

LUPILOPRAM TABLETS

Escitalopram oxalate (10mg and 20mg)

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1. What Lupilopram Tablets is used for

Lupilopram Tablets is used to treat depression (major depressive episodes) and anxiety disorders [such as panic disorder with or without agoraphobia (fear of leaving home, entering shops or fear of being at open and public places), social anxiety disorder (fear or avoidance of social situations) and obsessive-compulsive disorder (persistent, obsessive thoughts that make you carry out repetitive behaviour)].

2. How Lupilopram Tablets works

Lupilopram Tablets belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

3. Before you take Lupilopram Tablets

When you must not take it

Do not take:

- if you are allergic (hypersensitive) to escitalopram or any of the other ingredients of Lupilopram Tablets.
- If you take other medicines that belong to a group called

monoamine oxidase (MAO) inhibitors, including selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic). Taking Lupilopram with MAO inhibitors may cause serious and sometimes fatal reactions with features resembling serotonin syndrome such as high fever, agitation, confusion, trembling and abrupt contractions of muscles. If you feel like this, contact your doctor.

- If you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm (see section "Taking other medicines")

Before you start to take it

Before you start to take Lupilopram please inform your doctor:

- if you have epilepsy. Treatment with Lupilopram should be stopped if seizures (fits) occur for the first time, or if there is an increase in the seizure frequency (see also section **Side effects**).
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Lupilopram may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- if you have a decreased level of sodium in the blood.
- if you have a tendency to easily develop bleedings or bruises.
- if you are receiving electroconvulsive treatment (ECT) (usually used for severe depression).
- if you have coronary heart disease.

[see also subsection *Things to be*

careful of].

- if you have a history of mania (uncontrollable excitement that causes unusual behaviour) or hypomania (a condition similar to mania but less severe)
- if you have a history of suicide-related events
- if you are currently pregnant, breast-feeding, or trying to get pregnant.

Taking other medicines

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without prescription. Tell your doctor if you are taking any of the following medicines:

- "Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, or tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Lupilopram Tablets. After stopping Lupilopram Tablets you must allow 7 days before taking any of these medicines.
- "Reversible, selective MAO-A inhibitors", containing moclobemide (used to treat depression).
- "Irreversible MAO-B inhibitors", containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
- The antibiotic linezolid.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
- Clomipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (used against severe pain). These increase the risk of side effects.
- Cimetidine and omeprazole (used

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to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Lupilopram Tablets.

- St. John's Wort (hypericum perforatum) - a herbal remedy used for depression.
- Acetylsalicylic acid and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anti-coagulant). These may increase bleeding-tendency.
- Dipyridamole (medicines used to thin the blood, so called anti-coagulant). Your doctor will probably check the coagulation time of your blood when starting and discontinuing Lupilopram Tablets in order to verify that your dose of anti-coagulant is still adequate.
- Mefloquin (used to treat Malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat schizophrenia, psychosis) due to a possible risk of a lowered threshold for seizures, and antidepressants.
- Flecainide, propafenone, and metoprolol (used in cardio-vascular diseases) clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Lupilopram Tablets may need to be adjusted.

4. How to take Lupilopram Tablets

How much to take

Always take Lupilopram Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure

Adults

Depression

The normally recommended dose is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Panic disorder

The starting dose is 5 mg as one daily dose for the first week before increasing the dose to 10 mg per day. The dose may be further increased by your doctor to a maximum of 20 mg per day.

Social anxiety disorder

The normally recommended dose is 10 mg taken as one daily dose. Your doctor can either decrease your dose to 5 mg per day or increase the dose to a maximum of 20 mg per day, depending on how you respond to the medicine.

Obsessive-compulsive disorder

The normally recommended dose is 10 mg taken as one daily dose. The dose may be increased by your doctor to a maximum of 20 mg per day.

Elderly patients (above 65 years of age)

The normally recommended starting dose is 5 mg taken as one daily dose. The dose may be increased by your doctor to 10 mg per day.

Children and adolescents (below 18 years of age)

Lupilopram Tablets should not normally be given to children and adolescents. For further information please see section "Before you take Lupilopram Tablets".

You can take Lupilopram Tablets with or without food. Swallow the tablet with some water. Do not chew them, as the taste is bitter.

If necessary, you can divide the tablets by firstly placing the tablet on a flat surface with the score facing upwards. The tablets may then be broken by pressing down on each end

of the tablet, using both forefingers.

When to take it

Lupilopram Tablets is administered as a single daily dose and may be taken with or without food.

How long to take it

It may take a couple of weeks before you start to feel better. Continue to take Lupilopram Tablets even if it takes some time before you feel any improvement in your condition.

Do not change the dose of your medicine without talking to your doctor first.

Continue to take Lupilopram Tablets for as long as your doctor recommends. If you stop your treatment too soon, your symptoms may return. It is recommended that treatment should be continued for at least 6 months after you feel well again.

