

ESOPAM 10mg Tablet

Escitalopram oxalate eq. to Escitalopram (10 mg)

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What Esopam is used for

Esopam contains escitalopram and is used to treat:

- depression
- panic disorder with or without agoraphobia (e.g. fear of public or open spaces)
- social anxiety disorder/social phobia (fear or avoidance of social situations)
- generalized anxiety disorder (generally feeling very anxious or nervous, even when there is little or no reason to worry about them)
- obsessive-compulsive disorder (OCD) (persistent, obsessive thoughts that make you carry out repetitive behavior)

How Esopam works

Esopam contains the active substance Escitalopram. Esopam 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 disease.

Before you use Esopam

- When you must not use it

Do not take Esopam:

- If you are allergic to Escitalopram or any of the other ingredients of this medicine
- If you take other medicines which belong to a group called monoamine oxidase inhibitors (MAOIs)
- If you are born with or have had an episode of abnormal heart rhythm

- If you take medicines for heart rhythm problems or that may affect the heart's rhythm

Escitalopram should not be used in the treatment of pediatric population.

Pregnancy and breastfeeding

Do not take Esopam if you are pregnant or breastfeeding, unless you and your doctor have discussed the risks and benefits involved. Make sure your midwife and/or doctor know you are on Esopam. If used during pregnancy, Esopam should never be stopped abruptly.

If you take Esopam during the last 3 months, you should be aware that the following effects may be seen in your newborn baby: trouble with breathing, bluish skin, fits, body temperature changes, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, vivid reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness and sleeping difficulties. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Esopam may increase risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish. These symptoms usually begin during the first 24 hours after the baby is born.

If your newborn baby has any of these symptoms, please contact your midwife/doctor immediately.

It is expected that Esopam will be excreted into breast milk. Breastfeeding is not recommended during the treatment.

Please note that medicine like Esopam (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction. In some cases, these symptoms have continued after stopping treatment.

- Before you start to use it

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 Esopam should be stopped if seizures (fits) occur for the first time

or if there is an increase in the seizure frequency.

- If you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- If you have diabetes. Treatment with Esopam may alter glycemic control. Insulin and/or hypoglycemic 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 (usually used for severe depression).
- If you have coronary heart disease.
- If you suffer or have suffered from heart problems or have recently had a heart attack as a result of prolonged severe diarrhea 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.
- If you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

If you take Esopam near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor should be aware that you are taking Esopam so they can advise you.

- Taking other medicines

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including:

- Non-selective monoamine oxidase inhibitors (MAOIs), e.g. phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Esopam. After stopping Esopam, you must allow 7 days before taking any of these medicines.
- Reversible, selective MAO-A inhibitors, e.g. moclobemide (used to treat depression).
- Irreversible MAO-B inhibitors, e.g. selegiline (used to treat Parkinson's disease).
- Linezolid (antibiotics).

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- Lithium (used in the treatment of manic-depressive disorder) and tryptophan (an amino acid).
- Imipramine, desipramine (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, lansoprazole and omeprazole (used to treat stomach ulcers), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of Escitalopram.
- St. John's wort (*Hypericum perforatum* – a herbal remedy used for depression).
- Acetylsalicylic acid and non-steroidal anti-inflammatory drugs (NSAID), warfarin, dipyridamole, and phenprocoumon (used for pain relief or to thin the blood). These may increase bleeding-tendency.
- 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 mental disorders) and antidepressants due to a possible risk of a lowered threshold for seizures.
- Flecainide, propafenone, and metoprolol (used in cardiovascular diseases), clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (to treat people with schizophrenia). The dosage of Esopam may need to be adjusted.
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life-threatening heart rhythm disorder.

How to use Esopam

- How much to use

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

Safety of daily doses above 20 mg has not been demonstrated.

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

Major depressive episodes

Usual dosage is 10 mg once daily. Depending on individual patient response, the dose may be increased to a maximum of 20 mg daily.

Panic disorder with or without agoraphobia

An initial dose of 5 mg is recommended for the first week before increasing the dose to 10 mg daily. The dose may be further increased, up to a maximum of 20 mg daily, dependent on individual patient response.

Social anxiety disorder

The normally recommended dose is 10 mg once daily. Depending on individual patient response, the dose may be increased to a maximum of 20 mg daily. Treatment for 3 months is recommended to consolidate response. Long-term treatment of responders for 6 months has been shown to prevent relapse and can be considered on an individual basis; treatment benefits should be re-evaluated at regular intervals.

