

NEW ZEALAND CONSUMER MEDICINE INFORMATION

SUMAGRAN ACTIVE®

Sumatriptan (as the succinate) 50 mg film-coated tablet



What is in this leaflet

Please read this leaflet carefully before you start taking SUMAGRAN ACTIVE.

This leaflet answers some common questions about SUMAGRAN ACTIVE.

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 or pharmacist has weighed the risks of you taking SUMAGRAN ACTIVE 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 need to read it again.

What SUMAGRAN ACTIVE is taken for

SUMAGRAN ACTIVE contains the active ingredient sumatriptan succinate. It belongs to a group of medicines known as serotonin agonists.

SUMAGRAN ACTIVE is used for the acute relief of migraine attacks, with or without what is known as 'aura' or a forewarning of an attack. This may include visual disturbances such as brilliant flickering lights or blurring of vision; or sensory disturbances such as numbness or weakness of the limbs. SUMAGRAN ACTIVE is only suitable in patients who have a stable, well-established pattern of symptoms. It should not be used to

prevent migraine attacks from occurring.

Migraine attacks are thought to be caused by the swelling of blood vessels in the brain. Sumatriptan helps to relieve the symptoms of a migraine attack by reducing the size of the blood vessels back to normal. SUMAGRAN ACTIVE tablets help to relieve other symptoms that occur together with a migraine headache, such as feeling sick and sensitivity to light and sound.

This medicine does not relieve the symptoms of other headaches that are not migraine headaches.

SUMAGRAN ACTIVE is available from your pharmacist in packs of two tablets for use in patients who have a stable, well-established pattern of symptoms.

Ask your doctor or pharmacist if you have any questions about why this medicine has been recommended for you.

Before you take SUMAGRAN ACTIVE

When you must not take it

Do not take SUMAGRAN ACTIVE if you have an allergy to:

- any medicine containing sumatriptan succinate or sulphonamides.
- 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 ACTIVE if you have or have ever had:

- heart disease, or previous heart attack
- vascular problems (including a stroke or clot)
- high blood pressure
- angina, including Prinzmetal's angina
- shortness of breath, pain or tightness in the chest, neck, jaw or upper arm
- liver failure

Do not take SUMAGRAN ACTIVE if you have taken monoamine oxidase inhibitors (MAOIs), a type of medicine used for depression within the last 14 days.

Ask your pharmacist or doctor if you are unsure as to whether or not you are taking a MAOI (MAOIs are a type of medicine used for depression e.g. moclobemide, selegiline).

Do not take this medicine if you have taken any of the following medicines used to treat migraines in the past 24 hours:

- other sumatriptan containing medicines (e.g. Imigran)
- other medicines belonging to the group of medicines known as the triptans or serotonin agonists (e.g. naratriptan, rizatriptan)
- ergotamine containing preparations (e.g. Cafergot) or derivatives of ergotamine (including methysergide containing preparations e.g. Deseril)

Do not take SUMAGRAN ACTIVE if

- you are trying to prevent a migraine attack – only take it when your migraine headache begins
- you have kidney disease
- you have epilepsy or are prone to seizures

- your doctor has diagnosed you with one of the rare forms of migraine (hemiplegic, basilar or ophthalmoplegic migraines). Hemiplegic migraines are when you experience a temporary weakness on one side of their body as part of the migraine attack. Basilar migraines are when you might see spots or lines in your vision, as well as abnormal flashes of lights and then symptoms such as dizziness and lack of coordination as part of the migraine attack. Ophthalmoplegic migraines are when you experience pain around their eyeballs. The muscles around the eyes get weak and hard to move. You may have double vision. as part of the migraine attack.

Do not take this medicine if you are pregnant, plan to become pregnant or you are breastfeeding, without first discussing this with your doctor.

Your pharmacist or doctor will assess the risks and benefits of taking SUMAGRAN ACTIVE if you are pregnant or breastfeeding.

It may affect your developing baby if you take it during pregnancy.

Do not breast-feed if you are taking this medicine.

The active ingredient in SUMAGRAN ACTIVE passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to anyone under 18 or over 65 years of age.

Safety and effectiveness in adolescent and children younger than 18 years have not been established.

Experience of the use of sumatriptan in patients aged over 65 is limited.

Do not take this medicine after the expiry date printed on the pack or if 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 or pharmacist.

Before you start to take it

Tell your doctor or pharmacist if you have allergies to:

- any other medicines, foods, preservatives or dyes.
- lactose, or if you are lactose intolerant
- any other sulphonamide medicines.

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

- liver or kidney problems
- a stroke
- epilepsy or fits
- brain tumour, or any other condition effecting the brain
- any problems with your heart, including irregular heart-beat, or if you have a family history of heart problems
- high blood pressure
- high cholesterol
- angina or any other chest pain or tightness
- shortness of breath, pain of tightness in the chest, neck, jaw or upper arm

Tell your doctor or pharmacist if you:

- are over 50 years of age and this is your first headache of this type
- are taking a medicine for depression called a selective serotonin reuptake inhibitor (SSRI) or a serotonin noradrenaline reuptake inhibitor (SNRI).
Ask your pharmacist or doctor if you are unsure as to whether or not you are taking a SSRI or SNRI
- have not had your headache diagnosed by a doctor as a migraine
- feel this headache is different or worse than your usual migraine

- have these symptoms with your migraine headache; weakness on one side of your body, double vision, clumsy and uncoordinated movements, tinnitus (ringing in the ears), reduced levels of consciousness, seizure like movements, recent rash with a headache,
- took your first dose of SUMAGRAN ACTIVE at least 2 hours ago and your symptoms have not improved
- have headaches that usually last longer than 24 hours
- generally have four or more migraine attacks each month
- are taking oral contraceptive pills
- are taking long term painkillers
- have three or more of the following risk factors:
 - you are a man over 40, or a woman who has had the menopause
 - have high cholesterol
 - regular smoker
 - you are very overweight
 - have diabetes
 - have a close relative who developed early heart disease.

