PACKAGE LEAFLET: INFORMATION FOR THE USER

Sumatriptan 50 mg and 100mg tablets
Sumatriptan

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, t alk 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, the active substance in sumatriptan, belongs to a group of medicines called triptanes, 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) *(see also "Warnings and precautions"* if you are allergic to certain antibiotics (sulphonamides).
- if you have or have ever had heart problems, including a heart attack, angina (chest pain caused by exercise or effort), Prinzmetal's angina (chest pain which happens at rest) or have experienced heart related symptoms such as shortness of breath or pressure over the chest
- if you have problems with the blood circulation to your hands and feet (peripheral vascular disease)
- if you have had a stroke/cerebral infarction, also described as an "attack" or cerebral haemorrhage (CVA; cerebrovascular accident)
- if you have had a temporary disturbance of the blood supply to the brain that left little or no residual symptoms (TIA)
- if you have severe liver function impairment
- if you have high blood pressure

- if you are taking drugs containing ergotamine or ergotamine derivatives (migraine drugs such as methysergide) or any triptan/5-HT1 receptor agonist. These must not be taken at the same time as Sumatriptan (see also “Other medicines and Sumatriptan”)
- if you are currently taking or stopped taking MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease) two weeks ago. See also ´Other medicines and Sumatriptan´ below.

Warnings and Precautions
Talk to your doctor before taking Sumatriptanif:
- you are a heavy user of tobacco or products containing nicotine (patches or chewing gum), especially if you are a woman past the menopause or a man over 40 years. The doctor should examine you first.
- you have liver or kidney impairment. The doctor might adjust the dose.
- you have ever suffered seizures/fits (convulsions) or have a predisposition to seizures/fits (convulsions); sumatriptan can cause seizures/fits. Sumatriptan might increase the risk of seizures.
- you are allergic to certain antibiotics (sulphonamides). You may experience an allergic reaction after taking sumatriptan. Caution is advisable.

Sumatriptan must only be used if a diagnosis of “migraine” has been clearly established in your case and other factors have been excluded. Certain forms of migraine cannot be treated with sumatriptan.

After taking Sumatriptan you may feel pain in your chest and a feeling of pressure for a short time. This can be quite intensive and may radiate up towards your throat. In very rare cases this may be caused by effects on your heart. Therefore, if the symptoms do not disappear, contact your doctor.

If you take Sumatriptan too often, your headache may become worse. In this case, your doctor might recommend you stop taking sumatriptan.

Children and adolescents
Sumatriptan is not recommended in children and adolescents below the age of 18 years.

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

An interaction means that medicines used at the same time can influence the effect(s) and/or side effect(s) of each other. The following comments may also apply to medicines that you have used any time in the past or are to use in the near future.

- medicines containing ergotamine (migraine drugs, including methysergide) and triptans/5-HT1 receptor agonists. These must not be taken at the same time as Sumatriptan (see “Do not take Sumatriptan”). After taking medicines containing ergotamine or another triptan/5-HT1 receptor agonist, you are advised to wait at least 24 hours before taking Sumatriptan. After taking Sumatriptan you are advised to wait at least 6 hours before taking medicines containing ergotamine and at least 24 hours before taking another triptan/5-HT1 receptor agonist.

- MAO inhibitors (e.g. moclobemide for depression or selegiline for Parkinson's disease). Sumatriptan must not be taken at the same time as or within two weeks after stopping use of MAO inhibitors.

- medicines for depression and other mental conditions called SSRIs and SNRIs. Side effects may occur.

lithium (for manic/depressive (bipolar) disorders)

- Herbal products containing St John´s wort (Hypericum perforatum). Side effects may occur with greater frequency.

Please note that the above medicines may be known to you by other names, often the brand names. In this section only the active ingredient or therapeutic group of the medicine is given, and not the brand name.

Always thoroughly check the pack and information leaflet of the medicines you are already using for the active ingredient or therapeutic group of that medicine.

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 for advice before taking this medicine.

During pregnancy, sumatriptan must only be taken following consultation with your doctor. Sumatriptan should be used during pregnancy only if the potential benefit to the mother outweighs the potential risk to the unborn child and no other appropriate treatment option is available.

Sumatriptan passes into breast milk. Don't breast-feed your baby for 12 hours after using Sumatriptan. Do not feed your child with milk expressed during this period.

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
Migraine itsself as well as using sumatriptan can cause drowsiness, 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 contains lactose, sulphites 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 sulphites which may rarely cause severe hypersensitivity reactions and bronchospasm.

