

NEW ZEALAND CONSUMER MEDICINE INFORMATION

SUMAGRAN

Sumatriptan (as the succinate) film coated tablet 50mg & 100 mg



What is in this leaflet

Please read this leaflet carefully before you start taking SUMAGRAN.

This leaflet answers some common questions about SUMAGRAN.

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 taking SUMAGRAN 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 is used for

Your SUMAGRAN tablets contain the active ingredient, sumatriptan succinate. Sumatriptan belongs to a group of medicines known as serotonin agonists

SUMAGRAN 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 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 tablets help to relieve other symptoms that occur together with a migraine headache, such as feeling sick and sensitivity to light and sound.

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

Your doctor may have prescribed this medicine for another reason.

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

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

Before you take SUMAGRAN

When you must not take it

Do not take SUMAGRAN if you have an allergy to:

- any medicine containing Sumatriptan succinate or sulphur (e.g. sulfonamides)
- 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 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 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

Do not take SUMAGRAN if you have taken any of the following other 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 methylsergide containing preparations (e.g. Deseril))

DO not take SUMAGRAN if you have 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 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 passes into breast milk and there is a possibility that your baby may be affected.

Do not give this medicine to a child under the age of 18 years. Safety and effectiveness in children younger than 18 years have not been established.

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.

Before you start to take it

Tell your doctor if you have allergies to:

- any other medicines, foods, preservatives or dyes.
- Lactose, or if you are lactose intolerant
- Any other medicines, especially any medicines that contain sulfur.

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 affecting 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 if you:

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

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

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

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

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 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 SUMAGRAN.

Some medicines may interfere with SUMAGRAN. 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 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

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

The label on the pack will tell you how many tablets to take and how often you should take them.

They may differ from 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

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

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

If the first SUMAGRAN tablet does not relieve or help your migraine headache, do not take another SUMAGRAN 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. They can tell you what you may take.

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

How to take it

SUMAGRAN tablets should be swallowed whole with a glass of water. Do not crush or chew the tablets. It does not matter if you take SUMAGRAN before or after food.

When to take it

It is best to take your SUMAGRAN 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 SUMAGRAN tablet during the migraine attack, and not at the beginning as recommended, it may still work for you.

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

How long to take it

Stop using this medicine when the migraine has gone.

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

While you are taking SUMAGRAN

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you

are taking SUMAGRAN or have recently taken SUMAGRAN.

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

If you become pregnant, plan to become pregnant or are breast feeding while taking this medicine, tell your doctor immediately.

Keep all of your doctor's appointments so that your progress can be checked.

Things you must not do

Do not take SUMAGRAN to treat any other complaints.

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

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

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

Do not change the dose you take of your medicine without checking with your doctor.

Things to be careful of

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

Drowsiness may occur as a result of a migraine or its treatment with SUMAGRAN. It is therefore important that you are certain SUMAGRAN does not affect your performance before you drive a car or operate machinery.

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 SUMAGRAN. 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.

This medicine helps most people with migraine, 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 treatment if you get some of the side effects.

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, tightness or pain in different parts of the body including 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 (increase or decrease) or irregular heartbeat.
- shortness of breath, difficulty in 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

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 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 your doctor tells you to stop taking this medicine or the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

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

SUMAGRAN 100mg tablets are white, round, film coated tablets. They are marked with "SU100" on one side and "G" on the other side.

Ingredients

Active ingredient:

SUMAGRAN contains 50 mg or 100 mg of sumatriptan succinate as the active ingredient.

Inactive ingredient(s):

SUMAGRAN also contains:

- lactose
- microcrystalline cellulose
- croscarmellose sodium
- magnesium stearate
- titanium dioxide
- polydextrose hypromellose
- glycerol triacetate
- polyethylene glycol
- iron oxide red (50 mg only)
- iron oxide yellow (50 mg only)

This medicine contains lactose.

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 is supplied in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11183,
Ellerslie,
Auckland
NEW ZEALAND

Telephone: 0800 168 169

Date of Preparation

24 June 2021.

(Based on datasheet dated 24 June 2021)