

**Package leaflet: Information for the user**  
**Sumatriptan 50 mg Film-Coated Tablets**  
**Sumatriptan 100 mg Film-Coated 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, 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**
6. **Contents of the pack and other information**

**1. What Sumatriptan is and what it is used for**

Each Sumatriptan Film-Coated Tablet contains a single dose of sumatriptan, which belongs to a group of medicines called triptans (*also known as 5-HT<sub>1</sub> receptor agonists*).

**Sumatriptan is 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.

**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 a heart problem** such as narrowing of the arteries (*Ischaemic heart disease*) or chest pains (*angina*), or have already had a heart attack
- **If you have circulation problems in your legs** that cause cramp-like pains when you walk (*peripheral vascular disease*)
- **If you have had a stroke** or a mini-stroke (*also called a transient ischaemic attack or TIA*)
- **If you have high blood pressure.** You may be able to use Sumatriptan if your high blood pressure is mild and is being treated
- **If you have serious liver disease**
- **With other migraine medicines**, including those which contain ergotamine, or similar medicines such as methysergide maleate; or any triptan or 5HT<sub>1</sub> 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
  - **SSRIs** (*selective serotonin reuptake inhibitors*) including citalopram, fluoxetine, fluvoxamine, paroxetine and sertraline
  - **SNRIs** (*serotonin noradrenaline reuptake inhibitors*) including venlafaxine and duloxetine
- **For children under 18 years of age.**

If any of these apply to you:

**Tell your doctor, and do not take Sumatriptan Film-Coated Tablets.**

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Sumatriptan.

**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, 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 is 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 liver or kidney disease**

**If you have an intolerance to some sugars**

If any of these apply to you:

⊗ **Tell your doctor so that you can be supervised more closely**

**If you are allergic to antibiotics called sulphonamides**

If so, you may also be allergic to Sumatriptan. 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.**

**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.** Also see Other medicines and Sumatriptan, below.

**If you use Sumatriptan frequently.**

Using Sumatriptan too often may make your headaches worse.

⊗ **Tell your doctor if this applies to you.** He or she may recommend you stop using Sumatriptan.

**If you feel pain or tightness in your chest after you use Sumatriptan**

These effects may be intense but they usually pass quickly. If they do not pass quickly, or they become severe:

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

**Other medicines and Sumatriptan**

Tell your doctor or pharmacist if you are taking/using, have recently taken/used or might take/use any other medicines.

Some medicines must not be taken with Sumatriptan and others may cause adverse effects if they are taken with Sumatriptan.

**You must tell your doctor if you are taking:**

- **ergotamine** also used to treat **migraine**, or similar medicines such as methysergide (see section 2 Do not take Sumatriptan). Do not use Sumatriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan. Do not take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using Sumatriptan.
- **other triptans/5-HT<sub>1</sub> receptor agonists** (such as naratriptan, rizatriptan, zolmitriptan), also used to treat **migraine**, (see section 2 Do not use Sumatriptan). Do not use Sumatriptan at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan. Do not take another triptan/5-HT<sub>1</sub> receptor agonist again for at least 24 hours after using Sumatriptan.
- **MAOIs** used to treat **depression**. Do not use Sumatriptan if you have taken these in the last 2 weeks
- **SSRIs and SNRIs** used to treat **depression**. 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.
- **St John's Wort** (*Hypericum perforatum*). Taking herbal remedies that contain St John's Wort together with Sumatriptan may make side effects more likely.

**Pregnancy and breast-feeding**

- **If you are pregnant or breastfeeding, 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 until 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

- **Do not breastfeed your baby for 12 hours after using Sumatriptan.** If you express any breast milk during this time, discard the milk and do not give it to your baby.

### 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 contains lactose

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

## 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.

### When to take Sumatriptan

- It's best to take Sumatriptan **as soon as you feel a migraine coming on**, although - you can take it at any time during an attack
- **Do not use Sumatriptan** to try to 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 film-coated tablet, swallowed whole with water. Some patients may need a 100 mg dose - you should follow your doctor's advice.

#### *Children under 18*

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

#### *Older people (aged over 65)*

- **Sumatriptan** is not recommended for people aged over 65.

### If your symptoms start to come back

- You can take a second Sumatriptan film-coated tablet if at least 2 hours have passed since the first tablet. **Do not take more than 300 mg in total in 24 hours.**

### If the first tablet has no effect

- **Do not take a second tablet** or any other Sumatriptan preparation for the same attack. Sumatriptan can still be used for your next attack.

If Sumatriptan does not give you any relief:

⊗ **Ask your doctor or pharmacist for advice.**

### If you take more Sumatriptan than you should

- **Do not take more than six 50 mg tablets or three 100 mg tablets** (that's 300 mg in total) in 24 hours.

Taking too much Sumatriptan 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 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:

⊗ **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, 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.

**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
- Short-lived/temporary muscle spasms of the jaw affecting jaw movement.

**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 that you are taking Sumatriptan.

**Some patients may get 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 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 the lower left side of the stomach and bloody diarrhoea (*ischaemic colitis*)
- Diarrhoea
- Difficulty swallowing
- 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.

**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](http://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.

Do not use this medicine after the expiry date which is stated on the blister/carton after 'Exp (MM/YY)'. The expiry date refers to the last day of that month.

Do not store above 25°C.

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 to protect the environment.

## 6. Contents of the pack and other information

**What Sumatriptan contains**

- The active substance is sumatriptan.  
Sumatriptan 50 mg: Each film coated tablet contains 50 mg sumatriptan (as the succinate).  
Sumatriptan 100 mg: Each film coated tablet contains 100 mg sumatriptan (as the succinate).
- The other ingredients are: Core: lactose monohydrate, lactose, croscarmellose sodium, microcrystalline cellulose, magnesium stearate. Coating: Lactose monohydrate, mannitol (E421), titanium dioxide (E171), triacetin and talc.

**What Sumatriptan looks like and contents of the pack**

50 mg: Round white film coated tablets marked 'RDY' on one face and '292' on the other.

100 mg: Capsule shaped white film coated tablets marked 'RDY' on one face and '293' on the other.

**Pack sizes:**

2, 3, 4, 6, 12 and 18 tablets

Not all pack sizes may be marketed.

**Marketing Authorisation Holder and Manufacturer:**

Dr. Reddy's Laboratories (UK) Ltd,

410 Cambridge Science Park, Milton Road, Cambridge, CB4 0PE, United Kingdom

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Germany Sumatriptan beta 50 mg, 100 mg Filmtabletten

United Kingdom Sumatriptan 50 mg, 100 mg Film-Coated Tablets

**This leaflet was last revised in August 2022**