Package leaflet: Information for the patient

Sumatriptan 50 mg, tabletten
Sumatriptan 100 mg, tabletten

sumatriptan (as 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 [Nationally completed name] is and what it is used for

Sumatriptan, the active substance in **[Nationally completed name],** 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.

[Nationally completed name] works only when a migraine attack has started. It will not stop you from getting an attack.

You must not use **[Nationally completed name]** to prevent a migraine attack.

2. What you need to know before you take [Nationally completed name]

Do not take [Nationally completed name]
- 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 [sulfonamides]).
- 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 a “brain 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 (called transient ischaemic attack or TIA)
- if you have severe liver function impairment
- if you have high blood pressure. You may be able to use [Nationally completed name] if your high blood pressure is mild and is being treated.
- if you are taking medicines containing ergotamine or similar medicines such as methysergide or any triptan/5-HT1 receptor agonist (other medicines to treat migraine). These must not be taken at the same time as [Nationally completed name] (see also "Other medicines and [Nationally completed name]")
- if you are currently taking monoamine oxidase inhibitors (MAO inhibitors) (e.g. moclobemide for depression or selegiline for Parkinson's disease) or if you have taken these medicines in the last two weeks. See also "Other medicines and [Nationally completed name]" below.

Warnings and precautions
Talk to your doctor before taking [Nationally completed name] if:
- you are a heavy smoker or are using nicotine replacement therapy (patches or chewing gum), especially if you are a woman who has been through the menopause or are a man over 40 years. A 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 if you have other conditions which might make it more likely that you will have seizures/fits , for example a head injury or alcoholism. [Nationally completed name] might increase the risk of fits. Your doctor may need to supervise you more closely.
- you are allergic to certain antibiotics called sulfonamides. If so, you may also be allergic to sumatriptan.

[Nationally completed name] 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 [Nationally completed name] 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 [Nationally completed name] too often, your headache may become worse. In this case, your doctor might recommend you stop taking [Nationally completed name].

Children and adolescents
[Nationally completed name] is not recommended in children and adolescents below the age of 18 years.

Other medicines and [Nationally completed name]
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 medicines, including methysergide) and triptans/5-HT1 receptor agonists. These must not be taken at the same time as [Nationally completed name] (see "Do not take [Nationally completed name]"). After taking medicines containing ergotamine or another triptan/5-HT1 receptor agonist, you are advised to wait at least 24 hours before taking [Nationally completed name]. After taking [Nationally completed name] 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). [Nationally completed name] must not be taken at the same time as or within two weeks after stopping use of MAO inhibitors.
- SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake Inhibitors) used to treat depression. Using [Nationally completed name] with these medicines can cause serotonin syndrome (a collection of symptoms which can include restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasms, shivering, increased heart beat and shaking). Tell your doctor immediately if you are affected in this way.
- 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 substance 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 substance 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, [Nationally completed name] must only be taken following consultation with your doctor. [Nationally completed name] 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 [Nationally completed name]. 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 [Nationally completed name] can cause drowsiness, dizziness and weakness which may adversely affect your speed of reaction. Wait until you have found out how you react to [Nationally completed name] before you drive or use machines.

[Nationally completed name] 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 medicine.
This medicine contains sulphites which may rarely cause severe hypersensitivity reactions and bronchospasm.
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take [Nationally completed name]

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.

Elderly (over 65 years of age)
[Nationally completed name] is not recommended for this age group.

Patients with liver impairment
Your doctor may prescribe you low doses of ½ - 1 tablet [Nationally completed name] 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.

The tablet can be divided into equal doses.

If the first dose has no effect
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, [Nationally completed name] can be taken again.

If your symptoms start to come back
If, after the first dose, your symptoms are reduced, but then return, you may take a second 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 [Nationally completed name] than you should
When you take too much of [Nationally completed name], immediately contact your doctor or pharmacist. Side effects such as those mentioned under "Possible side effects" may occur.

