



# Escilam

(Escitalopram) USP

TABLETS

## COMPOSITION

### Escilam Tablet 10mg

Each tablet contains:

Escitalopram Oxalate (USP) equivalent to Escitalopram.....10mg

### Escilam Tablet 20mg

Each tablet contains:

Escitalopram Oxalate (USP) equivalent to Escitalopram.....20mg

## MODE OF ACTION

**Escilam** (Escitalopram) is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to normalize the levels of Serotonin in the brain. Disturbances in the Serotonin system of the brain are key factors in the development of depression and related disorders.

## INDICATIONS

**Escilam** (Escitalopram) is used for the treatment of depression, panic disorders, social anxiety disorder (also called social phobia) and generalized anxiety disorder. Depression characterized by low/depressed mood, lack of energy, melancholia, feeling of little or no worth, sleeping disorders, withdrawal and being unable to cope with daily tasks. Depression may also be accompanied by suicidal thoughts. Depressed patients may further suffer from symptoms of anxiety.

**Escilam** (Escitalopram) is also used for the treatment of panic disorder. Panic disorder is characterized by patients developing unexpected attacks of intense panic or anxiety when faced with particular situations or due to the fear of experiencing new attacks. Precisely what triggers the attacks varies from patient to patient. The attacks recur when the patient faces the same situation again. Social Anxiety Disorder or Social Phobia, is associated with excessive fear of social situations. Patients tend to avoid social situations that could cause anxiety or distress to themselves. Generalised Anxiety Disorder is characterized by excessive anxiety and/or worrying which is accompanied by several symptoms like restlessness, fatigue, difficulty in concentrating, irritability, muscle tension and disturbed sleep. Generalised Anxiety Disorder involves dysfunction in everyday life. **Escilam** (Escitalopram) will relieve these symptoms and make you feel better. Your doctor, however, may have prescribed **Escilam** (Escitalopram) for another illness. Ask your doctor if you have any questions about why **Escilam** (Escitalopram) has been prescribed for you.

## BEFORE YOU TAKE ESCILAM

### DO NOT TAKE ESCILAM

- If you are allergic to Escitalopram or any of the other ingredients. Consult your doctor if you think might be:
- At the same time as taking medication known as non-selective monoamine oxidase inhibitors (MAOIS), such as phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine which are also used for the treatment of depression.
- If you have taken any of these medicines you will need to wait 14 days before you start taking your Escilam tablets. After stopping Escilam you must allow 7 days before taking any of these medicines.

## TAKE SPECIAL CARE WITH ESCILAM

If your treatment is changed from the so called selective MAO-A inhibitor, moclobemide, (also used in the treatment of depression) to **Escilam** (Escitalopram) it is recommended that one day should elapse after you have finished taking moclobemide before you start taking your Escilam tablets. After stopping **Escilam** (Escitalopram) it is recommended to allow 7 days before starting moclobemide. Although not generally recommended, it may happen that your doctor decides that you should receive moclobemide concomitantly with **Escilam** (Escitalopram). This combination may in extraordinary cases prove beneficial. There exist, however, a risk of adverse effects from this combination. Therefore your doctor will usually prescribe low doses of both medicines at the start of the treatment. If you are treated

with both moclobemide and **Escilam** (Escitalopram) and experience symptoms like high fever and abrupt contractions of muscles with tremors, feel agitated and confused you must stop taking both medicines and see your doctor immediately.

## PRECAUTIONS FOR USE

**MEDICAL PROBLEMS:** Consult your doctor if you have any medical problems. Especially if you have a severe liver disease or diabetes, adjustment of the dose of medication for these diseases or your dose of **Escilam** (Escitalopram) may be warranted.

**EPILEPSY OR A HISTORY OF SEIZURES OR FITS:** Seizures are a potential risk with all antidepressant medication. If you experience seizures or an increased frequency of seizures while being treated with **Escilam** (Escitalopram) it is important to inform your doctor. The risk is further increased if you also take other medicines where the leaflet contains a warning similar to this one.

**EPISODES OF MANIA:** Some patients with manic-depressive illness may enter into a manic phase. This is characterized by profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity. In such cases, it is important to contact your doctor.

**SUICIDE:** Suicidal thoughts are common in patients suffering from depression. They will most often remain until the anti depressant effect of the medication become apparent. Tell your doctor immediately if you have distressing thoughts or experiences.

