

APO-Sumatriptan

Contains the active ingredient sumatriptan (as sumatriptan succinate)

Consumer Medicine Information

For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet

Read this leaflet carefully before taking your medicine.

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

The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:

- if there is anything you do not understand in this leaflet,
- if you are worried about taking your medicine, or
- to obtain the most up-to-date information.

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

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is APO-Sumatriptan. It contains the active ingredient sumatriptan (as sumatriptan succinate).

This medicine belongs to a group of drugs called serotonin agonists. It is used to relieve a migraine attack. It should not be used to prevent migraine attacks from occurring.

This medicine may be used for migraine headaches with or without what is known as 'aura'.

Ask your doctor if you have any questions about why this medicine has been prescribed for you. Your doctor may have prescribed this medicine for another reason.

This medicine is available only with a doctor's prescription.

How it works

It is thought that a migraine headache is due to widening of certain blood vessels in the head. This medicine works by narrowing the affected vessels, to ease the symptoms of migraine.

This medicine does not work in other types of headache which are not a migraine.

There is no evidence that this medicine is addictive.

Use in children

The effectiveness of this medicine has not been established in adolescents between 12 and 17; and the safety and effectiveness of this medicine in children under the age of 12 years has not been established.

Use in the elderly

It is not recommended that people over 65 use this medicine.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **you have or have had:**
 - heart disease or heart attack
 - shortness of breath, pain or tightness in the chest, jaw or upper arm
 - peripheral vascular disease (pain in the back of the legs) or you are prone to cold, tingling or numb hands and feet
 - Prinzmetal's angina (an uncommon form of angina where pain is experienced at rest rather than during activity)
 - angina
 - high blood pressure which is not controlled by medication
 - stroke or "mini-stroke"
 - severe liver disease
 - types of migraine called hemiplegic, basilar or ophthalmoplegic migraine
- **you are taking or have taken any of these medicines in the last 24 hours:**
 - Ergotamine (e.g. Cafergot)
 - Dihydroergotamine (e.g. Dihyergot)
 - Methysergide (e.g. Deseril)
- **you are taking or have taken any of these medicines in the last two weeks:**

- phenelzine, tranylcypromine and moclobemide, which are Monoamine Oxidase Inhibitors (MAOIs), used to treat depression
 - selegiline (a MAOI), used to treat Parkinson's disease
 - linezolid (a MAOI), used to treat certain infections
 - methylene blue (a MAOI), used to diagnose certain medical conditions
- The expiry date (EXP) printed on the pack has passed.
 - The packaging is torn, shows signs of tampering or it does not look quite right.
 - **You have 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 include shortness of breath, wheezing or difficulty breathing; swelling of the face, lips, tongue, throat or other parts of the body, rash, itching or hives on the skin, fainting and hay fever-like symptoms.

If you think you are having an allergic reaction, contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

Before you start to take it

Before you start taking this medicine, tell your doctor if:

1. You have allergies to:
 - foods, preservatives or dyes
 - any other medicines, including any that contain sulphur (e.g. sulphonamide antibiotics, certain diuretics ("water" tablets), certain epilepsy medicines, or celecoxib, darunavir, probenecid, or sulfasalazine.)
 - lactose. (these tablets contain lactose)

2. You are currently pregnant or you plan to become pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
3. You are currently breastfeeding or you plan to breastfeed. Do not take this medicine whilst breastfeeding until you and your doctor have discussed the risks and benefits involved.
4. You have or have had any medical conditions, especially the following:
 - liver or kidney problems
 - heart problems or you have conditions which may make you prone to heart problems such as:
 - high blood pressure, even if it is under control
 - high blood cholesterol levels
 - a family history of heart problems
 - obesity
 - diabetes
 - you are male and over 40 years of age
 - you are female and have undergone menopause
 - smoking
 - epilepsy, seizure, or fits or been told that you are prone to this problem
 - stroke or "mini-stroke"

5. You are planning to have surgery.
6. You are currently receiving or are planning to receive dental treatment

7 You are taking or are planning to take any other medicines, or you have taken any medicine in the last 2 weeks. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

Some medicines may interact with sumatriptan. These include:

- MAO inhibitors, such as phenelzine, tranylcypromine,

moclobemide, selegiline, linezolid, and methylene blue

Do not take this medicine with MAOIs or for two weeks after stopping taking a MAOI

- other triptans (similar to sumatriptan) such as naratriptan and zolmitriptan

Do not take sumatriptan for 24 hours before or after taking another triptan.

- other medicines for treating migraine such as ergotamine, dihydroergotamine or methysergide

You should not take sumatriptan for 24 hours after taking ergotamine-type medicines and you should not take ergotamine type medicines for 6 hours after taking sumatriptan.

- medicines for treating depression such as SSRIs and SNRIs (fluoxetine, paroxetine, fluvoxamine, sertraline, citalopram, venlafaxine, nefazodone, mirtazapine)
- St Johns Wort, a herbal medicine.

If you are taking any of these you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with sumatriptan.

