

APPROVED PATIENT INFORMATION LEAFLET

Read all of this leaflet carefully before you start taking AURO-GABAPENTIN.

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- **AURO-GABAPENTIN** 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.

S3

AURO-GABAPENTIN CAPSULES 100 mg (Capsule)

AURO-GABAPENTIN CAPSULES 300 mg (Capsule)

AURO-GABAPENTIN CAPSULES 400 mg (Capsule)

Gabapentin

1. WHAT AURO-GABAPENTIN CONTAINS

The active substance is gabapentin.

AURO-GABAPENTIN CAPSULES 100 mg: Each capsule contains 100 mg gabapentin.

AURO-GABAPENTIN CAPSULES 300 mg: Each capsule contains 300 mg gabapentin.

AURO-GABAPENTIN CAPSULES 400 mg: Each capsule contains 400 mg gabapentin.

The other ingredients are maize starch and talc. The empty hard gelatin capsule shells contains gelatin, sodium lauryl sulphate and titanium dioxide (C.I. No.: 77891), yellow iron oxide (C.I. No.: 77492) in **AURO-GABAPENTIN CAPSULES 300 mg** and **AURO-GABAPENTIN CAPSULES 400 mg**, and red iron oxide (C.I. No.: 77491) in **AURO-GABAPENTIN CAPSULES 400 mg**. The printing ink contains black iron oxide (C.I. No.: 77499), butyl alcohol, dehydrated alcohol, isopropyl alcohol, potassium hydroxide, propylene glycol, shellac and strong ammonia solution.

2. WHAT AURO-GABAPENTIN IS USED FOR

- **AURO-GABAPENTIN** is used to treat seizures (fits).

3. BEFORE YOU TAKE AURO-GABAPENTIN

Do not take **AURO-GABAPENTIN**:

- If you are hypersensitive (allergic) to gabapentin or any of the other ingredients of **AURO-GABAPENTIN**.
- If you are pregnant or breast-feeding your infant.
- If you are under the age of 12 years.

Take special care with **AURO-GABAPENTIN**:

- If you have a history of mental illness, **AURO-GABAPENTIN** should be used with caution
- If you have a history of kidney problems, **AURO-GABAPENTIN** should be used with caution.
- If you have to reduce your dose of **AURO-GABAPENTIN**, or completely stop it or if you are changing your treatment to another anti-seizure medication, you should do so exactly as your doctor has instructed you. If you abruptly stop taking **AURO-GABAPENTIN** you may suffer from a very severe, long-lasting, life-threatening seizure.

Taking **AURO-GABAPENTIN** with food and drink:

AURO-GABAPENTIN may be taken with or without meals.

Pregnancy and Breast-feeding:

The safety of **AURO-GABAPENTIN** in pregnancy and breast-feeding has not been established.

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

Driving and using machinery:

AURO-GABAPENTIN may affect your alertness and you should be careful when driving a vehicle,

operating machinery or performing risky or dangerous tasks.

If you use alcohol while taking **AURO-GABAPENTIN** these effects will be increased.

Taking other medicines with AURO-GABAPENTIN:

- **AURO-GABAPENTIN** does not interact with phenobarbitone, phenytoin, valproic acid, carbamazepine or carbamazepine 10, 11-epoxide.
- If you are taking any antacid medications, you should inform your doctor as you will have to then take **AURO-GABAPENTIN** about 2 hours after taking the antacid medication.
- If you are taking **AURO-GABAPENTIN** with alcohol or with other anti-seizure medication, your alertness will be further impaired.

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

4. HOW TO TAKE AURO-GABAPENTIN

Always take **AURO-GABAPENTIN** 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-GABAPENTIN** is too strong or too weak, talk to your doctor or pharmacist.

Adults and children over 12 years: The usual dose is initially 300 mg three times a day. The doctor may increase your dose gradually based on your response to the medication.

Children under 12 years: The safety and efficacy in children under 12 years have not been established.

If you take more AURO-GABAPENTIN than you should:

- The symptoms of overdose that you may experience include dizziness, double vision, slurred speech, drowsiness, lethargy and mild diarrhoea.

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

If you forget to take AURO-GABAPENTIN:

Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with AURO-GABAPENTIN is stopped:

If your medicine is stopped by your doctor or if you are required to take another medicine, it should be done gradually over at least one week. Your doctor will advise you on how to do this. Do not stop **AURO-GABAPENTIN** before talking to your doctor or pharmacist as it may cause a life-threatening persistent seizure if you are epileptic.

5. POSSIBLE SIDE EFFECTS

AURO-GABAPENTIN can have side effects.