**SUBCUTANEOUS BLEEDING:** There have been reports that medicines like **Escilam** (Escitalopram) may cause an increased incidence of subcutaneous bleeding (shown as e.g. increased tendency to develop bruises). The risk is increased if you have tendencies to develop bleedings, and if you also take medicines known to affect the rate of clotting of the blood (like aspirin, non-steroidal anti-inflammatory drugs, medicines used for pain relief, some anti psychotics or tricyclic antidepressants). The risk is also increased if you take ticlopidine, dipyridamole (both medicines are used to reduce the risk of thrombosis) or oral anticoagulants.

## CAN ESCILAM BE USED WITH OTHER MEDICINES?

Please tell your doctor if you are taking or have taken any other medicines (including those purchased without prescription) during the last 14 days. **Escilam** (Escitalopram) and the following medicines should be combined with caution:

- Lithium and selegiline, if you get high fever and abrupt contractions of muscles, feel agitated and confused you must see your doctor immediately.
- Imipramine, desipramine and metoprolol (a so-called beta-blocker) are eliminated from the body more slowly when administered together with **Escilam** (Escitalopram), leading to increased amounts of these drugs in your body. If you receive both **Escilam** (Escitalopram) and any of these medicines you should consult your doctor.
- Sumatriptan and similar medicines (tramadol), increase the risk of side effects. If you get any unusual symptoms when using this combination you should see your doctor.
- Cimetidine may cause increased blood levels of **Escilam** (Escitalopram) if used at high doses at or above 800 mg per day.
- Although side effects of **Escilam** (Escitalopram) have not been recorded, however, your doctor may decide to reduce your dose of **Escilam** (Escitalopram).
- St John's wort (*Hypericum perforatum*- a herbal remedy used against low spirits); the risk of side effects may increase if you take **Escilam** (Escitalopram) concomitantly with herbal remedies containing St John's wort.
- Oral anti-coagulants (medicines like warfarin used to treat e.g. blood clots in the legs/lungs); the efficacy of the oral anti-coagulant may be altered, and your doctor will probably check the coagulation time of your blood when starting and discontinuing **Escilam** (Escitalopram) in order to verify that your dose of anticoagulant is still adequate.

## PREGNANCY AND BREAST-FEEDING

If you are pregnant, trying to become pregnant or breast-feeding, discuss the risk and benefits with your doctor before you start taking **Escilam** (Escitalopram).

Pregnant women should not usually take **Escilam** (Escitalopram) nor should mothers breast-feed their babies while taking this medicine.

#### DRIVING AND USING MACHINES

**Escilam** (Escitalopram) does not cause drowsiness; however, as with any new medicine you should take care while driving or using machinery until you know how it affects you.

#### DOSAGE AND ADMINISTRATION

##### HOW MUCH TO TAKE

It is important to take your tablets as instructed by your doctor. However, the usual dosage may be as follows:

##### ADULTS

**DEPRESSION:** The usual dose is 10 mg per day. This may be increased by your doctor. The recommended maximum dose is 20 mg per day.

**PANIC DISORDER:** The starting dose is 5 mg per day for the first week before increasing the dose to 10-15 mg per day. The dose may be increased by your doctor to a maximum of 20 mg per day.

Patients who are prone to panic attacks may actually experience a temporary period of heightened anxiety after starting treatment which generally resolves during the first 1-2 weeks. Therefore, a low starting dose is recommended in panic disorder.

**SOCIAL ANXIETY DISORDER/ SOCIAL PHOBIA:** The usual dose is 10 mg per day. Usually 2-4 weeks are necessary to obtain symptom relief. Depending on how you feel after you have taken your medicine for a while, your doctor might adjust your dose to between 5 mg and 20 mg daily.

**GENERALISED ANXIETY DISORDER:** The usual dose is 10 mg per day. This may be increased by your doctor. The recommended maximum dose is 20 mg per day.

##### ELDERLY PATIENTS

The usual starting dose is 5mg per day. It is recommended that the maximum dose is kept below 20 mg.

##### PATIENTS WITH SPECIAL RISKS

It is recommended that patients with liver disease receive an initial dose of 5 mg daily for the first two weeks. Your doctor may increase the dose to 10 mg daily.

