

Package leaflet: Information for the user

Sumatriptan Aurobindo 50 mg tablets

Sumatriptan Aurobindo 100 mg 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 Aurobindo is and what it is used for
2. What you need to know before you take Sumatriptan Aurobindo
3. How to take Sumatriptan Aurobindo
4. Possible side effects
5. How to store Sumatriptan Aurobindo
6. Contents of the pack and other information

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

Sumatriptan Aurobindo belongs to a group of medicines called triptans (*also known as 5-HT₁ receptor agonists*), which are used to treat migraine headache.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. Sumatriptan Aurobindo 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 Aurobindo 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 Aurobindo

Do not take Sumatriptan Aurobindo

- 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 Aurobindo if your high blood pressure is mild and is being treated.
- if you have serious liver disease.
- With other migraine medicines, which contain ergotamine, or similar medicines such as methysergide or any triptan/5-HT₁ receptor agonist (medicines which are also used for treating migraine)
- With anti-depressants called MAOIs (monoamine oxidase inhibitors), or if you have taken these medicines in the last 2 weeks.

If any of these apply to you:

→ Tell your doctor, and don't take Sumatriptan Aurobindo.

Warnings and precautions

Talk to your doctor or pharmacist before taking Sumatriptan Aurobindo.

If you have any extra risk factors

- o If you are a heavy smoker, or are using nicotine replacement therapy and especially
- o If you are a man aged over 40, or
- o 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 Aurobindo 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.

If you have liver or kidney disease

→ 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 Aurobindo. 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 Aurobindo.

If you are taking anti-depressants called SSRIs (Selective Serotonin Reuptake inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake inhibitors)

→ Tell your doctor or pharmacist before you use Sumatriptan Aurobindo. Also see "Taking other medicines" below.

If you use Sumatriptan Aurobindo frequently

Using sumatriptan Aurobindo too often may make your headaches worse.

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

If you feel pain or tightness in your chest after you use Sumatriptan Aurobindo 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 of this leaflet has more information about these possible side effects.

Other medicines and Sumatriptan Aurobindo

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

Some medicines must not be taken with Sumatriptan Aurobindo and others may cause adverse effects if they're taken with Sumatriptan Aurobindo. 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 Aurobindo at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan Aurobindo. Don't take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using Sumatriptan Aurobindo.
- other triptans/5-HT₁ receptor agonists (such as naratriptan, rizatriptan, zolmitriptan), also used to treat migraine, (see section 2). Don't use Sumatriptan Aurobindo at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan Aurobindo. Don't take another triptan/5-HT₁ receptor agonist again for at least 24 hours after using Sumatriptan Aurobindo.
- SSRIs (Selective Serotonin Reuptake inhibitors) or SNRIs (Serotonin Noradrenaline Reuptake inhibitors) used to treat depression. Using Sumatriptan Aurobindo 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.
- MAOIs (monoamine oxidase inhibitors) used to treat depression. Don't use Sumatriptan Aurobindo if you have taken these in the last 2 weeks.
- St John's Wort (*Hypericum perforatum*). Taking herbal remedies that contain St John's Wort while you are using Sumatriptan Aurobindo may make side effects more likely.

Pregnancy, breast-feeding and fertility

- 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 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 Aurobindo while you are pregnant.
- **Don't breast-feed your baby for 12 hours after using Sumatriptan Aurobindo.** 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, don't drive or operate machinery.

Using sumatriptan can cause symptoms such as 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 Aurobindo contain sodium:

This medicine contains less than 1 mmol sodium (23 mg) per each tablet, that is to say essentially 'sodium-free'.

3. How to take Sumatriptan Aurobindo

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 Dosage is:

Adults:

The recommended dose is 50 mg Sumatriptan Aurobindo in the event of a migraine attack. Some patients may need to take a dose of 100 mg Sumatriptan Aurobindo.

Children and adolescents (under 18 years of age)

Sumatriptan Aurobindo is not recommended in children and adolescents.

Elderly (patients above 65 years of age)

Sumatriptan Aurobindo is not recommended for this age group.

Patients with liver impairment

Your doctor may prescribe you Sumatriptan Aurobindo 50 mg.

Method of administration:

Take the tablet with water, preferably as soon as possible after onset of the migraine attack. Do not chew or crush the tablets.

If you find the effect of Sumatriptan Aurobindo to be too strong or not strong enough, tell your doctor or pharmacist.

Duration of treatment:

If symptoms are not reduced after the first dose, you must not take a second dose for the same attack. In the event of a subsequent attack, Sumatriptan Aurobindo 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 you wait at least 2 hours between doses.

You must not take more than 300 mg of Sumatriptan Aurobindo in any 24-hour period.

The recommended dose must not be exceeded.

If you take more Sumatriptan Aurobindo than you should

When you take too much of Sumatriptan Aurobindo, immediately contact your doctor or pharmacist. Side effects such as those mentioned under “Possible side effects” may occur.

If you forget to take Sumatriptan Aurobindo

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 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 Aurobindo:

→ Don’t use any more. Contact a doctor straight away.

Common (may affect up to 1 in 10 people):

- Heaviness, pressure, tightness or pain in the chest, throat or other parts of the body, or feeling of 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),
- Tiredness or drowsiness.
- Dizziness, feeling weak, or getting hot flushes.
- Temporary increase in blood pressure.
- Shortness of breath.
- Aching muscles.

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

- Breast pain

Very rare (may 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 Aurobindo.

Some patients may have 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 diarrhea (ischaemic colitis).
- Diarrhoea.
- 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.
- Difficulty swallowing

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](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Sumatriptan Aurobindo

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

This medicine does not require any special storage conditions.

Do not use this medicine if you notice any visible signs of deterioration.

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 Sumatriptan Aurobindo 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: Croscarmellose sodium (E468), polysorbate 80 (E433), calcium hydrogen phosphate (E450), microcrystalline cellulose (E460), sodium hydrogen carbonate (E500) and magnesium stearate (E470b).

What Sumatriptan Aurobindo looks like and contents of the pack

Tablets.

Sumatriptan Aurobindo 50 mg tablets are white to off-white, capsule shaped, biconvex, uncoated tablets, debossed with 'C' on one side and '33' on the other side.

Sumatriptan Aurobindo 100 mg tablets are white to off-white, capsule, shaped, biconvex, uncoated tablets, debossed with 'C' on one side and '34' on the other side.

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

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[To be completed nationally]

For Sweden:
Aurobindo Pharma Ltd.
Ares, Odyssey Business Park
West End Road.
South Ruislip HA4 6QD
United Kingdom

Manufacturer

[To be completed nationally]

APL Swift Services (Malta) Limited
HF26, Hal Far Industrial Estate, Hal Far,
Birzebbugia, BBG 3000,
Malta

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

50 mg tablet

Name of the Member State	Name of the medicinal product
DE	Sumatriptan Aurobindo 50 mg Tabletten
NL	Sumatriptan Aurobindo 50 mg tabletten
ES	Sumatriptán Aurovitas 50 mg comprimidos EFG
SE	Sumatriptan Aurobindo 50 mg tabletter

100 mg tablet

Name of the Member State	Name of the medicinal product
DE	Sumatriptan Aurobindo 100 mg Tabletten
NL	Sumatriptan Aurobindo 100 mg tabletten
SE	Sumatriptan Aurobindo 100 mg tabletter

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