APPROVED PROFESSIONAL INFORMATION

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.

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AUROLIFT 50 mg (Tablet)

AUROLIFT 100 mg (Tablet)

Sertraline Hydrochloride

1. WHAT AUROLIFT CONTAINS

The active substance is Sertraline Hydrochloride.

AUROLIFT 50 mg:

Each film-coated tablet contains Sertraline Hydrochloride equivalent to Sertraline 50 mg.

AUROLIFT 100 mg:

Each film-coated tablet contains Sertraline Hydrochloride equivalent to Sertraline 100 mg.

The other ingredients are Calcium hydrogen phosphate dihydrate, Hydroxypropylcellulose, Magnesium stearate, Microcrystalline cellulose, Opadry White OY-S-7355 and Sodium starch glycolate.

2. WHAT AUROLIFT IS USED FOR

AUROLIFT is a psychoanaleptic (antidepressant) medicine used for the treatment of major depressive disorders such as single episodes and recurrent depression, obsessive compulsive disorder and panic disorder.

Panic disorder:

Panic disorder is characterised by the occurrence of unexpected panic attacks and associated concern about having additional attacks, worry about the implications or consequences of the attacks, and /or a significant change in behaviour related to the attacks.

Panic disorder is characterised by recurrent unexpected panic attacks, i.e., a discrete period of intense fear or discomfort in which four (or more) of the following symptoms develop abruptly and reach a peak within 10 minutes: (1) palpitations, pounding heart, or accelerated heart rate; (2) sweating; (3) trembling or shaking; (4) sensations of shortness of breath or smothering; (5) feeling of choking; (6) chest pain or discomfort; (7) nausea or abdominal distress; (8) feeling dizzy, unsteady, light-headed, or faint; (9) derealisation (feelings of unreality) or depersonalization (being detached from oneself); (10) fear of loosing control; (11) fear of dying; (12) paresthesias (numbness or tingling sensations); (13) chills or hot flushes.

3. BEFORE YOU TAKE AUROLIFT

Do not take AUROLIFT:

- if you are hypersensitive (allergic) to Sertraline Hydrochloride or any of the other ingredients of AUROLIFT.
- if you are using a monoamine oxidase inhibitor (MAOI).

Take special care with AUROLIFT:

- if activation of mania/hypomania occurs when treated with other antidepressants and antiobsessional agents.
- If significant weight loss is undesirable.
- AUROLIFT should be avoided in patients with unstable epilepsy and patients with controlled epilepsy should be carefully monitored. AUROLIFT should be discontinued if you develop seizures.
- If there is a possibility of a suicide attempt.
- If you have liver disease, a lower or less frequent dose should be considered.
- If you have kidney disease, the dose of AUROLIFT may have to be reduced.

- Abrupt discontinuation of AUROLIFT may lead to withdrawal symptoms which include dizziness, sweating, nausea, insomnia, tremor, confusion, sensory disturbances, agitation and anxiety.

Taking AUROLIFT with food and drink:

Take AUROLIFT tablets as a single daily dose with or without food.

Pregnancy and Breast-feeding:

Safety in pregnancy and lactation has not been established.

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:

Exercise caution when driving a car or operating machinery.

Taking other medicines with AUROLIFT:

AUROLIFT interacts with MAOI's (including selegiline and moclobemide), tryptophan, fenfluramine, CNS depressants and alcohol, diazepam, tolbutamide and warfarin.

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

4. HOW TO TAKE AUROLIFT

Always take AUROLIFT 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 AUROLIFT is too strong or too weak, talk to your doctor or pharmacist.

AUROLIFT tablets should be given as a single daily dose with or without food.

Depression

The starting dose is 50 mg daily and the usual therapeutic dose in depression is 50 mg daily. In difficult to treat patients, the dose may be titrated up in 50 mg increments at 2 weekly intervals, to 150 mg-200 mg.

Obsessive-Compulsive Disorder (OCD)

The minimum effective dose in OCD is also 50 mg daily and increases above 100 mg daily does not have any additional benefit. Full activity is usually seen after 2-4 weeks and even longer in OCD. Effect may however be seen within 7 days.

