

APPROVED PATIENT INFORMATION LEAFLET

August 2024

SCHEDULING STATUS:

S5

Cipralex 5, 10, 15 and 20 mg tablets
Escitalopram (as oxalate)
Sugar free

Read all of this leaflet carefully before you start taking Cipralex

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider
- Cipralex has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Cipralex is and what it is used for
2. What you need to know before you take Cipralex
3. How to take Cipralex
4. Possible side effects
5. How to store Cipralex
6. Contents of the pack and other information

1. What Cipralex is and what it is used for

Cipralex contains escitalopram and is used to treat depression (major depressive episodes) and anxiety disorders (such as panic disorder with or without agoraphobia, social anxiety, disorder, and generalised anxiety disorder and obsessive-compulsive disorder).

2. What you need to know before you take Cipralex**Do not take Cipralex**

- if you are allergic (hypersensitive) to escitalopram or any of the other ingredients of Cipralex (listed in section 6).
- if you are under 18 years of age
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs), such as selegiline, 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 Cipralex tablets. After stopping Cipralex you must allow 7 days before taking any of these medicines.

- 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

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(see section 2 'Other medicines and Cipralex')

- at the same time as taking linezolid.
- at the same time as taking pimoziide.

Warnings and precautions**Take special care with Cipralex:**

Tell your doctor or pharmacist if any of these apply. You may still be able to take Cipralex but discuss it with your doctor first. In particular, tell your doctor:

- if you have epilepsy. Treatment with Cipralex should be stopped if you develop seizures for the first time or if there is an increase in the seizure frequency (see also "Possible side effects"). You should not take Cipralex if you have unstable epilepsy. If your epilepsy is controlled, your doctor should watch you carefully.
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Cipralex 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, or if you are pregnant (see 'Pregnancy, breastfeeding and fertility').
- 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 heartrate 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.
- if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

Please note

Improvement is not achieved immediately. After the start of Cipralex treatment it may take several weeks before you experience any improvement. In the treatment of panic disorder it usually takes 2-4 weeks before any improvement is seen. In the beginning of the treatment certain patients may experience anxiety, which usually disappears during the continued treatment. Therefore, it is very important that you follow exactly your doctor's orders and do not stop the treatment or change the dose without consulting your doctor .

Occasionally, the symptoms of depression or panic disorder may include thoughts of suicide or self-harm. These symptoms may continue or get worse or the risk of suicide increase until the full antidepressant effect of the medicine becomes apparent and the risk is greater if you are less than 25 years old.

Some patients with manic-depressive illness may enter into a manic phase This is

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characterised 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.

Sometimes you may be unaware of the above-mentioned symptoms and therefore you may find it helpful to ask a friend or relative to help you to observe the possible signs of change in your behavior.

Cipralext may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

Tell your doctor immediately or contact the nearest hospital if you have distressing thoughts or experiences or if any of the above-mentioned symptoms occurs during the treatment.

Children and adolescents

Use in children and adolescents under 18 years of age

Cipralext 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.

Other medicines and Cipralext

Always tell your healthcare provider if you are taking any other medicines, including complementary or traditional medicines.

If you are taking any of the following medicines it is especially important that you tell your doctor or pharmacist:

- Monoamine oxidase inhibitors (MAOIs), containing selegiline, and tranylcypromine as active ingredients. If you have taken any of these medicines you will need to wait 14 days before you start taking Cipralext. After stopping Cipralext you must allow 7 days before taking any of these medicines.
- If you take other medicines which belong to a group called monoamine oxidase Inhibitors (MAOIs). MAOIs include medicines such as phenelzine; isocarboxazid; nialamide; tranylcypromine; selegiline (used in the treatment of Parkinson's disease); moclobemide (used in the treatment of depression) and linezolid (antibiotic).
- Lithium (used in the treatment of manic-depressive disorder) and selegiline (used in the treatment of Parkinson's disease); if you get high fever and abrupt contractions of muscles, feel agitated and confused you must see your doctor immediately.
- Imipramine and desipramine (both used to treat depression) and metoprolol (a so-called beta-blocker used in various cardiovascular diseases) are eliminated from the body more slowly when administered together with Cipralext, leading to increased amounts of these medicines in your body. If you receive both Cipralext and any of these medicines you

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should consult your doctor.