##### CHILDREN AND ADOLESCENTS (< 18 YEARS)

**Escilam** (Escitalopram) should not be given to children or adolescents.

##### FURTHER CONSIDERATIONS

The safety of daily doses of **Escilam** (Escitalopram) in excess of 20 mg has not yet been thoroughly investigated. Therefore, your doctor will only prescribe higher doses after careful consideration of the necessity.

##### ADMINISTRATION

**Escilam** is taken every day as a single daily dose. **Escilam** (Escitalopram) can be taken with or without food. Swallow the tablets with a drink of water.

##### DURATION OF TREATMENT

As with other medicines for the treatment of depression, panic disorder, social anxiety disorder and generalised anxiety disorder it may take a few weeks before you feel any improvement. Therefore you should continue to take **Escilam** (Escitalopram) even if it takes some time before you feel any improvement in your condition. Never change the dose of the medicine without consulting to doctor first. The duration of treatment may vary for each individual. You should continue to take the tablets for as long as your doctor recommends, even if you begin to feel better. The underlying illness may persist for a long time and if you stop your treatment too soon, your symptoms may return. Therefore it is recommended that treatment is continued for at least 6 months after you feel well again.

##### OVER-DOSAGE

If you or anyone else may have taken too many **Escilam** (Escitalopram) tablets contact your doctor or nearest hospital casualty department

immediately. Do this even if there are no signs of discomfort. Take the **Escilam** (Escitalopram) box with you if you go to a doctor or hospital.

##### IF YOU FORGET TO TAKE ESCILAM

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose.

##### EFFECTS WHEN TREATMENT WITH ESCILAM IS STOPPED

Abrupt cessation of this kind of medication may cause discontinuation symptoms such as dizziness, nausea and headache. When you have completed your course of treatment it is therefore advised that the dose of **Escilam** (Escitalopram) is gradually reduced over a couple of weeks.

##### POSSIBLE SIDE EFFECTS

Some people may experience unwanted effects (side-effects) while taking **Escilam** (Escitalopram). The side effects are generally mild and usually disappear after a few day's treatment. Please be aware that several of the effects may also be symptoms of your illness and therefore disappear when you start to get better. If the side effects are troublesome or last for more than a week or two, tell your doctor.

Side effects seen in clinical trials include:

Very common (more than 1 out of 10) Nausea.

Common (less than 1 out of 10 but more than 1 out of 100)

Sinusitis (clogged or running nose), decreased appetite, difficulties falling asleep, Feeling sleepy, dizziness, yawning, diarrhoea, constipation, increases sweating, sexual disturbances (delayed ejaculation, problems with erection, decreased sexual drive and women may experience difficulties achieving orgasm), Fatigue, Fever.

Uncommon (less than 1 out of 100) Disturbed sleep, Taste perversion

If you notice any other side effects not mentioned in this leaflet please tell your doctor or pharmacist. In addition a number of side effects are known to occur rarely with drugs that work in a similar way to Escitalopram, are: Dizziness when you stand up due to low blood pressure, decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused) blurring of vision, vomiting, dry mouth. Abnormal liver function test (increased amounts of liver enzymes in the blood) Pain in muscles and joints, high fever, agitation, confusion, trembling and abrupt contractions of muscles may be signs of a rare condition called Serotonin syndrome, seizures, tremors, movement disorders (involuntary movements of the muscles), hallucinations, mania, confusion, agitation, anxiety, depersonalization, panic attacks and nervousness, difficulties urinating, flow of milk in women that are not nursing, Rash, increased tendency to develop bruises, itching, and patches of circumscribed swellings.

##### STORAGE CONDITIONS

Store below 30°C. Protect from heat, light & moisture. Keep all medicines out of the reach of children. To be sold on the prescription of a registered medical practitioner only.

##### PRESENTATIONS

**Escilam** 10 mg tablets are available in Blister pack of 10's.

**Escilam** 20 mg tablets are available in Blister pack of 14's.

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(ایس سٹانو پیرام) ایو ایس بی

ہدایات: 30 ڈگری سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔ گرمی، روشنی اور نمی سے بچائیں۔  
تمام دوائیں بچوں کی پہنچ سے دور رکھیں۔ صرف مستند ڈاکٹر کے نسخے پر فروخت کریں۔



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