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 usual dose is 50 mg sumatriptan in the event of a migraine attack. Some patients may need to take a dose of 100 mg sumatriptan.

The tablet can be divided into equal doses.

<u>Older people (over 65 years of age)</u>
Sumatriptan is not recommended for this age group.

<u>Patients with liver impairment</u>
Your doctor may prescribe you low doses of ½ - 1 tablet Sumatriptan 50 mg.

Method of administration:
Take the tablet with water, preferably as soon as possible after onset of the migraine attack. The sumatriptan substance has a bitter taste. The bitter taste is masked with the aid of a grapefruit flavour.

Duration of treatment:

If symptoms are not reduced after the first dose, you must not take a second dose for the same attack. In these cases the attack can be treated with paracetamol, acetylsalicylic acid, or non-steroidal anti-inflammatory drugs, such as ibuprofen.
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 that there is a minimum interval of 2 hours between the two 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 of the symptoms reported as undesirable effects may be associated symptoms of migraine.

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:
Do not use Sumatriptan any more. Contact a doctor straight away.

The side effects are listed by the following frequency:

Common:may affect up to 1 in 10 people
- Feeling of heaviness or sensations of heat or cold, pressure or tightness.These effects may be intense, affect any part of the body including the chest and throat but generally pass quickly.
- Feeling dizzy
- Feeling sleepy
  Feeling of unusual sensations, including numbness or tingling
- Temporary increase in blood pressure, soon after intake
- Hot flushes
- Breathlessness
- Feeling sick and vomiting. This may be due to the migraine itself.
- Aching muscles
- Pain
- Feeling of weakness or tiredness. These effects are mostly mild to moderate in intensity and pass quickly.

Rare: (may affect up to 1 in 1,000 people)

- Breast pain

Very rare: may affect up to 1 in 10,000 people
- Disturbances in liver function tests

Frequency not known: frequency cannot be estimated fromthe available data
- Allergic reactions of all degrees of severity varying from skin reactions to allergic shock
- Temporary disturbances of the blood circulation of the heart, spasms of the blood vessels of the heart, chest pain, heart attack
- Slow heart beat, fast heart beat, irregular heart beat, palpitations
- Fits/seizures
- Tremor, tremor of the eyes
- Visual field disturbances
- Muscle tone disturbances
- Impaired vision, e.g. double vision, flickering and sometimes loss of vision with permanent impairment. Visual disturbances can also occur as a result of the migraine attack itself.
- Fall in blood pressure, reduced blood flow to the arms and legs and consequent pallor and blue tinge to the fingers and toes
- Spasms of the blood vessels of the gut, which can cause damage to your gut. You may notice stomach pain or bloody diarrhoea.
- Diarrhoea
- Difficulty swallowing
- Stiff neck, pain in the joints
- Minor disturbances in liver function tests
- 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.

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: 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

Keep out of the sight and reach of children.

Do not use Sumatriptan after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed off via wastewater or household waste. Ask your pharmacist how to dispose off 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 50 mg sumatriptan (as sumatriptan succinate).
Each tablet contains 100 mg sumatriptan (as sumatriptan succinate).

The other ingredients are: Ammonium methacrylate copolymer type A, carmellose sodium (E466), microcrystalline cellulose (E450), croscarmellose sodium (E468), lactose monohydrate, magnesium stearate (E470b), flavouring (grapefruit) (contains sulphites). The 50mg tablet also contains red iron oxide (E172) and yellow iron oxide (E172)

What Sumatriptan looks like and contents of the pack
Sumatriptan 50 mg tablets are pink, biconvex, oblong tablets with a break-line on both sides.
The tablet can be divided into equal halves.

Sumatriptan 100 mg tablets are white/off-white, biconvex, oblong tablets with a break-line on both sides.
The tablet can be divided into equal halves.

Sumatriptan 50 mg tablets are available in packs of
2, 3, 4, 6, 8, 12, 18, 20, 24, 30, 50 and 100 tablets.

Sumatriptan 100 mg tablets are available in packs of
2, 3, 4, 6, 12, 18, 19, 20, 24 and 30 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Sandoz Limited
Park View, Riverside Way
Watchmoor Park
Camberley, Surrey
GU15 3YL
United Kingdom

Manufacturer

Salutas Pharma GmbH, Otto-von-Guericke-Allee 1, 39179 Barleben, Germany
Rowa Pharmaceuticals Ltd., Newtown, Bantry, Co. Cork, Ireland

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