

SUMAGRAN ASPEN 50 SUMAGRAN ASPEN 100

sumatriptan succinate

Consumer Medicine Information

What is in this leaflet

Please read this leaflet carefully before you start taking SUMAGRAN ASPEN tablets.

This leaflet answers some common questions about SUMAGRAN ASPEN tablets. It does not contain all of 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 expected benefits of you taking SUMAGRAN ASPEN against the risks this medicine could 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 need to read it again.

What SUMAGRAN ASPEN is used for

SUMAGRAN ASPEN contain the active ingredient sumatriptan succinate. This medicine belongs to a group of drugs called serotonin agonists.

SUMAGRAN ASPEN are used to relieve a migraine attack. They should not be used to prevent migraine attacks from occurring. SUMAGRAN ASPEN may be used for migraine headaches with or without what is known as 'aura'.

It is thought that migraine headache is due to widening of certain blood vessels in the head.

SUMAGRAN ASPEN works by making those vessels normal again and eases the symptoms of migraine.

SUMAGRAN ASPEN does not work in other types of headache that are not a migraine.

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

SUMAGRAN ASPEN are not addictive.

SUMAGRAN ASPEN is available only with a doctor's prescription.

Use in children and adolescents

SUMAGRAN ASPEN is not recommended for use in children and adolescents under 12 years of age, as the safety and efficacy in this age group has not been established.

Use in elderly

SUMAGRAN ASPEN is not recommended for use in elderly patients aged over 65, as experience of its use in this age group is limited.

Before you take it

When you must not take it

Do not take SUMAGRAN ASPEN if you are allergic to sumatriptan succinate or 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 or other parts of the body; rash, itching or hives on the skin.

Do not take SUMAGRAN ASPEN 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 are prone to cold, tingling or numb hands and feet
- Prinzmetal's angina (uncommon form of angina where pain is experienced at rest rather than during activity)
- angina
- high blood pressure
- stroke
- severe liver disease.

Do not take SUMAGRAN ASPEN if you have taken any of these medicines in the last 24 hours:

- ergotamine (eg Cafergot)
- dihydroergotamine (eg Dihydergot)
- methysergide (eg Deseril)
- naratriptan (eg Naramig)
- zolmitriptan (eg Zomig).

Do not take SUMAGRAN ASPEN if you have taken monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression, in the last two weeks.

Do not take SUMAGRAN ASPEN if the expiry date (EXP) printed on the pack has passed.

Do not take SUMAGRAN ASPEN if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if you are allergic to foods, dyes, preservatives or any other medicines including those containing sulphur (eg sulphonamide antibiotics) or lactose (SUMAGRAN ASPEN tablets contain lactose).

Tell your doctor if you are taking or have taken any other medicines in the last two weeks, including those you buy without a prescription, particularly herbal preparations containing St John's wort.

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

Tell your doctor if you have or have had medical conditions like:

- liver or kidney problems
- heart problems; risk factors including high blood pressure (even it is under control), high blood cholesterol levels, a family history of heart problem, obesity, diabetes, smoking, male and over 40 years of age, female and have undergone menopause
- epilepsy, seizures or fits or been told that you are prone to this problem
- stroke.

Tell your doctor if you:

- 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 SUMAGRAN ASPEN.

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

Taking other medicines

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

Some medicines may be affected by SUMAGRAN ASPEN, or may affect how well it works. These include:

- ergotamine
- dihydroergotamine
- methysergide
- triptans such as naratriptan, zolmitriptan
- monoamine oxidase inhibitors
- St John's wort
- other medicines for depression.

Your doctor can tell you what to do if you are taking any of these medicines.

If you are not sure whether you are taking any of these medicines, check with your doctor or pharmacist.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking SUMAGRAN ASPEN.

How to take it

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

They may differ from the information contained in this leaflet.

If you do not understand what you should do, ask your doctor or pharmacist.

How much to take

The recommended starting dose for adults is 50 mg. However, you may need to have your dose increased to 100 mg. Your doctor will tell you which dose is right for you.

If the first SUMAGRAN ASPEN tablet helps your migraine, but the migraine comes back later, you may take another SUMAGRAN ASPEN tablet. Do not take more than 300 mg of SUMAGRAN ASPEN tablets in any 24-hour period. Six 50 mg or three 100 mg tablets contain 300 mg.

