

Apo-Sumatriptan

sumatriptan succinate

50mg and 100mg film-coated tablets

What is in this leaflet

Please read this leaflet carefully before you start using Apo-Sumatriptan.

This leaflet answers some common questions about Apo-Sumatriptan. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you using Apo-Sumatriptan against the benefits they expect it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Apo-Sumatriptan is used for

Apo-Sumatriptan tablets contain the active ingredient sumatriptan succinate. This medicine belongs to a group of drugs called serotonin agonists.

Apo-Sumatriptan tablets are used to relieve headache and other symptoms of a migraine attack. They should not be used to prevent migraine attacks from occurring. Apo-Sumatriptan tablets may be used for migraine headaches with or without what is known as 'aura'. There is no information on the use of Apo-Sumatriptan tablets in special kinds of migraine known as 'basilar migraine', 'ophthalmoplegic migraine' or 'hemiplegic migraine'.

It is thought that migraine headache is due to widening of certain blood vessels in the head. Apo-Sumatriptan tablets work by making those vessels normal again and ease the symptoms of migraine.

Your Apo-Sumatriptan tablets do not work in other types of headache which are not a migraine.

Your doctor may have prescribed Apo-Sumatriptan for another reason.

Ask your doctor if you have any questions about why Apo-Sumatriptan has been prescribed for you.

This medicine is available only with a doctor's prescription. However, Apo-Sumatriptan 50mg in packs of two tablets is available even without prescription.

Before you use Apo-Sumatriptan

When you must not use it

Do not use Apo-Sumatriptan if you have ever had an allergic reaction to sumatriptan succinate or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may be mild or severe. They usually include some or all of the following:

- wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash ("hives") or fainting.
- Do not take Apo-Sumatriptan tablets if you are pregnant, trying to become pregnant or breastfeeding, unless your doctor says you should.

Your doctor will discuss the risks and benefits of taking Apo-Sumatriptan tablets if you are pregnant or breastfeeding.

Do not take Apo-Sumatriptan tablets if you have or have had:

- heart disease, or previous heart attack.
- shortness of breath, pain or tightness in the chest, jaw or upper arm.
- Prinzmetal's angina.
- angina, or severe chest pain or tightness.
- high blood pressure.
- severe liver disease.

Do not take Apo-Sumatriptan tablets if you have taken any of these medicines in the last 24 hours:

- Ergotamine containing preparations (for example, Cafergot)
- Methysergide (for example, Deseril)
- Triptan containing preparations (for example, Naramig, Zomig and Maxalt)

Do not take Apo-Sumatriptan tablets if you have taken Monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression in the last two weeks.

Do not take Apo-Sumatriptan tablets after the expiry date (EXP) printed on the pack.

If you take them after the expiry date has passed, they may not work as well.

Do not take Apo-Sumatriptan tablets if the packaging is torn or shows signs of tampering.

If you are not sure whether you should start using Apo-Sumatriptan, talk to your doctor.

Before you start to use it

Tell your doctor if:

You must tell your doctor if you are allergic to:

- food, dyes or preservatives.
- lactose, or you are lactose intolerant.
- any medicine, including any that contain sulphur (for example, sulphonamide antibiotics).
- If you are allergic to an antibiotic but you are unsure if it belongs to this group, ask your doctor or pharmacist.

You must tell your doctor if you have or have had any of the following medical conditions:

- liver or kidney disease.
- a stroke.
- epilepsy or fits.
- brain tumour, or any other condition affecting the brain.
- irregular heart beats.
- heart disease, or previous heart attack.
- shortness of breath, pain or tightness in the chest, jaw or upper arm.
- Prinzmetal's angina.
- angina, or severe chest pain or tightness.
- high blood pressure.
- high blood cholesterol levels.
- a family history of heart problems.

Your doctor may decide to do tests to check if your heart is healthy before prescribing Apo-Sumatriptan tablets. Your doctor may also decide to do tests if you get certain symptoms with Apo-Sumatriptan. This is because Apo-Sumatriptan tablets can make certain types of heart disease worse.

You must tell your doctor if you:

- are over 65 years of age or under 18 years of age.
- are taking a selective serotonin reuptake inhibitor (SSRI), a type of medicine used to treat depression.
- have not had your headache diagnosed as migraine by a doctor.
- think that this headache is different and worse than your usual migraine.
- have difficulty moving one side of your body when you have the "migraine" headache.
- have not responded to your first dose of Apo-Sumatriptan tablets.

If you have not told your doctor about any of the above, tell them before you start using Apo-Sumatriptan.

Taking other medicines

Tell your doctor if you are taking any other medicines, including medicines that you buy without a prescription from your pharmacy, supermarket or health food shop. You should

also tell any health professional who is prescribing a new medication for you that you are taking Apo-Sumatriptan.

Some medicines may interfere with Apo-Sumatriptan or may affect how well it works. You may need different amounts of your medicine, or you may need to take different medicines.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Apo-Sumatriptan.

Use in children

There is no information on the use of Apo-Sumatriptan tablets in children under 18 years of age.

How to use Apo-Sumatriptan

Take your medicine as your doctor has told you. The label on the pack will tell you how many tablets to take and how often you should take them. If you do not understand what you should do, ask your doctor or pharmacist.

How much to take

The recommended starting dose for adults aged 18 to 65 is 50 mg, however you may need to have your dose of Apo-Sumatriptan tablets increased to 100 mg. Your doctor will tell you which dose is right for you.

Your Apo-Sumatriptan tablet may take up to four hours to work. **If the first Apo-Sumatriptan tablet helps your headache, but the headache comes back later**, you may take another Apo-Sumatriptan tablet. **Do not take more than 300 mg of Apo-Sumatriptan tablets in any twenty-four hours.** Six peach coloured (50 mg strength) or three white (100 mg strength) tablets contain 300 mg.

