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Product Name: Sumatriptan 50mg & 100mg Tablets
Size L: 100 x H: 610 mm

610 mm
305 mm

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PACKAGE LEAFLET: INFORMATION FOR THE USER

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 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

- What Sumatriptan Tablets are and what they are used for
- What you need to know before you take Sumatriptan Tablets
- How to take Sumatriptan Tablets
- Possible side effects
- How to store Sumatriptan Tablets
- Contents of the pack and other information

1. What Sumatriptan Tablets are and what they are used for

Sumatriptan Tablets have been developed for the treatment of migraine. The symptoms of migraine, which are thought to be due to temporary swelling 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. This in turn is thought to help 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.

These medicines are called 5-HT₁ receptor agonists or triptans.

2. What you need to know before you take Sumatriptan Tablets

Do not use Sumatriptan tablets:

- If you are allergic to sumatriptan or any of the other ingredients in Sumatriptan Tablets (listed in section 6).
- If you have a heart problem such as narrowing of the arteries (*Ischemic heart disease*) or chest pains (*angina*), or have already had a heart attack.
- If you have high blood pressure. You may be able to use Sumatriptan Tablets if your high blood pressure is mild and is being treated
- If you have poor blood circulation in your legs that causes cramp-like pain when you walk (*peripheral vascular disease*).
- If you have a history of stroke or a mini-stroke (*also called a transient ischemic attack or TIA*).
- If you have serious liver problems/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

If any of these apply to you:

- Tell your doctor, and don't use Sumatriptan Tablets.

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

Take special care with Sumatriptan Tablets:

Talk to your doctor or pharmacist before using Sumatriptan Tablets.

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 Sumatriptan Tablets, 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 Sumatriptan Tablets are 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'll 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 Tablets may not be suitable for you

- Tell your doctor or pharmacist before using Sumatriptan Tablets.

If you have liver or kidney disease

If either of these apply to you:

- Tell your doctor or pharmacist before using Sumatriptan Tablets.

If you are allergic to antibiotics called sulphonamides

If so, you may also be allergic to Sumatriptan Tablets. 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 Sumatriptan 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 Sumatriptan Tablets. Also see 'Other medicines and Sumatriptan Tablets', below.

If you are taking Buprenorphine.

The use of Buprenorphine together with Sumatriptan Tablets can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Sumatriptan Tablets').

- Tell your doctor or pharmacist before using Sumatriptan Tablets.

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 Sumatriptan 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 don't pass quickly, or they become severe:

Get medical help immediately. Section 4 has more information about these possible side effects.

Children and adolescents

Sumatriptan Tablets should not be used in children under 18 years of age, as the safety and effectiveness of this medicine in children has not been established.

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've bought without a prescription.

Some medicines must not be taken with Sumatriptan Tablets and other 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 Don't use Sumatriptan Tablets). Don't use Sumatriptan Tablets at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan Tablets. Don't 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 'Don't use Sumatriptan Tablets'). Don't use Sumatriptan Tablets at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan Tablets. Don't take another triptan/5-HT₁ receptor agonist again for at least 24 hours after using Sumatriptan Tablets.
- MAOIs used to treat depression. Don't use Sumatriptan Tablets if you have taken these in the last 2 weeks.
- SSRIs and SNRIs used to treat depression, or Buprenorphine/opioids used to manage pain and addiction. Using Sumatriptan Tablets with these medicines can cause serotonin syndrome (a collection of symptoms which can include restlessness, confusion, involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased heartbeat and shaking, increased muscle tension, body temperature above 38°C). 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 or breast-feeding, 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 Sumatriptan 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 Sumatriptan Tablets while you are pregnant.

- Don't breast-feed your baby for 12 hours after using 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

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

Sumatriptan Tablets contain lactose (a type of sugar)

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Further information about the ingredients of this medicine

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 has told you. If you are not sure, check with your doctor or pharmacist.

When to take Sumatriptan Tablets

- It is best to take sumatriptan tablets **as soon as you feel a migraine coming on**, although – you can take it at any time during an attack
- Don't use Sumatriptan Tablets** to try and 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 sumatriptan 50 mg tablet, swallowed whole with water. Some patients may need a 100 mg dose – you should follow your doctor's advice.

Children under 18:

- Sumatriptan Tablets** are not recommended for children under 18 years old.

Elderly (aged over 65):

- Sumatriptan Tablets** are not recommended for people aged over 65.

If your symptoms start to come back

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

If the first tablet has no effect

- Don't take a second tablet** or any other sumatriptan preparation for the same attack. Sumatriptan Tablets can still be used for your next attack.

If Sumatriptan Tablets do not give you any relief, **ask your doctor or pharmacist for advice.**

If you take more Sumatriptan Tablets than you should

- Don't take more than six 50 mg tablets or three 100 mg tablets (300 mg in total) in any 24 hours.**

Taking too many 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 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 may be caused by the migraine itself.

Allergic reaction: Contact your doctor or seek medical attention immediately if you experience an allergic reaction.

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 (affect up to 1 in 10 people)

- Pain, heaviness, pressure or tightness in the chest (angina), 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 (myocardial infarction).

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 weak, 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 Sumatriptan Tablets.
- Breast pain.

Some patients may get the following side effects but it is not known how often they occur

- Seizures/fits, tremors, muscle spasm, neck stiffness (usually in people with a history of epilepsy)
- 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 lower left side of stomach and bloody diarrhoea (*ischemic colitis*)
- Diarrhoea
- Pain in the joints (arthralgia)
- Feeling anxious
- Excessive sweating (hyperhidrosis)
- 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
- Short-lived/temporary muscle spasms of the jaw affecting jaw movement.

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 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 below 30°C. Do not use this medicine after the expiry date stated on the carton, blister and label after EXP. The expiry date refers to the last day of that month.

Do not throw away 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

- Each tablet contains either 50mg or 100mg sumatriptan (as the succinate)
- The other ingredients are lactose monohydrate, croscarmellose sodium, anhydrous lactose, microcrystalline cellulose, magnesium stearate, mannitol, titanium dioxide E171, talc, triacetin.

What Sumatriptan tablets look like and contents of the pack

Sumatriptan 50 mg Tablets are White, oval, biconvex, 6.5x12.7 mm coated tablets, embossed with 'SN' on one side and '50' on the other side. Sumatriptan 100 mg Tablets are White, oval, biconvex, 8.2x17mm coated tablets, embossed with 'SN' on one side and '100' on the other side.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Torrent Pharma (UK) Limited
3rd Floor, Nexus Building, 4 Gatwick Road Crawley
West Sussex RH10 9BG, United Kingdom.

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