

The PL includes alternative texts for different legal status in different countries as follows:
-Grey-shaded texts are only applicable for OTC versions.
-Boxed texts are only applicable for prescription versions (POM).

Package Leaflet: Information for the user

Sumatriptan Apofri 50 mg film-coated tablets

sumatriptan

POM only:

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, pharmacist or nurse.
- 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.

OTC only:

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- 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.
- You must talk to a doctor if you do not feel better or if you feel worse after 3 days.

[To be completed nationally]

What is in this leaflet

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

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

POM only:

Sumatriptan Apofri belongs to a group of medicines called triptanes (*also known as 5-HT₁ receptor agonists*).

Sumatriptan Apofri is used to treat migraine headaches.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. This medicine reduces 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 of being sick (nausea or vomiting) and sensitivity to light and sound.

OTC only:

Sumatriptan Apofri belongs to a group of medicines called triptanes (*also known as 5-HT₁ receptor agonists*).

Sumatriptan Apofri is used to treat migraine headaches.

Migraine symptoms may be caused by the temporary widening of blood vessels in the head. This medicine reduces 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 of being sick (nausea or vomiting) and sensitivity to light and sound.

Sumatriptan Apofri is used to treat migraine attacks with or without aura (a predisposition that usually consists of visual disturbances such as lightning, zigzag lines, stars or waves).

Sumatriptan Apofri must only be used when you have signs or symptoms of a migraine attack.

Migraine headaches are usually of moderate to severe intensity, unilateral (but can shift side between attacks) and have a pulsating nature. Symptoms such as nausea, sometimes vomiting, and palpable light and sound sensitivity are common in migraines.

Sumatriptan Apofri is not intended for the treatment of other types of headache, e.g. tension headache.

[To be completed nationally]

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

Do not use Sumatriptan Apofri

- **if you are allergic** to sumatriptan or any of the other ingredients of this medicine (listed in section 6).
- **if you have heart problem**, such as narrowing of the arteries (*Ischaemic heart disease*) or chest pains (*angina pectoris*), or have already had a heart attack
- **if you have circulation problems in your legs** that cause cramp-like pain 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 Apofri if your high blood pressure is mild and is being treated.
- **if you have severe liver disease**.
- **if you are taking other migraine medicines**, including those which contain ergotamine, or similar medicines such as methysergide) or any other triptans/5HT₁-receptor agonists, (medicines which are also used for treating migraine).
- **if you are treated with anti-depressants called monoamine oxidase inhibitors (MAOIs)** or if you have been taken these medicines within last two weeks.

If any of these apply to you:

➔ **Tell your doctor, and do not use Sumatriptan Apofri.**

Warning and precautions

Talk to your doctor, pharmacist or nurse before taking Sumatriptan Apofri.

If you have any extra risk factors

- **if you are a heavy smoker**, or are 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 Apofri, 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 larger risk of developing heart disease:

➔ **Tell your doctor so that your heart function can be checked** before taking Sumatriptan Apofri.

If you have a history of seizures or if you have other conditions which might increase the risk of seizures, for example, a head injury or alcoholism:

➔ Tell your doctor so that you can be monitored more closely.

If you have liver or kidney disease

➔ **Tell your doctor so that you can be monitored more closely.**

If you are allergic to antibiotics called sulphonamides

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

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 Apofri.**

See also “*Other medicines and Sumatriptan Apofri*”.

If you use Sumatriptan Apofri frequently

Using Sumatriptan Apofri too often may make your headache worse.

➔ **Tell your doctor if this applies to you.** Your doctor may recommend you stop using Sumatriptan Apofri.

If you experience pain or tightness in your chest after using Sumatriptan Apofri

These symptoms can be intense, but they usually disappear fast. If they do not disappear fast or if they get worse:

➔ Get medical help urgently. See section 4 in this leaflet for more information regarding this possible side effect.

Other medicines and Sumatriptan Apofri

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 have bought without a prescription

Some medicines must not be taken with Sumatriptan Apofri and others may cause adverse effects if they are taken with Sumatriptan Apofri. **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 use Sumatriptan Apofri). Do not use Sumatriptan Apofri at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan Apofri. Do not take any medicines which contain ergotamine or compounds similar to ergotamine again for at least 6 hours after using Sumatriptan Apofri.
- **other triptans/5-HT₁ receptor agonists** (such as naratriptan, rizatriptan, zolmitriptan), also used to treat **migraine**, (see section 2 Do not use Sumatriptan Apofri). Do not use Sumatriptan Apofri at the same time as these medicines. Stop taking these medicines at least 24 hours before using Sumatriptan Apofri. Do not take another triptan/5-HT₁ receptor agonist again for at least 24 hours after using Sumatriptan Apofri.
- **SSRIs** (*Selective Serotonin Reuptake Inhibitors*) or **SNRIs** (*Serotonin Noradrenaline Reuptake Inhibitors*) used to treat **depression**. Using Sumatriptan Apofri with these medicines can cause serotonin syndrome (a collection of symptoms which can include

restlessness, confusion, sweating, hallucinations, increased reflexes, muscle spasm, shivering, increased heart beat and shaking). Tell your doctor immediately if you are affected in this way.

- **MAOIs** (*monoamine oxidase inhibitors*) used to treat **depression**. Do not use Sumatriptan Apofri 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 Apofri 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 or pharmacist for advice before taking this medicine.

There is only limited information about the safety of Sumatriptan Apofri for pregnant women, although there is no evidence of any increased risk of birth defects to date. Your doctor will discuss with you whether you should use Sumatriptan Apofri during pregnancy.