- Sumatriptan and similar medicines (used to treat migraine), tramadol, pethidine and similar medicines (used against severe pain) increase the risk of side effects; if you get any unusual symptoms when using this combination you should see your doctor.
- Cimetidine and omeprazole (used to treat stomach ulcers) may cause increased blood levels of Cipralex. If you receive high doses of Cipralex and feel discomfort by the combination with cimetidine or omeprazole your doctor may decide to reduce your dose of Cipralex.
- St John's Wort (*Hypericum perforatum* - a herbal remedy used against low spirits); the risk of side effects may increase if you take Cipralex concomitantly with herbal remedies containing St John's Wort.
- Aspirin and non-steroidal anti-inflammatory medicines (medicines that can increase the risk of bleeding). These may increase the bleeding tendency.
- 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 Cipralex in order to verify that your dose of anti-coagulant is still adequate.
- Medicinal products capable of lowering the threshold for seizures; neuroleptics (medicines to treat schizophrenia, psychosis e.g. phenothiazines, thioxanthenes, butyrophenones) and antidepressants (desipramine, clomipramine, and nortriptyline, SSRIs), mefloquin (used to treat malaria), bupropion (used to treat depression) and tramadol (used to treat severe pain).
- Flecainide, propafenone, and metoprolol (used in cardio-vascular diseases) and desipramine, clomipramine, and nortriptyline (antidepressants) and risperidone, thioridazine, and haloperidol (antipsychotics). The dosage of Cipralex may need to be adjusted.

Cipralex with food, drink and alcohol

Cipralex can be taken with or without food (see section 'How to take Cipralex').

Cipralex has been shown not to increase the effects of alcohol. Nevertheless, it is recommended not to drink alcohol during treatment with Cipralex.

Pregnancy, breastfeeding and fertility

If you fall pregnant or have been breastfeeding your baby, please consult your doctor, pharmacist or other health care professional for advice before taking Cipralex.

Do not take Cipralex if you are pregnant.

Inform your doctor if you are pregnant or planning to become pregnant.

If you take Cipralex during the last 3 months of your pregnancy 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 and in most cases start immediately or within 24 hours of delivery. If your newborn baby has any of these symptoms, please contact your doctor immediately. There may also be a higher risk of persistent pulmonary hypertension in the newborn.

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If you take Cipralex 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 or midwife should be aware that you are taking Cipralex so they can advise you. Do not take Cipralex if you are breastfeeding.

Citalopram, a medicine like Cipralex, has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

Driving and using machines

Cipralex 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.

3. How to take Cipralex**How much to take**

Always take Cipralex exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure or need further information.

Do not share medicines prescribed for you with any other person.

How and when to take Cipralex

Cipralex is taken every day as a single daily dose. Cipralex can be taken with or without food. Swallow the tablets with a drink of water. Do not chew them (the taste is bitter).

If necessary, Cipralex 10, 15 and 20 mg tablets may be broken 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 as shown in the drawing.



The 10, 15 and 20 mg tablets can be divided into equal doses.

Duration of treatment

It may take a couple of weeks before you start to feel better. Continue to take Cipralex 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 Cipralex 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 take more Cipralex than you should

If you take more than the prescribed dose of Cipralex, contact your doctor or pharmacist, or nearest hospital emergency department or poison control centre immediately. Do this even if there are no signs of discomfort. Some of the signs of an overdose could be dizziness, tremor,

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agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance.

If you forget to take Cipralex

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

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 stop taking Cipralex

Do not stop taking Cipralex until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Cipralex is gradually reduced over a number of weeks.

When you stop taking Cipralex, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Cipralex is stopped. The risk is higher, when Cipralex has been used for a long time or in high doses or when the dose is reduced too quickly. 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 Cipralex, 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 disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

4. Possible side effects

Cipralex can cause side effects

Not all side effects reported for Cipralex are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Cipralex, please consult your health care provider for advice.

