

SUMAGRAN ACTIVE



Sumatriptan (as succinate) 50mg film coated tablet

What is in this leaflet

This leaflet answers some common questions about SUMAGRAN ACTIVE. It does not contain all the information available on this medicine. It does not take the place of talking to your pharmacist or doctor. All medicines have risks and benefits. Your pharmacist or doctor 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 pharmacist or doctor.

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

What SUMAGRAN ACTIVE is used for and how it works

Your SUMAGRAN ACTIVE tablets contain the active ingredient, sumatriptan succinate. Sumatriptan 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.

SUMAGRAN ACTIVE 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.

Before you take SUMAGRAN ACTIVE

When you must not take it

Do not take SUMAGRAN ACTIVE if you are allergic to sumatriptan succinate, sulfur (e.g. sulfonamides) or any 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 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

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

- **Other Sumatriptan containing medicines (eg. Imigran)**
- **Other medicines belonging to the group of medicines known as the triptans or serotonin agonists (eg. naratriptan, rizatriptan)**
- **Ergotamine containing preparations (eg. Cafergot) or derivatives of ergotamine (including methylsergide containing preparations (eg. Deseril)**

Do not take SUMAGRAN ACTIVE 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.

Do not take SUMAGRAN ACTIVE after the expiry date (EXP) printed on the pack.

If you take them after the expiry date has passed, they may not work as well.

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

If you have not told your pharmacist or doctor about any of the above, tell them before you take SUMAGRAN ACTIVE.

Before you take it

Tell your pharmacist or doctor if you are allergic to:

Any other medicines, foods, dyes or preservatives

Lactose, or if you are lactose intolerant

Any other medicines, especially any medicine that contains sulfur

Tell your pharmacist or doctor if you have, or have ever had any other health problems, especially the following:

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 beats, 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

If you have not told your pharmacist or doctor about any of the above, tell them before you take SUMAGRAN ACTIVE.

You must tell your pharmacist or doctor if:

You are over 65 or under 18 years of age
SUMAGRAN ACTIVE is only suitable for patients between 18 and 65 years of age
You 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
Your headache has not been diagnosed by a doctor as a migraine
You have different symptoms, or if you feel that this migraine is different or worse than your usual migraine
You have difficulty moving one side of your body when you have a “migraine” headache
It has been at least 2 hours since you took your first dose of SUMAGRAN ACTIVE and your symptoms have not improved.

Taking other medicines

Tell your pharmacist or doctor if you are taking any other medicines, or have taken any other medicines in the past two weeks, including any that you buy without a prescription from your pharmacy, supermarket or health shop.

Some medicines may affect how well other medicines work. Your pharmacist or doctor has more information on medicines to be careful with or avoid while taking SUMAGRAN ACTIVE.

How to take SUMAGRAN ACTIVE

Follow all directions given to you by your pharmacist or doctor carefully and read the instructions on the carton.

How much to take

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

If after taking the first SUMAGRAN ACTIVE tablet, your symptoms improve but return later, you may take a second SUMAGRAN ACTIVE tablet. Wait at least two hours after the first SUMAGRAN ACTIVE 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 SUMAGRAN ACTIVE tablet is not effective at relieving or helping your migraine symptoms, DO NOT take another tablet for the same attack. The second SUMAGRAN ACTIVE can be used at a later date to treat another migraine attack.

How to take it

SUMAGRAN ACTIVE 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 ACTIVE before or after food.

When to take it

It is best to take your SUMAGRAN ACTIVE 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 ACTIVE 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.

While you are taking SUMAGRAN ACTIVE

Things you must do

Tell all doctors, dentists and pharmacists who treat you that you are currently, or have recently taken SUMAGRAN ACTIVE.

If you are about to be started on any new medicine, remind your pharmacist or doctor that you are currently, or have recently taken SUMAGRAN ACTIVE.

If you are pregnant, plan to become pregnant or are breastfeeding, tell your doctor or pharmacist.

Things you must not do

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

Do not use SUMAGRAN ACTIVE to treat any other medical complaints.

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

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

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.

Side effects

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

Like all medicines, SUMAGRAN ACTIVE can have some unwanted 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.

Tell your pharmacist or doctor 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
- decreased feeling or sensitivity, especially in the skin.

These are generally mild adverse effects and may occur in a small number of people.

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 heart beat
shortness of breath or difficulty breathing

These may be serious side effects. You may require urgent medical attention. These side effects are rare.

Tell your doctor immediately or go to Accident and Emergency at your nearest hospital if you notice any of the following:

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

If you experience any of these side effects, you may have had a serious allergic reaction to SUMAGRAN ACTIVE. You may need urgent medical attention or hospitalisation. These side effects are very rare.

The list of side effects mentioned above is not complete. If you should suffer from any of these side effects or any other undesired effect please tell your pharmacist or doctor.

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

In case of overdose

Immediately contact your doctor or the National Poisons Information Centre (0800 POISON or 0800 764 766) or go to the Emergency department at your nearest hospital, if you think that you may have taken too much, or if anyone else has taken SUMAGRAN ACTIVE by mistake. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention. Take the pack of SUMAGRAN ACTIVE with you if you can.

Keep telephone numbers for these places handy.

Storage conditions

Storage

Keep SUMAGRAN ACTIVE 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 your SUMAGRAN ACTIVE 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 SUMAGRAN ACTIVE in the car or on window sills. Heat and dampness can destroy some medicines.

Disposal

If you do not take your SUMAGRAN ACTIVE tablet(s) or it has passed the expiry date, ask your pharmacist what to do with the remaining medicine.

List of ingredients

SUMAGRAN ACTIVE comes in a pack containing two tablets.

Each tablet contains 50mg of the active ingredient, sumatriptan.

Each tablet also contains lactose, microcrystalline cellulose, croscarmellose sodium, magnesium stearate, titanium dioxide, polydextrose, hypromellose, glycerol triacetate, polyethylene glycol, iron oxide red and iron oxide yellow.

If you want to know more

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

Who supplies this medicine

Distributed in New Zealand by:

Mylan New Zealand Ltd,
PO Box 11-183,
Ellerslie,
Auckland.
Free phone: 0800 168 169

Date of Information

2 February 2009
(Based on datasheet 2 February 2009)