If you forget to take it

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

If you do forget to take a dose, and you remember before you go to bed, take it straight away. Carry on as usual the next day. If you only remember during the night, or the next day, leave out the missed dose and carry on as usual.

If you take too much (overdose)

If you take more than the prescribed dose of Lupilopram Tablets, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance. Take the Lupilopram Tablets box/container with you when you go to the doctor or hospital.

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5. While you are using Lupilopram Tablets

Things you must do

- Always take Lupilopram Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
- Tell doctors, dentists and pharmacists treating you that you are on Lupilopram.
- Tell doctor immediately if you become pregnant while taking Lupilopram.

Things you must not do

You are advised not to drive a car or operate machinery until you know how Lupilopram Tablets affect you.

Things to be careful of

Do not take Lupilopram if you are pregnant, trying to get pregnant or breastfeeding unless you have discussed with your doctor on the risks and benefits involved. If Lupilopram is used during pregnancy, it should never be stopped abruptly.

Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:

- if you have epilepsy. Treatment with Lupilopram Tablets should be stopped if seizures occur for the first time or if there is an increase in the seizure frequency (see also section "side effects").
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Lupilopram Tablets may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- if you have a decreased level of sodium in the blood.
- if you have a tendency to easily

develop bleedings or bruises.

- if you are receiving electroconvulsive treatment.
- if you have coronary heart disease.
- if you suffer or have suffered from heart problems or have recently had a heart attack
- if you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up, which may indicate abnormal functioning of the heart rate.

Please note

Some patients with manic-depressive illness may enter into a manic phase. This is characterized by unusual and rapidly changing ideas, inappropriate happiness and excessive physical activity. If you experience this, contact your doctor.

Symptoms such as restlessness or difficulty to sit or stand still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourselves. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- If you have previously had thoughts about killing or harming yourself.
- If you are a **young adult**.

Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**

You may find it helpful to tell a relative or close friend that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

Use in children and adolescents under 18 years of age

Lupilopram Tablets should not be used for children and adolescents under 18 years. Also, you should know that patients under 18 have an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (predominately aggression, oppositional behaviour and anger) when they take this class of medicines.

Effects on Ability to Drive or Operate Machine

Although escitalopram has not been shown to affect your ability to drive and operate machinery, you should speak to your doctor for advice on when you will be able to drive or operate machines.

6. Side Effects

Like all medicines, Lupilopram Tablets can cause side effects, although not everybody gets them. The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

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See your doctor if you get any of the following side effects during treatment:

Very common:

- Feeling sick (nausea)

Common:

- Blocked or runny nose (sinusitis)
- Decreased or increased appetite
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy,
- dizziness, yawning, tremors, prickling of the skin
- Diarrhoea, constipation, vomiting, dry mouth
- Increased sweating
- Pain in muscle and joints (arthralgia and myalgia)
- Sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm)
- Fatigue, fever
- Increased weight

In addition, a number of side effects are known to occur with drugs that work in a similar way to escitalopram (the active ingredient of Escitalopram tablets). These are:

- Motor restlessness (akathisia)
- Anorexia

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

You may report any side effects or adverse drug reactions directly to The National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my [(Consumers → Reporting → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI))]

7. Storage and Disposal of

Lupilopram Tablets

Keep out of the reach and sight of children.

Do not use Lupilopram Tablets after the expiry date, which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month.

Blister: Store below 30°C.

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.

8. Product Description

What it looks like

Lupilopram 10mg Tablets

White, oval shaped, biconvex, film-coated tablets, with scoreline on one side, debossed with 'B' on left side of scoreline and '3' on right side of scoreline and plain on the other side.

Lupilopram 20mg Tablets

White, oval shaped, biconvex, film-coated tablets, with scoreline on one side, debossed with 'B4' on side of scoreline and plain on the other side.

Ingredients

Active Ingredient: escitalopram

Inactive ingredient: Microcrystalline Cellulose, Silica Colloidal Anhydrous, Croscarmellose sodium, Magnesium Stearate, Talc, Purified Water.

Coating agent: Hypromellose, Titanium dioxide, Macrogol /PEG 400.

MAL No.

Lupilopram 10mg Tablets:

MAL17085009ACZ

Lupilopram 20mg Tablets:

MAL17085010ACZ

9. Manufacturer and Product

Registration Holder

Manufacturer

Jubilant Generics Ltd.,
Village Sikandarpur Bhainswal,
Roorkee- Dehradun Highway,
Bhagwanpur, Roorkee,
District Haridwar, Uttarakhand 247
661, India

Product Registration Holder

Generic Health Sdn. Bhd.
Upper Penthouse, Wisma RKT,
No. 2, Jalan Raja Abdullah,
Off Jalan Sultan Ismail,
50300 Kuala Lumpur.

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26/Mar/2019

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