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 [nationally completed name]:
Do not use [nationally completed name] 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 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.
- 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.
- 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 from the available data
- Allergic reactions of all degrees of severity varying from skin reactions to allergic shock
- Fits/seizures
- Tremor, tremor of the eyes
- Visual field disturbances
- Muscle tonus 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.
- Slow heart beat, fast heart beat, irregular heart beat, palpitations
- Temporary disturbances of the blood circulation of the heart, spasms of the blood vessels of the heart, chest pain, heart attack
- Fall in blood pressure, reduced blood flow to the arms and legs and cosequent pallor and blur tinge to the fingers and toes
- Pain in the lower left side of the stomach and bloody diarrhoea (ischaemic colitis)
- Diarrhoe
- 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 national reporting system listed in Appendix V of the QRD template; to be completed nationally}. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store **[nationally completed name]**

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 carton and blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 protect the environment.

6. Contents of the pack and other information

What [nationally completed name] contains

The active substance is sumatriptan (as succinate).
Each tablet contains 50 mg sumatriptan (as succinate).
Each tablet contains 100 mg sumatriptan (as succinate).

The other ingredients are ammonium methacrylate copolymer type A, carboxymethylcellulose sodium (E 466), microcrystalline cellulose (E 450), croscarmellose sodium (E 468), lactose monohydrate, magnesium stearate (E 470b), flavouring (grapefruit) (contains sulphites), red iron oxide (E 172) and yellow iron oxide (E 172)
The other ingredients are ammonium methacrylate copolymer type A, carboxymethylcellulose sodium (E 466), microcrystalline cellulose (E 450), croscarmellose sodium (E 468), lactose monohydrate, magnesium stearate (E 470b) and flavouring (grapefruit) (contains sulphites)

What [nationally completed name] looks like and contents of the pack

50 mg tablets:
The tablets are pink, oblong tablets with a break notch on both sides.

100 mg tablets:
The tablets are white to slightly yellow, oblong tablets with a break notch on both sides.

The tablets are packed in aluminium/aluminium blister strips and inserted in a cardboard carton.

50 mg tablets:
2, 3, 4, 6, 8, 12, 18, 20, 24, 30, 50, 100 tablets

100 mg tablets:
2, 3, 4, 6, 12, 18, 19, 20, 24, 30 tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Houder van de vergunning voor het in de handel brengen en fabrikant
Sandoz B.V., Hospitaaldreef 29, 1315 RC Almere, Nederland

Fabrikanten
Salutas Pharma GmbH
Otto-von-Guericke Allee 1
39179 Barleben
Duitsland

Rowa Pharmaceuticals Limited
Newton, Bantry, Co. Cork
Ierland

In het register ingeschreven onder:
Sumatriptan 50 mg is in het register ingeschreven onder RVG 29126
Sumatriptan 100 mg is in het register ingeschreven onder RVG 29127

Dit medicijn is geregistreerd in lidstaten van de EEA onder de volgende namen:

België:	Sumatriptan Sandoz 50 mg tabletten
	Sumatriptan Sandoz 100 mg tabletten
Duitsland:	Sumatriptan - 1 A Pharma 50 mg Tabletten
	Sumatriptan - 1 A Pharma 100 mg Tabletten
Ierland:	SUMATRAN 50 mg Tablets
	SUMATRAN 100 mg Tablets
Noord-Ierland:	Sumatriptan 50 mg tablets
	Sumatriptan 100 mg tablets
Italië:	Triptalidon 50 mg compresse
	Triptalidon 100 mg compresse
Nederland:	Sumatriptan 50 mg, tabletten
	Sumatriptan 100 mg, tabletten
Slovakijë:	Sumatriptan Sandoz 50 mg tablety
	Sumatriptan Sandoz 100 mg tablety

Deze bijsluiter is voor het laatst goedgekeurd in september 2025.