Sipralexa

Notice: User information

Sipralexa 5 mg film-coated tablets,
Sipralexa 10 mg film-coated tablets,
Sipralexa 15 mg film-coated tablets,
Sipralexa 20 mg film-coated tablets
, escitalopram

Please read this leaflet carefully before taking this medicine because it contains important information for you.

- Keep these instructions. You may need to read them again.
- If you have any further questions, ask your doctor or pharmacist.
- This medication has been prescribed for you personally. Do not give it to other people. It could be harmful to them, even if their symptoms are the same as yours.
- If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

Que contient cette notice ?

1. WHAT IS SIPRALEXA AND WHAT IS IT USED FOR?

Sipralexa contains the active substance escitalopram. Sipralexa belongs to a group of antidepressants called Selective Serotonin Reuptake Inhibitors (SSRIs).

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

It may take about two weeks before you start to feel better. Continue taking Sipralexa even if you don't feel better for a long time.

You should consult your doctor if you do not feel any improvement or if you feel worse.

2. WHAT INFORMATION SHOULD YOU KNOW BEFORE TAKING SIPRALEXA?

Never take Sipralexa

- If you are allergic to escitalopram or any of the other ingredients of this medicine listed in section 6.
- If you are taking other medications belonging to the MAO inhibitor family, including selegiline (used to treat Parkinson's disease), moclobemide (used to treat depression) and linezolid (an antibiotic).
- If you were born with or have experienced an episode of heart rhythm disorder (seen on an ECG, a test done to assess how your heart is working).
- If you are taking medication for heart rhythm disorders that could affect your heart rhythm (see section “Other medicines and Sipralexa”).

Warnings and precautions

Talk to your doctor or pharmacist before taking Sipralexa. Tell your doctor about any other illnesses or medical history, as they may need to take this into account. In particular, tell your doctor:

- If you have epilepsy, treatment with Sipralexa should be stopped if seizures occur for the first time or if the frequency of seizures increases (see also section 4, "Possible side effects").
- If you have kidney (renal) or liver (hepatic) insufficiency, your doctor may need to adjust your medication dosage.
- If you are diabetic, treatment with Sipralexa may disrupt your blood sugar levels. An adjustment of your insulin and/or oral antidiabetic medication doses may be necessary.
- If you have a decreased amount of sodium in your blood.
- If you tend to bleed or bruise easily, or if you are pregnant (see "Pregnancy, breastfeeding and fertility").
- If you are receiving electroconvulsive therapy.
- If you have coronary artery disease.
- If you suffer or have suffered from heart problems or if you have recently had a heart attack.
- If you have a slow resting heart rate and/or if you know you are at risk of salt deficiency following severe and prolonged diarrhea or vomiting or following the use of diuretic treatments.
- If you experience a rapid or irregular heartbeat, fainting, dizziness, or lightheadedness when standing up, which could indicate abnormal heart rhythm.
- If you have or have had eye problems, such as certain types of glaucoma (increased pressure inside the eye).

Please note

Some patients with bipolar disorder may develop a manic phase. This is characterized by unusual and rapidly changing thoughts, inappropriate elation, and physical hyperactivity. If you experience these symptoms, contact your doctor.

Symptoms such as restlessness or difficulty sitting or standing still may also occur during the first few weeks of treatment. Inform your doctor immediately if you experience these symptoms.

Medicines like Sipralexa (called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have persisted after stopping treatment.

Suicidal thoughts and worsening of your depression or anxiety disorder

If you suffer from depression and/or anxiety disorders, you may sometimes have thoughts of self-harm or suicide. These symptoms may worsen at the beginning of antidepressant treatment, as this type of medication does not work immediately but only after two weeks or more of treatment. You are more likely to experience these symptoms in the following cases:

- if you have had suicidal thoughts or self-harm in the past.
- If you are a young adult. Clinical studies have shown that the risk of suicidal behavior is increased in adults under 25 years of age with a psychiatric illness and treated with antidepressants.

If you have suicidal thoughts or thoughts of self-harm, **contact your doctor immediately or go directly to the hospital.**
You can ask a friend or relative for help by explaining that you are depressed or suffering from an anxiety disorder, and asking them to read this leaflet. You can ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about any changes in your behavior.

Children and teenagers

Sipralexa should not normally be used in children and adolescents under 18 years of age. It is also important to know that patients under 18 have an increased risk of side effects, such as suicidal thoughts, suicidal behavior, and hostility (primarily aggression, oppositional behavior, and anger) when treated with this class of medications. Nevertheless, your doctor may decide to prescribe Sipralexa to patients under 18 if they decide it is in the patient's best interest. If your doctor has prescribed Sipralexa to a patient under 18 and you wish to discuss this, please contact them. You should inform your doctor if any of the symptoms listed above appear or worsen while a patient under 18 is taking Sipralexa. You should also be aware that the long-term safety regarding growth, maturation, and cognitive and behavioral development of Sipralexa has not yet been established in this age group.