Panic Disorder

For panic disorder, the minimum recommended effective dose of sertraline is 50 mg/day. However, therapy for panic disorder should commence at 25 mg/day, increasing to 50 mg/day after one week. This dosage regimen has been demonstrated to reduce the frequency of early treatment emergent side effects characteristic of panic disorder.

Use in the elderly - No special precautions are required. The usual adult dosage is recommended.

Use in children - The use of AUROLIFT in children is not recommended as safety and efficacy have not been established.

Use in hepatic and renal impairment - check with your doctor or pharmacist if you are unsure.

If you take more AUROLIFT than you should:

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 AUROLIFT:

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

5. POSSIBLE SIDE EFFECTS

AUROLIFT can have side effects.

Gastrointestinal disorders:

Common: Constipation, diarrhoea, nausea, vomiting, dyspepsia, flatulence, anorexia, abdominal pain, appetite increased, dry mouth, taste perversion.

Nervous system disorders:

Common: Headache, paresthesia, hypoesthesia, twitching, hypertonia, tremor; dizziness, insomnia, somnolence, convulsions.

Cardiac disorders: Palpitations

Skin and subcutaneous tissue disorders: Rash, erythema multiforme.

General disorders: Fatigue, increased sweating, hot flushes, fever, back pain.

Metabolism and nutrition disorders: Thirst.

Musculoskeletal, connective tissue and bone disorders: Myalgia arthralgia, movement disorders (such as gait abnormalities).

Psychiatric disorders: Agitation, nervousness, anxiety, yawning, impaired concentration, psychosis, depressive symptoms, hallucinations, aggressive reaction, agitation.

Renal and urinary disorders: Micturition frequency, micturition disorder, urinary retention.

Hepato-biliary disorders: Pancreatitis and serious liver events (including hepatitis, jaundice and liver failure).

Reproductive system and breast disorders: Menstrual Symptoms, female sexual dysfunction, sexual dysfunction (primarily ejaculatory delay in males).

Respiratory, thoracic and mediastinal disorders: Rhinitis, pharyngitis.

Eye disorders: Vision abnormal.

Ear and labyrinth disorders: Tinnitus.

Investigations:

Asymptomatic elevations of serum transaminases (SGOT and SGPT) have been reported infrequently (approximately 0,8%) in association with AUROLIFT therapy. There have been rare reports of altered platelet function and/or abnormal clinical laboratory results in patients taking AUROLIFT.
Hyponatraemia, possibly due to inappropriate antidiuretic hormone secretion, has been associated with the use of antidepressants, particularly in the elderly.

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 AUROLIFT

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

Store below 25 °C.

Return all unused medicine to your pharmacist.

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

7. PRESENTATION OF AUROLIFT

Two types of blister packaging material:

1. Tablets are packed in Clear PVC (250 microns) as the forming material and aluminium foil (25 microns) as the lidding material. Each blister contains 10 tablets.
2. Tablets are packed in Clear PVC (250 microns) coated with PVdC (60gsm) as the forming material and aluminium foil (25 microns) as the lidding material. Each blister contains 10 tablets.

AUROLIFT 50 mg: 30's (3 x 10's)

AUROLIFT 100 mg: 30's (3 x 10's)

8. IDENTIFICATION OF AUROLIFT

AUROLIFT 50 mg- White coloured, biconvex, capsule shaped film coated tablets debossed with 'A' on one side and with a score line in between '8' and '1' on the other side.

AUROLIFT 100 mg- White coloured, biconvex, capsule shaped film coated tablets debossed with 'A' on one side and '82' on the other side.

9. REGISTRATION NUMBER/REFERENCE NUMBER

AUROLIFT 50 mg: A40/1.2/0654

AUROLIFT 100 mg: A40/1.2/0655

10. NAME AND ADDRESS OF REGISTRATION HOLDER

Aurogen South Africa (Pty) Ltd

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11. DATE OF PUBLICATION

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