If the first Apo-Sumatriptan tablet does not relieve or help your migraine headache, do not take another Apo-Sumatriptan tablet for this same attack. You may take something else for the pain but **do not** take medicine containing ergotamine or dihydroergotamine or methysergide. If you are not sure what to do, ask your doctor or pharmacist. He or she can tell you what you may take.

If the first Apo-Sumatriptan tablet does not relieve your migraine, you may use Apo-Sumatriptan tablets on another occasion to treat another migraine attack.

Your Apo-Sumatriptan tablet should be swallowed with a drink of water. Do not crush or chew the tablet as it has a bitter taste.

When to take it

It is best to take your Apo-Sumatriptan tablet -

1. when the migraine headache begins; or
2. when other symptoms of the migraine headache begin. These symptoms may be nausea (feeling sick), vomiting or your eyes becoming sensitive to light.

If you take your tablet later during the migraine attack it will still work for you. Do not take your Apo-Sumatriptan tablet before the above symptoms occur.

How long to take it

If you are not sure how long to take it, contact your doctor or pharmacist.

If you forget to take it

NIL

While you are using Apo-Sumatriptan

Things you must do

Tell your doctor if you become pregnant or are trying to become pregnant.

If you are about to be started on any new medicine tell your doctor and pharmacist that you are taking Apo-Sumatriptan.

Tell your doctor if, for any reason, you have not taken your medicine exactly as prescribed.

Otherwise, your doctor may think it was not effective and change your treatment unnecessarily.

Things you must not do

Do not give Apo-Sumatriptan to anyone else, even if they have the same condition as you.

Do not change the dose of your Apo-Sumatriptan tablets without first checking with your doctor.

Things to be careful of

Be careful driving or operating machinery until you know how Apo-Sumatriptan tablets affect you.

Apo-Sumatriptan tablets generally do not cause any problems with your ability to drive a car or operate machinery. However, as with many other medicines, Apo-Sumatriptan tablets may cause drowsiness in some people.

If you use Apo-Sumatriptan tablets too often, it may make your headache worse. If this happens, your doctor may tell you to stop taking Apo-Sumatriptan tablets.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Apo-Sumatriptan.

Do this even if there are no signs of discomfort or poisoning.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are using Apo-Sumatriptan.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the adverse effects. Ask your doctor or pharmacist to answer any questions you may have.

Tell your doctor at your next visit if you notice any of the following after taking Apo-Sumatriptan tablets:

- pain, tingling, heat or flushing in any part of the body.
- feeling of sleepiness, dizziness or tiredness.
- nausea (feeling sick) or vomiting.
- a change in blood pressure.
- feeling of faintness.
- visual disturbances.
- shaking or tremors.
- shortness of breath.

Tell your doctor immediately and do not take any more Apo-Sumatriptan tablets if you:

- feel heaviness, pressure or tightness in any part of the body, including the chest or throat.
- feel abnormal heart beats - too fast, too slow, or irregular heart beats, palpitations.
- have a fit or convulsion.

These side effects are likely to be serious. If you have them stop taking Apo-Sumatriptan tablets and seek medical attention straight away.

If you think you are having an allergic reaction to Apo-Sumatriptan tablets, tell your doctor immediately or go to your casualty department at your nearest hospital.

Symptoms of an allergic reaction usually include some or all of the following:

- wheezing.
- swelling of the lips/mouth.
- difficulty in breathing.
- hay fever.
- lumpy rash ("hives").
- fainting.

This is not the complete list of all possible side-effects. Other adverse effects not listed above may also occur in some patients. Tell your doctor if you notice any other effects.

Do not be alarmed by this list of possible adverse effects. You may not experience any of them.

After using Apo-Sumatriptan

Storage

Keep this medicine where young children cannot reach it.

A locked cupboard at least one-and-a half metres above the ground is a good place to store medicines.

Keep Apo-Sumatriptan tablets in the blister pack in a cool, dry place where it stays below 30°C.

Do not store them, or any other medicine, in a bathroom or near a sink.

Do not leave them in the car or on window sills.

Heat, light and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking Apo-Sumatriptan tablets, or the tablets have passed the expiry date, ask your pharmacist what to do with any tablets left over.

Product description

What it looks like

50mg tablets: peach coloured capsule shaped, biconvex film-coated tablets with 'BL' embossing on one side and plain on the other side.

100mg tablets: white capsule shaped, film-coated tablets with 'BL' embossing on one side and plain on the other side.

Prescription medicine: Available in blister pack of 2, 4, 6, 12, 100 and 500 tablets.

Restricted medicine (50mg only): Available in blister pack of 2 tablets.

*Not all presentations may be marketed.

Ingredients

Active ingredient:

- Each tablet contains 50mg or 100mg of the active ingredient sumatriptan succinate.

Inactive ingredients:

- Lactose monohydrate
- Microcrystalline cellulose
- Pregelatinised starch
- Purified water
- Croscarmellose sodium
- Magnesium stearate
- Hypromellose
- Titanium dioxide
- Purified Talc
- Macrogol 6000
- *Ferric oxide red
- *Ferric oxide yellow

*Colourants are only for Apo-Sumatriptan 50mg.

This medicine is glucose free but contains lactose.

Sponsor Details

Apo-Sumatriptan is supplied in New Zealand by:

Apotex NZ Ltd

32 Hillside Road

Glenfield

Private Bag 102995

North Shore

North Shore City 0745

Auckland

NEW ZEALAND

Telephone: (09) 444 2073

Date of Preparation

This leaflet was prepared on 22 November 2016.