

APO-Sumatriptan

Sumatriptan succinate

Consumer Medicine Information

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

What is in this leaflet

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.

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.

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

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

What this medicine is used for

Sumatriptan is used to relieve a migraine attack. This medicine may be used for migraine headaches with or without what is known as 'aura'.

Sumatriptan belongs to a group of drugs called serotonin agonists.

How it works

It is thought that a migraine headache is due to widening of certain blood vessels in the head. Sumatriptan works by making the affected vessels normal again, to ease the symptoms of migraine.

This medicine does not work in other types of headache which are not a migraine. It should not be used to

prevent migraine attacks from occurring.

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.

This medicine is not addictive.

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.

Sumatriptan is not recommended for use in people aged over 65 years.

Before you take this medicine

When you must not take it

Do not take this medicine if you have an allergy to:

- sumatriptan succinate
- any of the ingredients listed at the end of this leaflet.

Some of the 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

Do not take this medicine if you have or have had any of the following medical conditions:

- 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

Do not take this medicine if 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)

Do not take this medicine if you are taking or have taken Monoamine Oxidase Inhibitors (MAOIs) in the last two weeks, such as:

- phenelzine, tranylcypromine and moclobemide, used to treat depression
- selegiline, used to treat Parkinson's disease
- linezolid, used to treat certain infections

- methylene blue, used to diagnose certain medical conditions.

Do not take this medicine if you are taking or have taken SSRIs (Selective Serotonin Reuptake Inhibitors) or SNRIs (Serotonin-Noradrenaline Reuptake Inhibitors) used to treat depression in the last two weeks.

Do not use this medicine after the expiry date printed on the pack or the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if you are allergic to any medicines that contain sulphur, such as sulphonamide antibiotics.

Tell your doctor if you are lactose-intolerant or unable to consume lactose, as these tablets contain lactose.

Tell your doctor if you are pregnant or plan to become pregnant or are breastfeeding.

Do not take this medicine until you and your doctor have discussed the risks and benefits involved.

Tell your doctor if you have or have had any of the following medical conditions:

- 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, seizures, or fits, or been told that you are prone to this problem
- stroke or 'mini-stroke'

If you have not told your doctor about any of the above, tell them before you start taking this medicine.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, or you have taken any medicine in the last 2 weeks, including any that you get without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and sumatriptan may interfere with each other. 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. Do not take sumatriptan for 6 hours before or 24 hours after taking ergotamine-type medicines.
- medicines for treating depression such as SSRIs and SNRIs (e.g. fluoxetine, paroxetine, fluvoxamine, sertraline, citalopram, venlafaxine, nefazodone, mirtazapine)
- St John's wort, a herbal medicine.

These medicines may be affected by this medicine or may affect how well it works. You may need different amounts of your medicines, or you may need to take different medicines.

Your doctor and pharmacist have more information on medicines to be

careful with or avoid while taking this medicine.

Other medicines not listed above may also interact with sumatriptan.

How to take this medicine

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ to the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

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. If you have liver problems you may be prescribed a lower dose.

The recommended starting dose for adults aged 18 to 65 is 50 mg, however your dose may be increased to 100 mg if needed.

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

If the first dose has not provided any relief from your symptoms, do not take any more sumatriptan for this attack. Your doctor should review your treatment to check if this medicine is still appropriate for you.

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 of sumatriptan.

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.

If your migraine is not relieved by this medicine, you may use sumatriptan tablets on another

occasion to treat another migraine attack. Provided there are no side effects, you can use sumatriptan tablets to treat at least three separate migraine attacks before you and your doctor decide this medicine is ineffective for you.

How to take it

Swallow the tablets whole with a glass 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 with or without 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)

Immediately telephone your doctor or the Poisons Information Centre (telephone 13 11 26) for advice, or go to Accident and Emergency at your nearest hospital, if you think that you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking this medicine

Things you must do

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

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking this medicine.

Tell your doctor 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.

If you become pregnant while taking this medicine, tell your doctor immediately.

Tell your doctor if you are going to have surgery or are going into hospital.

Things you must not do

Do not give this medicine to anyone else, even if they have the same condition as you.

Do not take your medicine to treat any other complaint unless your doctor tells you to.

Do not change the dosage without first checking with your doctor.

Things to be careful of

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

This medicine may cause drowsiness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

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.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel

well while you are taking sumatriptan.

This medicine helps most people with migraine headaches, but it may have unwanted side effects in a few people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some of the side effects.

Do not be alarmed by the following lists of side effects. You may not experience any of them.

Ask your doctor or pharmacist to answer any questions you may have.

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

- 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 or jittery eye movements
- shaking or tremors, uncontrolled movements

The above list includes the more common side effects of your medicine. Mostly, these are mild and short-lived.

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

- pain in the lower tummy and bloody diarrhoea (signs of ischemic colitis)
- breathing problems
- feeling faint due to a drop in blood pressure

The above list includes serious side effects that may need medical attention.

If any of the following happen, stop taking your medicine and contact your doctor immediately or go to Accident and Emergency at your nearest hospital:

- 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 (signs of an allergic reaction)

- 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)
- problems with speech, and/or lack of muscle movement on one side of your body (signs of a stroke)
- persistent purple or white discolouration and/or pain in the fingers, toes, ears, nose or jaw, sometimes in response to cold

The above list includes very serious side effects. Stop taking sumatriptan tablets and seek medical attention straight away. Most of these side effects are rare.

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

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

Storage and disposal

Storage

Keep your medicine in the pack until it is time to take it.

If you take your medicine out of the pack it may not keep well.

Keep your medicine in a cool dry place where the temperature stays 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 tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine left over.

Product description

What it looks like

50 mg tablets: pink coloured, capsule shaped, biconvex film coated tablets, debossed with '50' on one side and plain on the other side.

Available in blister packs containing 2 or 4 tablets. AUST R 160188.

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

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

Ingredients

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

It also contains the following:

- lactose
- croscarmellose sodium
- microcrystalline cellulose
- crospovidone
- colloidal silica anhydrous
- magnesium stearate
- Opadry Pink (50 mg only) which contains hypromellose, macrogol 400, titanium dioxide, iron oxide red and iron oxide black
- Opadry White (100 mg only) which contains hypromellose, macrogol 400, titanium dioxide

This medicine does not contain gluten, sucrose, tartrazine or any other azo dyes.

Contains sugars (as lactose).

Sponsor

Arrotex Pharmaceuticals Pty Ltd,
15 – 17 Chapel st.,
Cremorne VIC 3121

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