Tell your doctor immediately if you experience any of the following side effects, or go to the hospital straight away:

- Difficulties urinating
- Seizures (fits), see also section "Take special care with Cipralex"
- Yellowing of the skin and the white in the eyes are signs of liver function impairment/hepatitis

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

- Unusual bleeds, including gastrointestinal bleeds

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- If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction), contact your doctor or go to a hospital straight away.
- If you have a high fever, agitation, confusion, trembling and abrupt contractions of muscles these may be signs of a rare condition called serotonin syndrome. If you feel like this contact your doctor.
- Suicidal thoughts or self harm while you are taking Cipralex or after you have stopped taking Cipralex.
- Fast irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsade de Pointes
- Sudden swelling of skin or mucosa (angioedemas)

Tell your doctor if any of the following side effects continue or are bothersome:

Frequent side effects

- Feeling sick (nausea)
- 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

Less frequent side effects

- Nettle rash (urticaria), rash, itching (pruritus)
- Grinding one's teeth, agitation, nervousness, panic attack, confusion state
- Disturbed sleep, taste disturbance, fainting (syncope)
- Enlarged pupils (mydriasis), visual disturbance, ringing in the ears (tinnitus)
- Loss of hair
- Excessive menstrual bleeding
- Irregular menstrual period
- Decreased weight
- Fast heartbeat
- Swelling of the arms or legs
- Nosebleeds
- Aggression, depersonalisation, hallucination
- Slow heartbeat
- Suicide-related events, see also section "Take special care with Cipralex"
- Decreased levels of sodium in the blood (the symptoms are feeling sick and unwell with weak muscles or confused)
- Dizziness when you stand up due to low blood pressure (orthostatic hypotension)

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- Abnormal liver function test (increased amounts of liver enzymes in the blood)
- Movement disorders (involuntary movements of the muscles)
- Persistent, painful erections
- Bleeding disorders including skin and mucous bleeding (ecchymosis) and low level of blood platelets (thrombocytopenia)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breastfeeding and fertility' in section 2 for more information
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Increased blood levels of the hormone prolactin
- Flow of milk in women that are not nursing
- Mania
- 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).

In addition, a number of side effects are known to occur with medicines that work in a similar way to escitalopram (the active ingredient of Ciprallex). 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.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects to SAHPRA via the "6.04 Adverse Drug Reaction Reporting Form", found online under SAHPRA's publications: <https://www.sahpra.org.za/Publications/Index/8>. By reporting side effects, you can help provide more information on the safety of Ciprallex.

5. How to store Ciprallex

Store all medicine out of the reach of children.

Store at or below 30°C.

Do not use Ciprallex after the expiry date, which is stated on the label or carton.

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.

6. Contents of the pack and other information**What Ciprallex contains**

The active substance is escitalopram as oxalate.

Each Ciprallex tablet contains either 5 mg, 10 mg, 15 mg or 20 mg escitalopram as oxalate salt.

The other ingredients are croscarmellose sodium, hypromellose, macrogol 400, magnesium stearate, microcrystalline cellulose silicified, talc and titanium dioxide (E-171).

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What Cipralex looks like and contents of the pack

Cipralex is presented as 5 mg, 10 mg, 15 mg and 20 mg film-coated tablets. The tablets are described below.

5 mg: Round, white biconvex film-coated tablets marked with “EK” on one side.

10 mg: Oval, white film-coated tablets. The tablets are scored and marked with “E” and “L” on each side of the score on one side of the tablet.

15 mg: Oval, white film-coated tablets. The tablets are scored and marked with “E” and “M” on each side of the score on one side of the tablet.

20 mg: Oval, white film-coated tablets. The tablets are scored and marked with “E” and “N” on each side of the score on one side of the tablet.

Cipralex is available in the following pack sizes:

5, 10, 15 and 20 mg tablets: 28 tablets in blisters (transparent) in cardboard box.

Holder of Certificate of Registration

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