

PACKAGE LEAFLET: INFORMATION FOR THE USER
Sumatriptan 50mg Film-coated tablets
Sumatriptan 100mg Film-coated tablets
(sumatriptan)

Read all of this leaflet carefully before you start taking this medicine:

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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours. If any of the side effects are serious or you notice any side effects not listed in this leaflet please tell your doctor or pharmacist.



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1. What Sumatriptan is and what it is used for

Sumatriptan is used in acute treatment of migraine attacks with or without aura. The symptoms of migraine may be caused by a temporary swelling of blood vessels in your head. This type of medicine works by reducing this swelling. These are one of a group of medicines called 5HT₁ receptor agonists that are used to treat migraine. Sumatriptan cannot prevent a migraine attack.

2. Before you take Sumatriptan

Do not take sumatriptan if you

- are allergic to sumatriptan, sulphonamides or any of the other ingredients in Sumatriptan tablets listed in Section 6, do not take this medicine.
- have previously had a heart attack or are suffering from any cardiovascular disease or you have blood circulation problems in your legs that cause cramp like pain when you walk (called peripheral vascular disease).
- have history of stroke or a minor form of stroke that lasts less than 24 hours (Transient ischaemic attack).
- have significantly high blood pressure, or if your blood pressure is high despite medication.
- have serious problems with your Liver.
- use or have recently used medicines that contain ergotamine.
- use or recently used, so called MAO inhibitors.

Take special care with Sumatriptan

- if you have symptoms of heart disease, such as transient chest pains or a feeling of pressure in the chest and possibly radiating up to throat.
- if you use medicines belonging to the group known as selective serotonin reuptake inhibitors
- if you have impaired liver or kidney function.
- if you have epilepsy or any other disease that lowers the seizure threshold.
- if you are hypersensitive to sulphonamides (sulpha drugs)
- if you are considered to have risk factors for developing heart disease such as a family history of heart disease, diabetes, high blood cholesterol, overweight
- if you are smoking regularly or you are a man over 40 years old or a postmenopausal woman.

Sumatriptan should only be used where there is clear diagnosis of migraine. The recommended dose should not be exceeded. Overuse of Sumatriptan can cause chronic daily headache or aggravate headache. If this happens contact your doctor. It may be necessary to discontinue the treatment.

Using other medicines

Certain medicines may influence the effect of Sumatriptan and Sumatriptan may also influence the effect to other medicines. Please tell your doctor or pharmacist if you are taking or have recently taken other medicines, including medicines obtained without prescription, herbal medicines or natural remedies.

This is particularly important when using medicines that contain:

- ergotamine or derivatives of ergotamine, such as ergotamine tartrate or methysergide maleate. You should stop taking them at least 24 hours before taking Sumatriptan tablets. Conversely it is advised to wait at least six hours following use of sumatriptan before administering an ergotamine containing product
- any drugs to treat depression including medicines called lithium, Monoamine Oxidase Inhibitors (MAOIs), or other antidepressants called SSRIs (for example citalopram, fluoxetine, fluvoxamine, paroxetine, or sertraline)
- medicines belonging to the group known as selective serotonin reuptake inhibitors for depression or other psychological complaints
- medicines to help lose weight or treat epilepsy
- herbal remedy like St John's Wort (*Hypericum perforatum*)

Your doctor may still want you to take these tablets and will advise you about taking these tablets.

Taking Sumatriptan with food and drink

Food/meal have no influence on Sumatriptan.

Pregnancy and Breast feeding

There is limited experience of use of sumatriptan during pregnancy. Therefore you should ask your doctor before using it during pregnancy.

Sumatriptan passes into the breast milk. Breast-feeding should be avoided for 12 hours after taking sumatriptan

Driving and using machines

You may suffer drowsiness, dizziness or other related symptoms either due to the migraine itself or the use of these tablets. If affected do not operate machinery or drive.

Important information about some of the ingredients of Sumatriptan

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.

3. How to take Sumatriptan

Always use Sumatriptan exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will decide on a dose which suits you personally. The recommended dose should not be exceeded.

Dosage: The usual dose for adults is one 50 mg tablet for a migraine attack. Some patients may require 100 mg. The maximum dose per day is 300 mg.

How to take Sumatriptan:

- The tablets should be swallowed whole with a glass of water.

