctor or pharmacist before taking Sumatriptan
• if you have risk factors for heart disease such as:
- a family history of heart disorders,
- diabetes,
- high blood cholesterol,
- are overweight,
- smoking regularly or using any form of nicotine replacement therapy (NRT),
- being a male and over 40 years old or a postmenopausal woman.

• if you are being treated for mildly high blood pressure (hypertension) that is being controlled.
• if you have had fits (convulsions) or epilepsy in the past,
• if you have kidney problems,
• if you have liver problems,
• if you are allergic to antibiotics called sulfonamides (such as co-trimoxazole),
• if you use sumatriptan at the same time as medicines used to treat depression (see 'Other medicines and Sumatriptan' for more information) as this can cause increased heart rhythm, shivering, sweating, fever, high blood pressure, agitation, confusion, hallucinations, shaking which are signs of serotonin syndrome.

If you use Sumatriptan regularly
Using sumatriptan too often may cause or worsen headaches. This may also occur if you find that you need to use other medicines, such as painkillers, regularly for migraine. Talk to your doctor or pharmacist if this applies to you.

Sumatriptan can cause tightness in the chest and throat
You may notice pain or a feeling of tightness in your chest and throat after taking sumatriptan. If these symptoms don't pass quickly, tell your doctor immediately.

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

- antidepressants called SSRIs (for example citalopram, fluoxetine, fluvoxamine, paroxetine, or sertraline), SNRIs (like venlafaxine or duloxetine (which may also be used for urinary problems)). If you are taking SSRIs and SNRIs and take sumatriptan, this may increase the risk of developing a potentially serious side effect called serotonin syndrome (see 'Warning and precautions'). Your doctor may want to keep an eye on you.
- lithium (see 'Do not take Sumatriptan' for further information).
- medicines used to treat depression or Parkinson's disease called Monoamine Oxidase Inhibitors (MAOIs). Do not take sumatriptan if you have taken an MAOI in the last 2 weeks.
- herbal medicines containing St John's Wort.

If you are taking or have taken other migraine medicines
If you have taken another medicine for migraine such as ergotamine or ergotamine derivatives (such as methysergide), or a triptan/5-HT_1 agonist (such as naratriptan or zolmitriptan) you should wait for at least 24 hours before you take sumatriptan.
If you have taken sumatriptan you should wait for at least 6 hours before taking ergotamine or ergotamine derivatives (such as methysergide) and wait for at least 24 hours before taking triptan/5-HT_1 agonist.

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.
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.
If taken when breast-feeding, you should be aware that sumatriptan is excreted in breast milk. Don´t breast-feed your baby for 12 hours after taking sumatriptan. The breast milk should be expressed and discarded during this period.

Driving and using machines
You may feel sleepy, dizzy or sick either due to the migraine itself or the use of these tablets. If ever occur, this may influence the ability to drive and to operate machinery. Caution is recommended if you engage in such activities.

Sumatriptan contains lactose and sodium
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

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.
- Take this medicine as soon as possible after the start of the migraine attack, although you can take it at any time during an attack.
- This medicine should not be taken to prevent a migraine attack.

Adults
The recommended dose is one 50 mg tablet. In some cases, 25 or 100 mg dose may be needed. Since the tablet cannot be divided into two equal doses, if necessary, the doctor should prescribe other medicinal product with the same active ingredient, dosage and pharmaceutical form available in divisible tablet.
If the first dose helps but the headache returns, you can take a second dose within 24 hours, provided there is a minimum 2 hours interval between the two doses. The maximum dose is 300 mg of sumatriptan in 24 hours. Swallow the tablet whole with a glass of water.

Do not take a second dose if the first dose has no effect. If Sumatriptan has no effect after the first dose, a painkiller such as paracetamol or a non-steroidal anti-inflammatory drug (NSAID) e.g. aspirin (acetylsalicylic acid) or ibuprofen, may be taken instead.

Use in children and adolescents (under 18 years)
Sumatriptan is not recommended for children and adolescents.

Use in elderly (over 65 years)
Sumatriptan is not recommended.

Patients with liver problems
If you have mild to moderate liver problems, your doctor may recommend that you take a lower dose.

