

APPROVED PATIENT INFORMATION LEAFLET

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

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

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AURO-CITALOPRAM 10 mg (Tablet)

AURO-CITALOPRAM 40 mg (Tablet)

Citalopram hydrobromide

1. WHAT AURO-CITALOPRAM CONTAINS

The active substance is citalopram.

AURO-CITALOPRAM 10 mg:

Each film-coated tablet contains citalopram hydrobromide corresponding to 10 mg of citalopram.

AURO-CITALOPRAM 40 mg:

Each film-coated tablet contains citalopram hydrobromide corresponding to 40 mg of citalopram.

The other ingredients are cellulose microcrystalline, copovidone, croscarmellose sodium, lactose monohydrate, magnesium stearate and maize starch. The coating material contains hypromellose, macrogol 400 and titanium dioxide (C.I number: 77891).

2. WHAT AURO-CITALOPRAM IS USED FOR

AURO-CITALOPRAM belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). **AURO-CITALOPRAM** is used for the treatment of depression and when you feel better, to help prevent these symptoms recurring. **AURO-CITALOPRAM** is also used to treat other mental conditions such as obsessive-compulsive disorder (an anxiety disorder where a

person has recurrent and unwanted thoughts called obsessions and/or repetitive behaviour called compulsions), and panic attacks.

3. BEFORE YOU TAKE AURO-CITALOPRAM

Do not take AURO-CITALOPRAM:

- If you are hypersensitive (allergic) to citalopram, or any of the other ingredients of **AURO-CITALOPRAM**.
- At the same time as taking a medicine known as a monoamine oxidase inhibitor (MAOI). You must wait at least 14 days after stopping a MAOI before you can take **AURO-CITALOPRAM**. After you stop taking **AURO-CITALOPRAM**, you must wait at least 7 days before taking a MAOI.
- If you have severe kidney disease.
- If you are pregnant or breast-feeding.
- In children under 18 years of age – Because the safety and effectiveness of **AURO-CITALOPRAM** has not been determined in children.

Take special care with AURO-CITALOPRAM:

- Before taking **AURO-CITALOPRAM**, tell your doctor:

- If you have or have had mania. Contact your doctor if you enter into a manic phase while taking **AURO-CITALOPRAM**, since **AURO-CITALOPRAM** should be discontinued.
- If you have epilepsy or a history of seizures or fits. If you experience seizures (convulsions or fits) while taking **AURO-CITALOPRAM**, consult your doctor immediately.
- If you have diabetes.
- If you are receiving electroconvulsive treatment (ECT).
- If you have liver disease. Your doctor may need to lower your dosage.
- If you have kidney disease.
- If you suffer from heart problems or an abnormal heart rate.

- If you have thoughts of harming or killing yourself at any time or worsening of depression, contact your doctor or go to a hospital straight away. If you are depressed you can sometimes have thoughts of harming or killing yourself. Since **AURO-CITALOPRAM** may take time to work, an improvement may not occur during the first few weeks or more of treatment.

- Tell your doctor immediately if you notice any of the following symptoms, especially if they are severe, abrupt in onset, or are not usually part of your depressive symptoms:

- anxiety
- akathisia (restlessness or difficulty in sitting or standing still)
- agitation, irritability, hostility (aggressiveness), impulsivity
- panic attacks
- insomnia (difficulty sleeping)
- hypomania, mania (mood of excitement, over-activity and uninhibited behaviour)

- Caution is advised when using **AURO-CITALOPRAM** in the elderly, because they may require a lower dose.

- A serious condition called serotonin syndrome, is more likely to occur after an increase in dose.

Taking AURO-CITALOPRAM with food and drink:

- **AURO-CITALOPRAM** may be taken with or without food.
- Avoid drinking alcohol while taking **AURO-CITALOPRAM**.

Pregnancy and Breast-feeding:

- The safe use of **AURO-CITALOPRAM** during pregnancy and breast-feeding has not been determined.
- **AURO-CITALOPRAM** passes into breast milk.