- Sumatriptan should be taken at the first sign of a migraine attack, but may also be taken during an ongoing attack.
- Sumatriptan should not be used as a preventative (prophylactically).

If migraine symptoms are first relieved after the first dose of the medicine but later return the dose may be repeated once, in rare cases a maximum of twice, during 24 hours. A daily dose of 300 mg must not be exceeded.

If migraine symptoms are NOT relieved after the first dose and the medicine has no effect, you should not take further doses during the same migraine attack. Next time you get migraine, you can try Sumatriptan again.

If you experience that the effect of Sumatriptan is too strong or too weak, talk to your doctor or pharmacist.

If you use 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 product ask your doctor or pharmacist.

4. Possible side effects

Like all medicines Sumatriptan can cause side effects, although not everybody gets them. Some of the symptoms below may be part of the migraine attack itself.

If you experience any of the following rare but serious side effects, stop taking these tablets and contact your doctor **immediately** as you may be allergic to these film-coated tablets:

- Severe skin rash or itching, red spots, swelling of the face, mouth or lips, swelling of eyelids
- Sudden wheeziness, difficulty swallowing, difficulty breathing or shortness of breath, fluttering or tightness in the chest, chest pain or collapse.

Common side effects: (affects 1 to 10 users in 100)

- Flushing (redness of the face lasting for few minutes), pins and needles, dizziness, feeling of weakness, tiredness and drowsiness.
- temporary increases in blood pressure soon after treatment
- nausea (feeling sick) and vomiting (being sick)- when not part of the migraine attack.
- feelings of heat or pain, tingling, feelings of heaviness, pressure or tightness (these usually pass quickly but may be intense and can occur in any part of the body including the chest and throat). **If these effects continue or are particularly severe, especially chest or heart pain which spreads to the arms, tell your doctor immediately as there have been rare reports of such problems being caused by a heart attack.**

Uncommon: (affects 1 to 10 users in 1,000)

- Feelings of weakness and fatigue (feeling very tired), these are usually mild and pass quickly.

Very rare: (affects less than 1 user in 10,000)

- Hypersensitive reactions like nettle rash, pruritus, shortness of breath and swelling. You should contact your doctor immediately if you notice symptoms that suggest an anaphylactic reaction (pruritus, shortness of breath and swelling)
- visual disorders including double vision or even a temporary loss of vision (these are rare and may be due to the migraine itself).
- lowering of blood pressure that can lead to feeling of faintness especially on standing up.
- an increase or a decrease in heart rate (palpitations), heart problems which show up as irregular heart beats or a heart attack
- seizures (epileptic fits), shaking, tremors, uncontrolled (involuntary) movements
- inflammation of the colon (this may show as a pain in the lower left side of your belly and bloody diarrhoea)
- Raynaud's syndrome (a condition where the fingers and toes become white and numb)
- neck stiffness.
- Sumatriptan may affect liver function tests. If you have any blood tests to monitor your liver function, tell the doctor or nurse that you are taking these tablets.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. How to store your Sumatriptan

Keep out of the reach and sight of children.

Do not use Sumatriptan tablets 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.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further information

What Sumatriptan contains

The active substance is sumatriptan.

Sumatriptan 50 mg: Each film coated tablet contains 50mg sumatriptan (as the succinate).

Sumatriptan 100 mg: Each film coated tablet contains 100mg sumatriptan (as the succinate).

The other ingredients are: Core: lactose monohydrate, lactose anhydrous, 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

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

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

Pack sizes:

50mg: 2, 3, 4, 6, 12 and 18 tablets
100mg: 2, 3, 4, 6, 12 and 18 tablets

Marketing Authorisation Holder and Manufacturer:

Dr. Reddy's Laboratories (UK) Ltd, 6 Riverview Rd, Beverley, HU17 0LD, UK

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

Bulgaria	Nazdav50 мг, 100 мг филмирани таблетки
Germany	Sumatriptan beta 50 mg, 100 mg Filmtabletten
Italy	Sumatriptan Dr. Reddy's 50 mg, 100 mg compresse rivestite con film
Spain	Sumatriptan Aphar 50mg, 100mg comprimidos EFG
United Kingdom	Sumatriptan 50mg, 100mg film-coated tablets

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