How to take this medicine

Follow carefully all directions given to you by your doctor or pharmacist. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor or pharmacist will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The recommended starting dose for adults is 50 mg, however you may need to have your dose increased to 100 mg. If you have liver problems the dose may be smaller. Your doctor

will tell you which dose is right for you.

If the first tablet helps your migraine, but the migraine comes back later, you may take another tablet.

If the first dose has not provided any relief from your symptoms do not take any more sumatriptan and go to see your doctor again.

If your doctor says it is OK, you may use this medicine again, if you get another migraine.

Do not take more than 300 mg of this medicine in any 24 hours.

Six pink (50 mg strength) or three white (100 mg strength) tablets contain 300 mg.

You may take your usual headache relief medication provided it does not contain ergotamine, methysergide, naratriptan or zolmitriptan. If you are not sure what to do, ask your doctor or pharmacist.

How to take it

This medicine should be swallowed with a drink of water. Do not crush or chew this medicine as it has a bitter taste.

When to take it

It is best to take this medicine:

- when the migraine headache begins, or
- when other symptoms of the migraine begin, such as nausea (feeling sick), vomiting or your eyes becoming sensitive to light.

If you take this medicine later during the migraine attack, it will still work for you.

Do not take this medicine before the above symptoms occur.

It does not matter if you take it before, with or after food.

How long to take it for

This medicine is not to be used on a regular basis. Use it only when you have migraine symptoms, and if the tablets do not relieve your migraine

then do not take any more for that migraine.

If you take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively go to the Accident and Emergency Department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that you are taking this medicine if:

- for any reason, you have not taken this medicine exactly as directed. Otherwise your doctor may think that it is not working and change your treatment unnecessarily.
- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breastfeed
- you are going to have surgery or are going into hospital.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- Give this medicine to anyone else, even if their symptoms seem similar to yours
- Take your medicine to treat any other condition unless your doctor or pharmacist tells you to

- Change the dosage, without first checking with your doctor.

Things to be careful of

This medicine may cause drowsiness in some people.

Be careful when driving or operating machinery until you know how this medicine affects you.

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

Possible side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking sumatriptan or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor or pharmacist if you notice any of the following and they worry you.

This list includes the more common side effects. Mostly, these are mild and short-lived:

- pain, tingling, burning, prickling, cold or flushing in any part of the body
- loss of touch sensitivity
- feeling of sleepiness, dizziness weakness or tiredness
- nausea (feeling sick) or vomiting
- a change in blood pressure
- feeling of faintness
- problems with your eye sight
- jittery eye movements
- shaking or tremors
- uncontrolled movements
- mild rash or itching

Tell your doctor as soon as possible if you notice any of the following.

These may be serious side effects. You may need medical attention. Most of these side effects are rare.

- pain in the lower tummy and bloody diarrhoea (ischemic colitis)
- problems breathing
- persistent purple or white discolouration and/or pain in the fingers, toes, ears, nose or jaw, sometimes (but not always) in response to cold.
- feeling faint due to a drop in blood pressure

If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

These are very serious side effects. You may need urgent medical attention or hospitalisation.

- Neck pain or stiffness, feeling of heaviness, pressure or tightness in any part of the body including the head, chest or throat
- chest pain or angina; or symptoms of a heart attack such as chest pain, shortness of breath, nausea, vomiting, palpitations, sweating, anxiety.
- fast, slow, thumping or irregular heartbeats
- seizures (fits)
- symptoms of a stroke, which include problems with speech, and/or lack of muscle movement on one side of your body.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to sumatriptan, tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

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

- shortness of breath, wheezing or difficulty breathing.
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hayfever-like symptoms

Storage and disposal

Storage

Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 30°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where children cannot reach it.

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

Disposal

If your doctor or pharmacist tells you to stop taking this medicine or they have passed their expiry date, your pharmacist can dispose of the remaining medicine safely.

Product description

What APO- Sumatriptan looks like

APO-Sumatriptan tablets is available in 50 mg strength. Sumatriptan tablets are available in 50 mg and 100 mg strengths.

50 mg tablets are pink coloured, capsule shaped, biconvex film coated

tablets, debossed with '50' on one side and plain on the other side.

They are available in blister packs containing 2 or 4 tablets.

100 mg tablets are white, capsule shaped, biconvex film coated tablets debossed with '100' on one side and plain on the other side.

They are available in blister packs containing 2 tablets.

Not all strengths, pack types and/or pack sizes may be available.

Ingredients

Each tablet contains 50 mg or 100 mg of sumatriptan (as sumatriptan succinate) as the active ingredient.

It also contains the following inactive ingredients:

- lactose
- croscarmellose sodium
- microcrystalline cellulose
- crospovidone
- colloidal silica anhydrous
- magnesium stearate
- Opadry Pink (50 mg only) which contains hypromellose, polyethylene glycol, titanium dioxide, iron oxide red and iron oxide black
- Opadry White (100 mg only) which contains hypromellose, polyethylene glycol, titanium dioxide

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

Australian Registration Numbers

APO-Sumatriptan 50 mg tablets:
AUST R 160188.

Sponsor

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