Generalized anxiety disorder

The normally recommended dose is 10 mg once daily. Depending on the individual patient response, the dose may be increased to a maximum of 20 mg daily. Treatment for 3 months is recommended to consolidate response. Long-term treatment of responders for 6 months has been shown to prevent relapse and can be considered on an individual basis; treatment benefits should be re-evaluated at regular intervals.

Obsessive-Compulsive Disorder

The normally recommended dose is 10 mg once daily. Depending on the individual patient response, the dose may be increased to a maximum of 20 mg daily. As OCD is a chronic disease, patients should be treated for a sufficient period to ensure that they are symptom free. This period may be several months or even longer.

Elderly patients (> 65 years of age):

Initial treatment with half the usually recommended dose and a lower maximum dose should be considered.

Children and adolescents (< 18 years):

Escitalopram should not be used in the treatment of children and adolescents under the age of 18 years.

Reduced renal function

Dosage adjustment is not necessary in patients with mild or moderate renal impairment. Caution is advised in patients with severely reduced renal function.

Reduced hepatic function

An initial dose of 5 mg daily for the first two weeks of treatment is recommended. Depending on individual patient response, the dose may be increased to 10 mg daily.

Poor metabolizers of CYP2C19

For patients who are known to be poor metabolizers with respect to CYP2C19, an initial dose of 5 mg daily during the first two weeks of treatment is recommended. Depending on individual patient response, the dose may be increased to 10 mg daily.

Discontinuation symptoms seen when stopping treatment

When stopping treatment with Esopam, the dose should be gradually reduced over a period of at least one to two weeks in order to avoid possible discontinuations symptoms.

- When to use it

You can take Esopam with or without food. Swallow the tablet with some water.

As with many medicines, combining Esopam with alcohol is not advisable, although Esopam is not expected to interact with alcohol.

- How long to use it

It may take a couple of weeks before you start to feel better. Continue to take Esopam even if it takes some time before you feel any improvement in your condition for as long as your doctor recommends.

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

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.

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- If you forget to use 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 use too much (overdose)

If you take more than the prescribed dose of Esopam, 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 Esopam box/container with you when you go to hospital.

While you are using it

- Things you must do

Esopam should not be used for children and adolescents under 18 years.

Take Esopam exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking Esopam.

Tell your doctor immediately if you become pregnant while taking Esopam.

- Things you must not do

Do not stop taking Esopam until your doctor tells you to do so.

When you have completed your course of treatment, it is generally advised that the dose of Esopam is gradually reduced over a number of weeks. When you stop taking Esopam, especially if it is abruptly, you may feel discontinuation symptoms.

Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients, they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Esopam, please contact your doctor. He or she may ask you to start taking your

tablets again and come off them more slowly.

Discontinuation symptoms include: Feeling dizzy (unsteady or off-balance), feelings like pins and needles, burning sensations and (less commonly) electric shock sensations, including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disoriented, feeling emotional or irritable, diarrhea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

- Things to be careful of

Driving and using machines

You are advised not to drive a car or operate machinery until you know how Esopam affects you.

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 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 yourself. 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 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 behavior in adults aged less than 25 years with psychiatric conditions who were treated with antidepressants.

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 behavior.

Side effects

Like all medicines, this medicine 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.

If you experience any of the following symptoms, you should contact your doctor or go to the hospital straight away:

Very Common

- Feeling sick (nausea)
- Headache

Common

- Blocked or runny nose (sinusitis)
- Decreased or increase appetite
- Anxiety, restlessness, abnormal dreams, difficulties falling asleep, feeling sleepy, dizziness, yawning, tremors, prickling of the skin
- Diarrhea, 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 to above, the following side effects have been reported:

- An increased risk of bone fractures has been observed in patients taking this type of medicines
- Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, electrical activity of the heart)

You may report any side effects or adverse drug reactions directly to the

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National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Date of Revision

05/06/2024

Serial Number

NPRA (R2) 21/013

Storage and Disposal of Esopam**-Storage**

Keep medicines out of reach of children.

Store at temperature of not more than 30°C.

-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 you protect the environment.

Product Description**- What it looks like?**

White, elliptical, biconvex, film coated tablet with scored on one side and plain on the other.

- Ingredients**- Active ingredient:**

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- Inactive ingredients:

Prosolv SMCC 90 (Silicified microcrystalline cellulose), Croscarmellose sodium, Sodium metabisulfite, Talc, Magnesium stearate, Hypromellose (HPMC 2910), Titanium dioxide, Butylated hydroxytoluene (BHT), Polyethylene glycol (PEG 400), Isopropyl alcohol and Purified water

- MAL Number:

MAL21126007AZ

Manufacturer

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Product Registration Holder

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