

PROPOSED PATIENT INFORMATION LEAFLET

Scheduling Status

S5

Proprietary Name, Strength and Pharmaceutical Form

Cipralex-5, 10, 15 and 20 mg film-coated tablets

Escitalopram (as oxalate)

Read all of this leaflet carefully before you start taking Cipralex

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- 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.
- 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.

WHAT CIPRALEX CONTAINS

The active substance is escitalopram as oxalate.

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

The other ingredients are: colloidal anhydrous silica, croscarmellose sodium, hypromellose, macrogol 400, magnesium stearate, microcrystalline cellulose, talc and titanium dioxide (E-171)

WHAT CIPRALEX 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).

BEFORE YOU TAKE CIPRALEX

Do not take Cipralelex

- if you are allergic (hypersensitive) to escitalopram or any of the other ingredients of Cipralelex (see section 1 "What Cipralelex contains").
- 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 Cipralelex tablets. After stopping Cipralelex you must allow 7 days before taking any of these medicines.

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

Take special care with Cipralelex

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

- if you have epilepsy. Treatment with Cipralelex 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 Cipralelex 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 Cipralelex 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.

Please note

Improvement is not achieved immediately. After the start of Cipralelex 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 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.

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.

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.

Use in children and adolescents under 18 years of age

Cipralelex 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.

Taking Cipralelex with food and drink

Cipralelex can be taken with or without food (see section "How to take Cipralelex").

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

Pregnancy and breast-feeding

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

Do not take Cipralelex if you are pregnant.

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

If you take Cipralelex 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.

Do not take Cipralelex if you are breast-feeding.

Driving and using machines

Cipralelex 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.

Taking other medicines with Cipralelex

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 Cipralex. After stopping Cipralex 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 Cipralex, leading to increased amounts of these medicines in your body. If you receive both Cipralex and any of these medicines you should consult your doctor.
- Sumatriptan and similar medicines (used to treat migraine), tramadol and pethidine (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.

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

HOW TO TAKE CIPRALEX

How much to take

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

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, 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.



Duration of treatment

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

If you take more than the prescribed dose of Cipralelex, 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, agitation, convulsion, coma, nausea, vomiting, change in heart rhythm, decreased blood pressure and change in body fluid/salt balance.

If you forget to take Cipralelex

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 Cipralelex

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

When you stop taking Cipralelex, especially if it is abruptly, you may feel discontinuation symptoms. These are common when treatment with Cipralelex is stopped. The risk is higher, when Cipralelex 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 Cipralelex, 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).

POSSIBLE SIDE EFFECTS

Cipralelex can cause side effects

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.

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
- 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.

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

- 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
- 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
- Vaginal bleeding
- Decreased weight
- Fast heart beat
- Swelling of the arms or legs
- Nosebleeds
- Aggression, depersonalisation, hallucination
- Slow heart beat
- 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)
- 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)
- Sudden swelling of skin or mucosa (angioedemas)
- Increase in the amount of urine excreted (inappropriate ADH secretion)
- Flow of milk in women that are not nursing
- Mania

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 CipraleX). These are:

- Motor restlessness (akathisia)
- Anorexia

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 doctor, pharmacist or other health care professional for advice.

HOW TO STORE CIPRALEX

Store all medicine out of the reach of children.

Do not store above 30°C.

Do not use Cipralex 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.

FURTHER INFORMATION

PRESENTATION OF CIPRALEX

Cipralex is available in the following pack sizes:

5, 10, 15 and 20 mg tablets:

28 tablets in blisters (transparent) in cardboard box.

IDENTIFICATION OF CIPRALEX

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.

REGISTRATION NUMBER

5 mg: 36/1.2/0318

10 mg: 36/1.2/0319

15 mg: 36/1.2/0320

20 mg: 36/1.2/0321

NAME AND ADDRESS OF REGISTRATION HOLDER

H. Lundbeck (Pty) Ltd

252 Montrose Avenue

North Riding

2194

DATE OF PUBLICATION

To be inserted.

