

SETROF TABLET

Sertraline (50mg)

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What Setrof Tablet is used for

Setrof Tablet is indicated for treatment of:

- symptoms of depression including depression accompanied by symptoms of anxiety
- obsessions (persistent ideas) and compulsions (repetitive behaviour) in patients with obsessive-compulsive disorder (OCD)
- panic disorder with or without agoraphobia (fear of open spaces)

How Setrof Tablet works

This medicine contains Sertraline as the active ingredient. Sertraline is one of a group of medicines called Selective Serotonin Re-uptake Inhibitors (SSRIs).

SSRIs block the reabsorption of the naturally occurring chemicals called serotonin in the brain. Changing the balance of serotonin helps control your mood.

Before you use Setrof Tablet

- When you must not use it

Do not take this medicine if:

- you are allergic to sertraline or any other ingredients of Setrof Tablet.
- you are taking or have taken medicine called monamine oxidase inhibitors (MAOIs) (such as Selegiline, Moclobemide) or MAOI like drugs such as Linezolid. After stopping treatment with MAOI, you must wait at least 2 weeks before you can start treatment with Setrof Tablet.

Do not take this medicine after the expiry date printed on the pack or if the packaging is damaged.

If you are not sure whether you should start taking this medicine, talk to your pharmacist or doctor.

- Before you start to use it

Tell your doctor/pharmacist if you suffer from or have suffered in the past:

- Epilepsy or a history of seizures
- Liver disease
- Mania (feeling elated or over-excited, which causes unusual behaviour)
- Nervous system (neurological) impairment
- Kidney disease
- Sensitivity to Sertraline
- Weight loss

Safety of Setrof Tablet in pregnancy and breastfeeding has not been established. If you are pregnant or breastfeeding, or planning to get pregnant, ask your doctor or pharmacist for advice before you take Setrof Tablet.

- Taking other medicines

Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtain without a prescription.

Taking Setrof Tablet with the following medicine may cause serious side effects:

- i. Concurrent use of MAOIs with sertraline may result in hyperpyretic episodes (extremely high fever), severe convulsions (fits), hypertensive crises (sudden, severe increase in blood pressure), or the serotonin syndrome (a potentially life-threatening set of symptoms including confusion, restless, shivering, fast heartbeat, etc.); fatalities have occurred.
- ii. Sertraline may inhibit the metabolism of tricyclic depressants (TCAs).
- iii. Concurrent use of terfenadine (antihistamine for allergy relief) with sertraline may increase the risk of cardiac arrhythmias (irregular heartbeat).
- iv. Concurrent use of a highly protein-bound drug (e.g. digitoxin [for heart problem] and warfarin [for blood thinning]) with sertraline may lead

to increased serotonin-associated side effects.

- v. Concurrent use of lithium (for mental illness) with sertraline may lead to an increased incidence of serotonin-associated side effects.

Other interactions not stated may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use Setrof Tablet

- How much to use

Adults

Depression - Starting dose is 50mg daily. In some patients, doses higher than 50mg may be required.

OCD - Starting dose is 50mg daily. Therapeutic dose range is 50 to 200mg daily.

Post-Traumatic Stress Disorder (PTSD) (anxiety caused by a traumatic event) - Starting at 25mg/day for 1st week. After 1 week dose should be increased to 50mg once daily.

Children of age 6 – 17 years

Treatment should only be initiated by specialists.

- When to use it

To be taken orally once daily.

- How long to use it

Dosing should be reviewed periodically by your doctor to determine your response to therapy and treatment should be withdrawn if there is no clear evidence of efficacy.

- If you forget to use it

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

If you forget to take your dose, take it as soon as you remember. Skip the missed dose if it is almost time for your next dose.

Do not stop taking Setrof Tablet unless your doctor advise you to.

- If you use too much (overdose)

Contact your doctor immediately as soon as you realize you have taken too much.

Symptoms of overdose may include drowsiness, nausea and vomiting, rapid heart rate, shaking, agitation, dizziness and serotonin syndrome (symptoms see Taking other medicines).

While you are using Setrof Tablet

- Things you must do

- Always take Setrof Tablet exactly as your doctor has told you.
- Check with your doctor or pharmacist if you are not sure.

- Things you must not do

Do not:

- give your medicine to anyone else even if they have the same condition as you
- take your medicine to treat any other complaints unless you are told by your doctor or pharmacist
- take more or less than the recommended dose unless your pharmacist or doctor tells you to
- stop taking Setrof Tablet without consulting your doctor or pharmacist

- Things to be careful of

Setrof Tablet may influence your ability to drive or use machine. You should therefore not drive or operate machine, until you know how the medication affects your ability to perform these activities.

Avoiding alcohol while you are being treated with Setrof Tablet.

Side effects

Setrof Tablet can cause side effects, although not everyone gets them.

Tell your doctor immediately if you think you are experiencing any of the following possible unwanted side effects while taking the medicine.

Common side effects:

- Dizziness
- Anorexia (loss of appetite)
- Nausea
- Anxiety

- Agitation
- Tremor

Other unwanted side effects not listed may occur. Tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction monitoring by calling Tel: 03-78835550, or visiting the website portal.bpfk.gov.my (Consumers→Reporting)

Storage and Disposal of Setrof Tablet

- Storage

Keep out of reach of children.

Store below 30⁰C.

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product description

- What it looks like?

Oblong, white to off white film coated tablet, shallow convex with break bar on one-side and HD embossed on the other side.

- Ingredients

- Active ingredients

Each Setrof Tablet contains:
Sertraline Hydrochloride 56mg
equivalent to Sertraline 50mg

- Inactive ingredients

- Colloidal Silicon Dioxide
- Magnesium Stearate
- Sodium Starch Glycolate
- Dicalcium Phosphate Dihydrate
- Microcrystalline Cellulose
- Propylene Glycol
- Isopropyl Alcohol
- Talc
- Hydroxypropyl Methylcellulose
- Titanium Dioxide

-MAL Number (s):
MAL06121046AZ

Manufacturer

HOVID Bhd.
Lot 56442, 7 ½ Miles, Jalan Ipoh/
Chemor, 31200 Chemor, Malaysia.

Product Registration Holder

HOVID Bhd.
121, Jalan Tunku Abdul Rahman,
30010 Ipoh, Malaysia.

Date of revision

10/07/2015

Serial Number

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