Sumatriptan passes into breast milk. Do not breast-feed your baby for 12 hours after using Sumatriptan Apofri. During this time, breast milk should be pumped out and discarded.

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 medicines

Drowsiness may occur as a result of migraine or its treatment with sumatriptan and this may influence the ability to drive and to operate machinery. **If you are affected, do not drive or operate machinery.**

Sumatriptan Apofri contains lactose and sodium

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

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that to say it is essentially "sodium-free".

3. How to take Sumatriptan Apofri

Sumatriptan Apofri should only be used when a migraine attack has started.

Do not use Sumatriptan Apofri must not be used to prevent an attack.

Do not take more than 2 tablets during a 24-hour period. (OTC only)

Do not take more than 2 tablets during the same migraine attack. (OTC only)

POM only:

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

OTC only:

Always take this medicine exactly as described in this leaflet or as your doctor or pharmacist have told you. Check with your doctor or pharmacist if you are not sure.

Dosage:

POM only:

Adults (18-65 years):

The usual dose is 1 tablet à 50 mg at migraine attack. Some patients may need a dose of 2

tablets (100 mg) during a period of 24 hours. Higher single dose than 100 mg does not provide better effect.

Sumatriptan Apofri is not recommended for people younger than 18 years or older than 65 years.

Take the tablet with water, preferably as soon as possible after the onset of migraine attack. The tablets must not be chewed or crushed.

When to use Sumatriptan Apofri

- **It is best to take Sumatriptan Apofri as soon as you feel the first sign of a migraine attack**, but you can also take Sumatriptan Apofri later during the attack.

If the symptoms start to come back

- You can take a second dose if the symptoms return. At least 2 hours must have passed between the doses. **Do not take more than 300 mg (6 tablets á 50 mg) during a period of 24 hours.**

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

If the first tablet has no effect

- **Do not take a second tablet**, or any other sumatriptan-containing product for the same attack if Sumatriptan Apofri does not give you any relief:

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

If you take more Sumatriptan Apofri than you should

- **Do not take more than 300 mg (6 tablets á 50 mg) during a period of 24 hours.** Using too much Sumatriptan Apofri could make you ill. If you have used more than 300 mg in 24 hours:

→ **Contact your doctor or pharmacist for advice.**

OTC only:

Adults (18-65 years):

The usual dose is 1 tablet á 50 mg at migraine attack. A maximum of 2 tablets over a 24-hour period

Take the tablet with water, preferably as soon as possible after the onset of migraine attack. The tablets must not be chewed or crushed.

Sumatriptan Apofri is not recommended for people younger than 18 years or older than 65 years.

When to use Sumatriptan Apofri

- **It is best to take Sumatriptan Apofri as soon as you feel the first sign of a migraine attack**, but you can also take Sumatriptan Apofri later during the attack.

If the symptoms start to come back

- You can take a second dose if the symptoms return. At least 2 hours must have passed between the doses. **Do not take more than 100 mg (2 tablets á 50 mg) during a period of 24 hours.**

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

If the first tablet has no effect

- **Do not take a second tablet**, or any other sumatriptan-containing product for the same attack if Sumatriptan Apofri does not give you any relief:

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

If you take more Sumatriptan Apofri than you should

- **Do not take more than 100 mg (2 tablets á 50 mg) during a period of 24 hours.**

Using too much Sumatriptan Apofri could make you ill. If you have used more than 100 mg in 24 hours:

➔ **Contact your doctor for advice**

If you have ingested too much medicine, contact a doctor. Side effects such as those mentioned under “Possible side effects” may occur.

If you forget to take Sumatriptan Apofri

Do not take a double dose to make up for a forgotten dose.

If you stop taking Sumatriptan Apofri

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

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 immediately

The following side effects have occurred in a very small number of people 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 Apofri:
➔ Don’t use any more. Contact a doctor straight away

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

- Pain, heaviness, pressure, tightness or pain in the chest, throat or other parts of the body, or feelings 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

- Feeling sick or vomiting. These symptoms may be due to the migraine itself.
- Tiredness or drowsiness
- Dizziness, feeling weak, or getting hot flushes.
- Temporary increase in blood pressure.
- Shortness in breath
- Muscle pain

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 Apofri.

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 some cases even permanent defects (although these may be due the migraine attack itself).

- Heart problems, where your heart beat 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.
- If you have 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.
- Pain in the joints.
- Feeling anxious.
- Difficulty swallowing.
- Excessive sweating.

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 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 Apofri

Store in the original packaging in order to protect from light.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after expiry date which is stated on the carton after EXP. The expiry date refers to the last date of that month.

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 Apofri contains

- The active substance is sumatriptan succinate equivalent to 50 mg sumatriptan in each tablet.
- The other ingredients are:
Tablet core: lactose monohydrate, microcrystalline cellulose (E460), pregelatinised maize starch, croscarmellose sodium, magnesium stearate (E470b).
Coating: hypromellose (E464), titanium dioxide (E171), talc (E553b), ferric oxide red (E172), ferric oxide yellow (E172), macrogol

What Sumatriptan Apofri looks like and content of the pack

Sumatriptan Apofri 50 mg film-coated tablet are peach colored, capsule shaped, biconvex tablets, 10.6 x 4.4 mm and available in blister in packs of 2, 3, 4, 6 and 12 tablets.

Marketing authorisation holder

[To be completed nationally]

Manufacturer

[To be completed nationally]

This leaflet was last revised
2026-07-09