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

Driving and using machinery:

- **AURO-CITALOPRAM** can cause side-effects that may impair your thinking or reactions.

If you are affected in any way, you should not drive or operate machinery.

Taking other medicines with AURO-CITALOPRAM:

Before taking **AURO-CITALOPRAM**, tell your doctor if you are using any of the following medicines:

- Monoamine oxidase inhibitors (MAOI's) e.g. moclobemide, tranylcypromine, phenelzine.

AURO-CITALOPRAM should not be used together with a monoamine oxidase inhibitor (MAOI).

Taking monoamine oxidase inhibitors (MAOI's) with **AURO-CITALOPRAM** could result in serious, even fatal (causing death) reactions.

- Imipramine (used to treat depression).
- Other medicines that increase serotonin e.g. lithium, sibutramine, tramadol. Taking medicines that increase serotonin together with **AURO-CITALOPRAM** could result in a serious, sometimes fatal (causing death) condition called the serotonin syndrome.
- Moclobemide (used to treat depression). A serious condition called the serotonin syndrome has occurred in patients taking too much moclobemide and **AURO-CITALOPRAM**.
- Warfarin (used to thin the blood). Taking warfarin with **AURO-CITALOPRAM** may cause you to bruise or bleed easily.
- Cimetidine (used to treat stomach ulcers).

AURO-CITALOPRAM should not be used with any of the above medicines.

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

4. HOW TO TAKE AURO-CITALOPRAM

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

- **AURO-CITALOPRAM** may be taken in the morning or evening.

- It may take 2 to 4 weeks before you start to feel better. **AURO-CITALOPRAM** should be taken for as long as your doctor tells you to. Do not stop taking **AURO-CITALOPRAM** even if you begin to feel better, unless you are told to do so by your doctor. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return. Your doctor should continue to treat you with **AURO-CITALOPRAM** until you have been free of symptoms for at least 6 months.

Depression:

- The usual starting dose of **AURO-CITALOPRAM** is 20 mg taken as one daily dose. This may be increased by your doctor by 20 mg a day at intervals of at least one week to a maximum of 60 mg a day, depending on how you respond to **AURO-CITALOPRAM**.

Panic Disorder:

- The usual starting dose of **AURO-CITALOPRAM** is 10 mg as one daily dose for the first week before increasing the dose to 20 mg a day. Thereafter, the dose may be further increased by your doctor to a maximum of 60 mg a day, depending on how you respond to **AURO-CITALOPRAM**.

Obsessive-Compulsive Disorder:

- The usual starting dose of **AURO-CITALOPRAM** is 20 mg as one daily dose. Thereafter, the dose may be increased by your doctor to a maximum of 60 mg a day, depending on how you respond to **AURO-CITALOPRAM**.

Elderly patients:

- The usual dose of **AURO-CITALOPRAM** is 20 mg taken as one daily dose. This may be increased by your doctor to a maximum of 30 mg a day, depending on how you respond to **AURO-CITALOPRAM**.

Patients with liver disease:

- The dose of **AURO-CITALOPRAM** in patients with liver disease should be halved.

Patients with kidney disease:

- It is not necessary to adjust the dosage in mild or moderate kidney disease.

If you take more AURO-CITALOPRAM than you should:

- Symptoms of overdose may include tiredness, weakness, sedation (having a soothing, calming or tranquilizing effect), dizziness, tremor (shaking), nausea (feeling sick), sleepiness and rapid heartbeat.

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

If you forget to take AURO-CITALOPRAM:

- Take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take the medicine at your next regularly scheduled time. Do not take a double dose to make up for forgotten individual doses.

Effects when treatment with AURO-CITALOPRAM is stopped:

- Do not suddenly stop taking **AURO-CITALOPRAM**, as this can cause unpleasant symptoms. Your doctor will decrease your dose gradually.

5. POSSIBLE SIDE-EFFECTS

AURO-CITALOPRAM can have side-effects.

Get emergency medical help if you have any of these **signs of an allergic reaction**:

- hives; difficulty breathing; swelling of your face, lips, tongue, or throat.