Do not take more SUMAGRAN ASPEN tablets, or any other form of medications containing sumatriptan, if the first dose has not provided any relief from your symptoms. You may take your usual headache relief medication provided it does not contain ergotamine, dihydroergotamine or methysergide. If you are not sure what to do, ask your doctor or pharmacist.

If your migraine is not relieved by SUMAGRAN ASPEN, you may use it on another occasion to treat another migraine attack.

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

How to take SUMAGRAN ASPEN

Swallow the tablets with a drink of water. Do not crush or chew the tablet as it has a bitter taste.

When to take SUMAGRAN ASPEN

It is best to take your SUMAGRAN ASPEN:

- 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 your tablet later during the migraine attack, it will still work for you.

Do not take SUMAGRAN ASPEN before the above symptoms occur.

If you take too much SUMAGRAN ASPEN (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (telephone 13 11 26), or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SUMAGRAN ASPEN.

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

You may need urgent medical attention.

While you are taking it

Things you must do

Tell any other doctors, dentists and pharmacists who treat you that you are taking SUMAGRAN ASPEN.

If you are about to be started on any new medicine, tell your doctor, dentist or pharmacist that you are taking SUMAGRAN ASPEN.

Tell your doctor if you become pregnant or are trying to become pregnant while taking SUMAGRAN ASPEN.

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed. Otherwise, your doctor may think that it is not working and change your treatment unnecessarily.

Things you must not do

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

Do not use SUMAGRAN ASPEN to treat any other medical complaints unless your doctor tells you to.

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

Things to be careful of

Be careful driving or operating machinery until you know how SUMAGRAN ASPEN affect you.

As with many other medicines, SUMAGRAN ASPEN may cause drowsiness in some people.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking SUMAGRAN ASPEN.

Like all other medicines, SUMAGRAN ASPEN may have unwanted side effects in some people. 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 this list of possible side effects.

You may not experience any of them.

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

Tell your doctor if you experience any of the following after taking SUMAGRAN ASPEN:

- 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
- problems with your eyesight
- pain in the lower tummy and bloody diarrhoea (ischaemic colitis)
- shaking or tremors
- uncontrolled movements.

If you notice any of the following while taking SUMAGRAN ASPEN, stop taking it and tell your doctor immediately or go to Accident and Emergency at your nearest hospital:

- feel heaviness, pressure or tightness in any part of the body including the chest or throat
- feel irregular heartbeat
- have a fit or convulsion
- have persistent purple discolouration and/or pain in the fingers, toes, ears, nose or jaw in response to cold
- have wheezing, swelling of the lips or mouth, difficulty in breathing, hay fever, lumpy rash ("hives") or fainting. These could be a symptom of an allergic reaction.

These side effects are likely to be serious. You may need urgent medical attention or hospitalisation.

Other side effects not listed above may also occur in some patients. Tell your doctor if you notice anything that is making you feel unwell.

After using it

Storage

Keep SUMAGRAN ASPEN 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.

Keep the tablets in a cool, dry place where the temperature stays below 30°C.

Keep the tablets in their pack until time to take.

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

Do not store SUMAGRAN ASPEN in the bathroom or near a sink.

Do not leave SUMAGRAN ASPEN in the car or on window sills.

Heat and dampness can destroy some medicines.

Disposal

If your doctor tells you to stop taking SUMAGRAN ASPEN, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Product description

What it looks like

SUMAGRAN ASPEN tablets come in two strengths:

- SUMAGRAN ASPEN 50 - pink, capsule shaped, biconvex film coated tablets debossed with "50" on one side and plain on the other. Each pack contains 2 or 4 tablets.
- SUMAGRAN ASPEN 100 - white, capsule shaped, biconvex film coated tablets debossed with "100" on one side and plain on the other. Each pack contains 2 tablets.

Ingredients

The active ingredient in SUMAGRAN ASPEN is sumatriptan (as succinate).

- each SUMAGRAN ASPEN 50 contains 50 mg of sumatriptan

- each SUMAGRAN ASPEN 100 contains 100 mg of sumatriptan.

The tablets also contain:

- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- anhydrous lactose
- crospovidone
- Opadry complete film coating system
- silica - colloidal anhydrous

The tablets do not contain gluten, sucrose, tartrazine or any other azo dyes.

Sponsor

Aspen Pharma Pty Ltd
34-36 Chandos St
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Australia

Australian registration numbers:

SUMAGRAN ASPEN 50 - AUST R 160185
SUMAGRAN ASPEN 100 - AUST R 160193

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