If you take more Sumatriptan than you should
Contact your doctor or local Accident and Emergency (casualty) department immediately.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Some of the side effects reported may be associated side effects of migraine.

If you experience any of the following side effects, stop taking this medicine immediately and seek urgent medical advice:
Not known (frequency cannot be estimated from the available data):

- sudden life-threatening reaction with signs of allergy such as rash, itching or hives on the skin, swelling of the face, lips, tongue or other parts of the body, shortness of breath, wheezing or trouble breathing (anaphylactic reaction),
- epileptic seizures or fits (these are more likely in patients prone to epilepsy),
- heart attack (myocardial infarction) presenting as chest pain, shortness of breath, indigestion, nausea, vomiting, lack of energy or discomfort in the upper body,
- chest pain (angina pectoris) or reduced blood flow to your heart muscles with signs of chest pain (ischaemic heart disease),
- inflammation of the colon (which may show as a pain in the left side of your stomach with bloody diarrhoea).

Other side effects

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

- sensations such as tingling, prickling and numbness of the hands or feet (paraesthesia), decreased feeling or sensitivity especially (hypoesthesia) of the skin or feeling warmth or cold, pain, heaviness, pressure or tightness which can affect any part of the body including the throat and chest,
- feeling flushed (sudden reddening of the face (often cheeks), neck or upper chest), dizzy or drowsy,
- tiredness, weakness, but these effects should pass,
- increased blood pressure,
- feeling sick (nausea) or being sick (vomiting),
- shortness of breath (dyspnoea),
- muscle pain, muscle tenderness or weakness, not caused by exercise (myalgia).

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

- Changes in your liver test results (this may show up in blood tests).

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

- problems with your eyes or eyesight such as flickering, double vision, reduced vision, spot-like reduced vision (visual field defect), loss of vision, which could be permanent. You may also experience repetitive, involuntary to-and-fro oscillations of the eye (nystagmus),
- twisting and repetitive movements or abnormal postures (dystonia),
- tremors,
- anxiety,
- irregular such as slow or rapid heartbeat, changes in heart rhythm or beating (this may show up in 'ECG' tests used to monitor the electrical activity of the heart), palpitations,
- spasms of the blood vessels supplying the heart, which can cause chest pain,
- low blood pressure,
- diarrhoea,
- Raynaud's phenomenon which causes pale skin and numbness or pain in the fingers and toes when you are cold,
- neck stiffness,
- painful, swollen joints (arthralgia),
- excessive sweating (hyperhidrosis),
- difficulty swallowing,
- 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.

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 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 this medicine out of the sight and reach of children.
• This medicinal product does not require any special storage conditions.
• Do not take this medicine after the expiry date which is stated on the carton or blister 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 to protect the environment.

6. Contents of the pack and other information

What Sumatriptan contains

There are two strengths of your medicine available. Each film-coated tablet contains either 50 mg or 100 mg of the active ingredient sumatriptan (as succinate). The tablets also contain lactose monohydrate, cellulose, microcrystalline, croscarmellose sodium and magnesium stearate. The tablet coating contains, titanium dioxide (E171), polydextrose, hypromellose, triacetin and macrogol. In addition, the coating of the 50 mg tablets contains iron oxide red (E172) and iron oxide yellow (E172). (see section 2 'Sumatriptan contains lactose and sodium')

What Sumatriptan looks like and contents of the pack

The 50 mg tablets are round, pink and marked 'SU 50' on one side; the 100 mg tablets are round, white to off white and marked 'SU 100' on one side. All tablets have a 'G' on the other side.

Sumatriptan tablets are available in blister packs of 2, 3, 4, 4x1, 5, 6, 10, 12, 18, 20 & 24 tablets. Not all pack sizes may be marketed.

The blister pack may contain empty triangular shaped supporting knobs which do not contain any tablets. Only the round blister pockets contain tablets.

Marketing Authorisation Holder and Manufacturer

Mylan, Potters Bar, EN6 1TL, United Kingdom.

Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Mylan Hungary Kft, Mylan utca 1., Komárom, 2900, Hungary.

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