

APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

S4

AURO-SUMATRIPTAN TABLETS 50 mg (tablet)

AURO-SUMATRIPTAN TABLETS 100 mg (tablet)

Sumatriptan succinate

1. WHAT AURO-SUMATRIPTAN TABLETS CONTAINS

The active substance is Sumatriptan.

AURO-SUMATRIPTAN TABLETS 50 mg: Each uncoated tablet contains sumatriptan succinate equivalent to sumatriptan anhydrous 50 mg.

AURO-SUMATRIPTAN TABLETS 100 mg: Each uncoated tablet contains sumatriptan succinate equivalent to sumatriptan anhydrous 100 mg.

The other ingredients contained in AURO-SUMATRIPTAN TABLETS 50 mg and AURO-SUMATRIPTAN TABLETS 100 mg are croscarmellose sodium, polysorbate 80, calcium hydrogen phosphate anhydrous, cellulose microcrystalline, sodium hydrogen carbonate and magnesium stearate.

2. WHAT AURO-SUMATRIPTAN TABLETS ARE USED FOR

AURO-SUMATRIPTAN TABLETS belongs to a group of medications called serotonin agonists. It is thought that migraine is due to widening of certain blood vessels in the head. AURO-SUMATRIPTAN TABLETS work by narrowing blood vessels in the head. AURO-SUMATRIPTAN TABLETS are used to relieve the symptoms of a migraine attack. AURO-SUMATRIPTAN

TABLETS may be used for migraine attacks with or without what is known as “aura”.

3. BEFORE YOU TAKE AURO-SUMATRIPTAN TABLETS

Do not take AURO-SUMATRIPTAN TABLETS:

- If you have ever had an allergic reaction to sumatriptan succinate or any ingredient of the product.
- If you are allergic to any medicine that contains sulphur (e.g. sulphonamide antibiotics).
- If you have or have ever had a heart attack; heart disease; angina, or severe chest pain or tightness; or brain blood vessel disease.
- If you have uncontrolled high blood pressure.
- Together with ergotamine containing preparations.
- If you have taken a monoamine oxidase inhibitor (MAOI), a type of medicine used for depression in the last two weeks.
- If you have severe liver disease.
- If you have certain types of migraines (e.g. Hemiplegic, basilar or ophthalmoplegic).

Take special care with AURO-SUMATRIPTAN TABLETS:

- Do not take more of this medicine or take it more often than prescribed by your doctor.
- AURO-SUMATRIPTAN TABLETS should only be used in patients who have been given a diagnosis of migraine by their doctors.
- Your doctor may decide to check if your heart is healthy before prescribing AURO-SUMATRIPTAN TABLETS.
- Caution is recommended in women after menopause, men over 40 years old and patients with risk factors for heart disease (such as diabetes, smoking, being overweight, family history of heart disease, high blood pressure and high cholesterol).

Tell your doctor:

- If you have high blood pressure, even if it is controlled.
- If you are taking a selective serotonin reuptake inhibitor (SSRI), a type of medicine used to treat depression. Some patients may have a reaction called serotonin syndrome when they use SSRIs, while taking AURO-SUMATRIPTAN TABLETS.
- If you have or have had epilepsy or fits.

- If you have liver disease.
- If you are over 65 years of age or under 18 years of age. Safety and effectiveness of AURO-SUMATRIPTAN TABLETS in these age groups have not been confirmed.

Pregnancy and Breast-feeding:

Do not use this medication without telling your doctor if you are pregnant, think you may be pregnant, are planning a pregnancy or are breast-feeding. The safety of this medication in pregnant women and during breast-feeding has not been confirmed.

If you are pregnant or breast-feeding your baby while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

Driving and using machinery:

AURO-SUMATRIPTAN TABLETS may cause drowsiness. Be careful driving or operating machinery until you know how AURO-SUMATRIPTAN TABLETS affect you.

Taking other medicines with AURO-SUMATRIPTAN TABLETS:

- Do not take AURO-SUMATRIPTAN TABLETS if you have taken ergotamine containing preparations in the last 24 hours.

Ergotamine containing preparations should not be taken until 6 hours have passed after taking

AURO-SUMATRIPTAN TABLETS.
- Do not take AURO-SUMATRIPTAN TABLETS if you have taken a monoamine oxidase inhibitor

(MAOI), a type of medicine used for depression in the last two weeks.
- Tell your doctor if you are taking a selective serotonin reuptake inhibitor (SSRI), a type of medicine used to treat depression. Your doctor may need to change the doses of your medications, or monitor you more carefully for side-effects.

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **AURO-SUMATRIPTAN TABLETS** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional, for advice.

4. HOW TO TAKE AURO-SUMATRIPTAN TABLETS:

- This medication is used to treat migraine attacks once they occur.