Tell your doctor or pharmacist if you are pregnant or plan to become pregnant or are breast-feeding.

Your pharmacist or doctor can discuss with you the risks and benefits involved.

If you have not told your doctor or pharmacist about any of the above, tell him/her before you start taking SUMAGRAN ACTIVE.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, or have taken any other medicines in the past two weeks, including any that you get without a prescription from your pharmacy, supermarket or health food shop (including St John's wort, a herbal remedy to support mood).

Some medicines may interfere with SUMAGRAN ACTIVE. These include:

- ergotamine/ergotamine derivatives or triptan/5-HT1 agonist medicines used to treat migraine headache and cluster headaches.
- monoamine oxidase inhibitors (MAOIs) and Selective serotonin reuptake inhibitors (SSRIs) medicines which are used to treat depression.
- the herbal remedy St John's Wort which is often used to treat depression.

These medicines may be affected by SUMAGRAN ACTIVE 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.

How to take SUMAGRAN ACTIVE

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

The label on the box will tell you how many tablets to take and how often to take. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

Take ONE tablet at once at the first sign of a migraine attack.

If after taking the first tablet, your symptoms improve but return later, you may take a second tablet. Wait at least two hours after the first tablet was taken.

DO NOT take more than two SUMAGRAN ACTIVE tablets in 24 hours and DO NOT take more than two tablets for the same attack.

If the first tablet is not effective at relieving or helping your migraine symptoms, DO NOT

take another tablet for the same attack. The second tablet can be used at a later date to treat another migraine attack.

How to take it

Swallow the tablet whole with a full glass of water. Do not crush or chew the tablets. It does not matter if you take SUMAGRAN ACTIVE before or after food.

When to take it

It is best to take your tablet either when the migraine headache begins or when other symptoms of the migraine headache begin. These symptoms may include nausea (feeling sick), vomiting or your eyes becoming sensitive to light.

If you take your first tablet during the migraine attack, and not at the beginning as recommended, it may still work for you.

Do not take your SUMAGRAN ACTIVE tablet before the above symptoms occur

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

While you are taking SUMAGRAN ACTIVE

Things you must do

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

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine or have recently taken this medicine.

Things you must not do

Do not take SUMAGRAN ACTIVE to treat any other complaints.

Do not take SUMAGRAN ACTIVE for any other headache that is not a migraine headache. SUMAGRAN ACTIVE only treats migraine headaches.

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

Do not take SUMAGRAN ACTIVE to try and prevent a migraine attack.

Do not change the dosage without checking with your pharmacist or doctor.

Things to be careful of

Be careful driving or operating machinery until you know how SUMAGRAN ACTIVE affects you. Drowsiness may occur as a result of a migraine or its treatment with SUMAGRAN ACTIVE. It is therefore important that you are certain SUMAGRAN ACTIVE does not affect your performance before you drive a car or operate machinery.

If you take SUMAGRAN ACTIVE frequently, it may make your headaches worse. Tell your doctor or pharmacist if this applies to you.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may have taken too much SUMAGRAN ACTIVE. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

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

This medicine helps most people with migraines 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:

- flushing, dizziness or feelings of weakness
- drowsiness or fatigue (tiredness)
- nausea (feeling sick) or vomiting
- feelings of tingling, warmth, cold, heaviness, pressure, or pain in different parts of the body including in the chest and throat
- decreased feeling or sensitivity, especially in the skin.
- increased blood pressure

The above list includes the more common side effects of your medicine
They are usually mild and short lived.

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

- visual disturbances including flicking, double vision or changes in your vision
- shaking, tremors or uncontrolled movement
- changes in the speed of your heart rate or irregular heart beat
- shortness of breath or difficulty breathing chest tightness.
- seizures following migraine attacks

The above list includes serious side effects that may require medical attention. Serious side effects are rare.

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

- pain, heaviness, pressure or tightness in any part of the body including the chest or throat
- swelling of the face, lips or tongue which may cause difficulty in swallowing or breathing
- wheezing
- sudden or severe itching, skin rash or hives
- fainting, seizures or fits.

The above list includes very serious side effects. You may need urgent medical attention or hospitalisation. These side effects are very rare.

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

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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

After taking SUMAGRAN ACTIVE

Storage

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

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store SUMAGRAN ACTIVE 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 it 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 you do not take your tablet(s) or the expiry date has passed,

ask your pharmacist what to do with the remaining medicine.

Product description

What it looks like

SUMAGRAN ACTIVE 50 mg tablet are pink, round, film-coated tablets. They are marked with 'SU50' on one side and 'G' on the other.

Ingredients

Active ingredient:
SUMAGRAN ACTIVE contains 50 mg of sumatriptan succinate as the active ingredient.

Inactive ingredient(s):
SUMAGRAN ACTIVE also contains:

- lactose monohydrate
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- titanium dioxide
- polydextrose
- hypromellose
- glycerol triacetate
- polyethylene glycol
- iron oxide red
- iron oxide yellow

Contains sugars as lactose.

Contains 4.32 mg polydextrose per recommended maximum daily dose. This may have a laxative effect or cause diarrhoea.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

SUMAGRAN ACTIVE is supplied in New Zealand by:

Viatrix Ltd,
PO Box 11-183,
Ellerslie,
Auckland.
www.viatrix.co.nz

Telephone: 0800 168 169

Date of Information

27 March 2023

(Based on datasheet dated 27
March 2023)

SUMAGRAN ACTIVE® is a Viatris
company trade mark.