If you experience any of the following side effects, you should report to your doctor or the nearest hospital IMMEDIATELY:

- Difficulty in breathing, with or without swelling of the face, lips, tongue and/or throat.
- Swelling of the face, lips, tongue and/or throat, which may cause difficulty in swallowing.
- Severe itching of the skin (with raised lumps).
- If you have experience any unusual aches or pains in your muscles which go on for longer than you might expect.

If you experience the following side effects, you should report to your doctor AS SOON AS POSSIBLE:

- Abnormal thinking and confusion
- Emotional instability and depression
- Drowsiness and dizziness
- Change in muscle coordination
- Involuntary, rapid, rhythmic, movement of eye ball
- Involuntary trembling
- Double vision
- Pain in the muscles
- Fatigue
- Swelling of legs and hands
- Fever
- Nervousness
- Back pain, headache and increase in weight

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

6. STORING AND DISPOSING OF AURO-GABAPENTIN

Keep all the medicines out of the reach and sight of children.

1) PVC / PVdC Blister:

Store at or below 25 °C. Keep blisters in the original carton until required for use.

2) HDPE Container:

Store at or below 25 °C. Keep the containers tightly closed.

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-GABAPENTIN

AURO-GABAPENTIN CAPSULES 100 mg:

1) Blister:

Capsules are packed in polyamide / aluminium foil / PVC film and printed aluminium foil with heat seal lacquer. Each blister contains 10 capsules.

Pack size: 100's – Each carton contains 10 blisters of 10 capsules.

2) HDPE Container:

Capsules are packed in a 100 ml white opaque HDPE container with a white opaque polypropylene child resistant closure with induction seal wad.

A desiccant (silica gel sachet) is included in the container. Each container contains 100 capsules.

Pack size: 100's – One white opaque HDPE container with 100 capsules.

AURO-GABAPENTIN CAPSULES 300 mg:

1) Blister:

Capsules are packed in polyamide / aluminium foil / PVC film and printed aluminium foil with heat seal lacquer. Each blister contains 10 capsules.

Pack size: 100's – Each carton contains 10 blisters of 10 capsules.

2) HDPE Container:

Capsules are packed in a 120 ml white opaque HDPE container with a white opaque polypropylene child resistant closure with induction seal wad.

A desiccant (silica gel sachet) is included in the container. Each container contains 100 capsules.

Pack size: 100's – One white opaque HDPE container with 100 capsules.

AURO-GABAPENTIN CAPSULES 400 mg:

1) Blister:

Capsules are packed in polyamide / aluminium foil / PVC film and printed aluminium foil with heat seal lacquer. Each blister contains 10 capsules.

Pack size: 100's – Each carton contains 10 blisters of 10 capsules.

2) HDPE Container:

Capsules are packed in a 200 ml white opaque HDPE container with a white opaque polypropylene child resistant closure with induction seal wad.

A desiccant (silica gel sachet) is included in the container. Each container contains 100 capsules.

Pack size: 100's – One white opaque HDPE container with 100 capsules.

8. IDENTIFICATION OF AURO-GABAPENTIN

AURO-GABAPENTIN CAPSULES 100 mg: White / White size '3' hard gelatin capsules imprinted with 'D' on white cap and '02' on white body with black edible ink filled with white to off-white crystalline powder.

AURO-GABAPENTIN CAPSULES 300 mg: Yellow / Yellow size '1' hard gelatin capsules imprinted with 'D' on yellow cap and '03' on yellow body with black edible ink filled with white to off-white crystalline powder.

AURO-GABAPENTIN CAPSULES 400 mg: Orange / Orange size '0' hard gelatin capsules imprinted with 'D' on orange cap and '04' on orange body with black edible ink filled with white to off-white crystalline powder.

9. REGISTRATION NUMBER

AURO-GABAPENTIN CAPSULES 100 mg (Capsule): 43/2.5/0284

AURO-GABAPENTIN CAPSULES 300 mg (Capsule): 43/2.5/0285

AURO-GABAPENTIN CAPSULES 400 mg (Capsule): 43/2.5/2086

Applicant/PHCR: AUROGEN SOUTH AFRICA (PTY) LTD
Product proprietary name: AURO-GABAPENTIN CAPSULES 100 mg/ 300 mg/ 400 mg
Dosage form and strength: CAPSULE 100 mg/ 300 mg/ 400 mg **Amended: 29/01/2021**



Aurogen South Africa (Pty) Ltd
Woodhill Office Park, Building 1
53 Phillip Engelbrecht Avenue
Meyersdal, Ext. 12
1448, Johannesburg
South Africa

10. DATE OF PUBLICATION

Date of registration:

6 March 2014

Date of revision:

09 February 2022