AURO-SUMATRIPTAN TABLETS SHOULD NOT BE USED TO PREVENT MIGRAINE ATTACKS FROM OCCURRING.

- Take this medicine only as directed by your doctor.
- The recommended starting dose is 50 mg. However, you may need to have your dose of AURO-SUMATRIPTAN TABLETS increased to 100 mg. Your doctor will tell you which dose is right for you.
- If the first AURO-SUMATRIPTAN TABLET helps your migraine, but the symptoms of a migraine comes back later, you may take another AURO-SUMATRIPTAN TABLET at any time in the next 24 hours. However, do not take more than 300 mg of AURO-SUMATRIPTAN TABLETS (ie. 3 x 100 mg strength tablets or 6 x 50 mg strength tablets) in any 24 hours and you must wait at least two hours between taking each dose.
- If the first AURO-SUMATRIPTAN TABLET does not relieve or help your migraine, do not take another AURO-SUMATRIPTAN TABLET for this same attack.
- Your AURO-SUMATRIPTAN TABLET should be swallowed whole with a drink of water.
- Tell your doctor if you have liver disease, since your dose should be reduced.
- It is best to take your AURO-SUMATRIPTAN TABLET at the first sign of a migraine.

Always take **AURO-SUMATRIPTAN TABLETS** exactly as your doctor has instructed you. You should check with your doctor or pharmacist if you are unsure. If you have the impression that the effect of **AURO-SUMATRIPTAN TABLETS** is too strong or too weak, talk to your doctor or pharmacist.

If you take more AURO-SUMATRIPTAN TABLETS than you should:

You may need urgent medical attention, and your doctor will need to monitor you for at least ten hours.

In the event of overdose, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

5. POSSIBLE SIDE EFFECTS:

AURO-SUMATRIPTAN TABLETS can have side-effects.

Get emergency medical help immediately if you have any of these symptoms of an allergic reaction:

- Wheezing
- Difficulty in breathing
- Swelling of your face, lips, tongue, or throat
- Hives

Tell your doctor immediately if you:

- have chest pain or feel heaviness, pressure or tightness in any part of the body, including the chest or throat.
- feel abnormal heart beats – too fast, too slow, or irregular heart beats, palpitations.
- have a fit or convulsion.

Inform your doctor of other side-effects which may include:

- tingling, heat or flushing in any part of the body.
- a change in blood pressure
- nausea (feeling sick) or vomiting
- dizziness
- feelings of weakness, tiredness and drowsiness

Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other health care professional for advice.

6. STORING AND DISPOSING OF AURO-SUMATRIPTAN TABLETS:

Store at or below 30 °C (room temperature).

KEEP OUT OF REACH OF CHILDREN.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

7. PRESENTATION OF AURO-SUMATRIPTAN TABLETS:

AURO-SUMATRIPTAN TABLETS 50 mg:

1. Cold form Alu - Alu Blister Pack:

Tablets are packed in 25 micron Polyamide/45 micron Aluminium foil / 60 micron PVC and 25 microns Printed Aluminium foil with 6-8 gsm Heat seal Lacquer. Each blister contains 2 tablets.

Pack size: 2's - Each carton contains 1 blister of 2 tablets.

2. Cold form Alu - Alu Blister Pack:

Tablets are packed in 25 micron OPA/45 micron Aluminium foil / 60 micron PVC and 25 microns Printed Aluminium foil with 6-8 gsm Heat seal Lacquer. Each blister contains 6 tablets.

Pack size: 6's - Each carton contains 1 blister of 6 tablets.

AURO-SUMATRIPTAN TABLETS 100 mg:

Cold form Alu - Alu Blister Pack:

Tablets are packed in 25 micron Polyamide/45 micron Aluminium foil / 60 micron PVC and 25 microns Printed Aluminium foil with 6-8 gsm Heat seal Lacquer. Each blister contains 4 tablets.

Pack size: 4's – Each carton contains 1 blister of 4 tablets.

8. IDENTIFICATION OF AURO-SUMATRIPTAN TABLETS:

AURO-SUMATRIPTAN TABLETS 50 mg:

White to off white, capsule shaped, biconvex uncoated tablets, debossed with 'C' on one side and '33' on other side.

AURO-SUMATRIPTAN TABLETS 100 mg:

White to off white, capsule shaped, biconvex uncoated tablets, debossed with 'C' on one side and '34' on other side.

9. REGISTRATION NUMBER/REFERENCE NUMBERS

AURO-SUMATRIPTAN TABLETS 50 mg: 42/7.3/0269

AURO- SUMATRIPTAN TABLETS 100 mg: 42/7.3/0276

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

Woodhill Office Park, Building 1, 53 Phillip Engelbrecht Avenue

Meyersdal, Ext. 12, 1448

Johannesburg

South Africa

11. DATE OF PUBLICATION

Date of registration:

09 December 2008

Date of revision:

17 January 2022