Call your doctor at once if you have any of these serious side-effects:

- **AURO-CITALOPRAM** may cause a very serious condition called serotonin syndrome. Symptoms of serotonin syndrome include: Fever, confusion, abnormal movements, shivering, muscle spasms, agitation and progress to coma or loss of consciousness, restlessness, sweating, hallucinations, exaggeration of reflexes, muscle cramps, rapid heart rate.
- **AURO-CITALOPRAM** may cause a very serious condition called neuroleptic malignant syndrome. Symptoms of neuroleptic malignant syndrome include: Rigid, stiff muscles; muscle cramps; agitation; confusion; tremor (shakes); heavy sweating; high body temperature; fast heart rate; rapid breathing.
- Thoughts of harming or killing yourself at any time.
- Hallucinations (seeing things or hearing voices that do not exist) or mania (unusual excitement).

- Seizures (fits) or convulsions.

Other side-effects include: palpitations (rapid irregular action of heart); tremor (shake); slow heart rate; disturbed sleep; numbness, tingling, pins and needles; restlessness; sleepiness; headache; dizziness;

excessive tiredness; agitation; confusion; difficulty concentrating; generally feeling unwell; loss of or increase in weight; nausea (queasiness; feeling that one is about to vomit); constipation; diarrhoea (frequent or loose watery stools); indigestion; dry mouth; too much saliva in the mouth; difficulties urinating; sexual disturbances (ejaculation problems, decreased sexual drive, problems in reaching orgasm); inflammation of the liver; lack of energy; abnormal vision; large pupils (the dark centre of the eye); stuffy nose; sweating; rash; yawning.

Tell your doctor if any of the above side-effects are severe, bothersome, do not go away or about any concerns you have while taking **AURO-CITALOPRAM**.

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

6. STORING AND DISPOSING OF AURO-CITALOPRAM

Store in a cool, dry place, at or below 25 °C (room temperature). Keep the container well closed. Do not remove the blister strip from the carton until required for use.

Keep all medicines out of the reach and sight 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-CITALOPRAM

AURO-CITALOPRAM 10 mg:

Tablets are packed in clear 250 micron PVC film coated with 60 gsm PVdC and printed aluminium foil with 7 gsm heat seal lacquer. Each blister contains 10 and 14 tablets.

Pack size: 30's & 28's – Each carton contains 3 blisters of 10 tablets and 2 blisters of 14 tablets each.

Tablets are packed in 40 ml white opaque HDPE container of 38 mm neck finish (OFC 51 ml) with 38 mm - 400 RS white opaque closure with induction seal wad. The void space of the container is filled with rayon coil. Each container contains 30 tablets.

Pack size: 30's - One HDPE container of 30 tablets.

AURO-CITALOPRAM 40 mg:

Tablets are packed in clear 250 micron PVC film coated with 60 gsm PVdC (width 188 mm) and printed aluminium foil with 7 gsm heat seal lacquer coating. Each blister contains 10 and 14 tablets.

Pack size: 30's & 28's – Each carton contains 3 blisters of 10 tablets and 2 blisters of 14 tablets each.

Tablets are packed in 40 ml white opaque HDPE container of 33 mm neck finish (OFC 51 ml) with 33 mm-400 RS white opaque closure with induction seal wad. The void space of the container is filled with rayon coil. Each container contains 30 tablets.

Pack size: 30's: One HDPE container of 30 tablets.

8. IDENTIFICATION OF AURO-CITALOPRAM

AURO-CITALOPRAM 10 mg: White coloured, biconvex, round shaped, film coated tablets debossed with 'A' on one side and '05' on the other side.

AURO-CITALOPRAM 40 mg: White coloured, biconvex, capsule shaped, film coated tablets debossed with 'A' on one side and with a score line in between '0' and '7' on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

AURO-CITALOPRAM 10 mg: 42/1.2/0850

AURO-CITALOPRAM 40 mg: 42/1.2/0850

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

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11. DATE OF PUBLICATION

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