Other medications and Sipralexa

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

If you are taking any of the following medications, tell your doctor:

- Non-selective monoamine oxidase inhibitors (MAOIs) contain the active ingredients phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine. If you have taken any of these medications, a 14-day interval is required between stopping these medications and starting treatment with Sipralexa. After stopping Sipralexa, a 7-day interval is required before starting treatment with any of these medications.
- “Selective reversible MAO-A inhibitors” containing moclobemide (used in the treatment of depression).
- "Irreversible MAO-B inhibitors," containing selegiline (used in the treatment of Parkinson's disease), increase the risk of adverse effects.

- Linezolid (an antibiotic).
- Lithium (used in the treatment of manic-depressive disorders) and tryptophan.
- Imipramine and desipramine (both used in the treatment of depression).
- Sumatriptan and similar medications (used to treat migraines) and tramadol and similar medications (opioids, used for severe pain) increase the risk of side effects.
- Cimetidine, lansoprazole, and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine (an antidepressant), and ticlopidine (used to reduce the risk of stroke) are all medications that may increase escitalopram levels in the blood.
- St. John's wort (*Hypericum perforatum*) - an herbal preparation used in depression.
- Acetylsalicylic acid and nonsteroidal anti-inflammatory drugs (NSAIDs) (medicines used to relieve pain or thin the blood, called anticoagulants). These medications can increase the risk of bleeding.
- Warfarin, dipyridamole, and phenprocoumon (medicines used to thin the blood, called anticoagulants). Your doctor will likely check your blood clotting time at the beginning and end of your Sipralexa treatment to ensure your anticoagulant dosage is still appropriate.
- Mefloquine (used in the treatment of malaria), bupropion (used in the treatment of depression) and tramadol (used in the treatment of severe pain) due to a possible risk of increased risk of seizures.
- Neuroleptics (medicines used in the treatment of schizophrenia and psychoses) and antidepressants (tricyclic antidepressants and SSRIs) due to a possible risk of increased risk of seizures.
- Flecainide, propafenone, metoprolol (used for cardiovascular diseases), clomipramine, nortriptyline (antidepressants), risperidone, thioridazine, and haloperidol (antipsychotics). Sipralexa doses may be adjusted if necessary.
- Medications that decrease the amount of potassium or magnesium in the blood, as such a combination increases the risk of life-threatening heart rhythm disorders.

Do not take Sipralexa if you are taking medications used to treat heart rhythm disorders or that can disrupt heart rhythm, such as class IA and III antiarrhythmics, antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (such as sparfloxacin, moxifloxacin, IV erythromycin, pentamidine, antimalarial drugs, especially halofantrine), or certain antihistamines (astemizole, hydroxyzine, mizolastine). Contact your doctor if you have any questions.

Sipralexa with food, drinks and alcohol

Sipralexa can be taken during or between meals (see section 3 “How to take Sipralexa?”).

As with many medications, alcohol consumption with Sipralexa is not recommended, although an interaction between Sipralexa and alcohol is not expected.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant, or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. If you are pregnant or breastfeeding, do not take Sipralexa unless you have first discussed the potential risks and benefits of treatment with your doctor.

If you take Sipralexa during the last three months of your pregnancy, you should be aware that the following effects may occur in your newborn: breathing difficulties, bluish discoloration of the skin, seizures, changes in body temperature, feeding difficulties, vomiting, hypoglycemia, muscle twitching or relaxation, brisk reflexes, tremors, tremors, irritability, lethargy, constant crying, drowsiness, and sleep disturbances. If your newborn experiences any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor know you are taking Sipralexa. If taken during pregnancy, especially during the last 3 months, medicines like Sipralexa can increase the risk of a serious condition in the baby called persistent pulmonary hypertension of the newborn (PPHN), which is characterized by faster breathing and a bluish discoloration of the skin. These symptoms usually appear within the first 24 hours after birth. If this occurs in your baby, contact your midwife and/or doctor immediately.

If you take Sipralexa late in pregnancy, there may be an increased risk of heavy vaginal bleeding shortly after delivery, especially if you have a history of bleeding disorders. Your doctor or midwife should be informed that you are taking Sipralexa so they can advise you.

If used during pregnancy, Sipralexa should never be stopped abruptly.

Escitalopram is expected to pass into breast milk.

Animal studies have shown that citalopram, a drug similar to escitalopram, reduces sperm quality. Theoretically, fertility could be affected, but no impact on human fertility has been observed to date.

Driving vehicles and using machinery

It is not recommended to drive a vehicle or operate machinery until you know how Sipralexa affects you.

Sipralexa contains sodium

This medicine contains less than 1 mmol (23 mg) of sodium per tablet, that is to say it is essentially 'sodium free'.

3. HOW TO TAKE SIPRALEXA?

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

Adults
Depression
The usual recommended dose of Sipralexa is 10 mg once daily. Your doctor may increase the dose up to a maximum of 20 mg daily.

Panic disorder:
The initial dose of Sipralexa during the first week of treatment is 5 mg once daily, then increased to 10 mg daily. Your doctor may further increase the dose up to a maximum of 20 mg daily.

Social anxiety disorder:
The usual recommended dose of Sipralexa is 10 mg once daily. Your doctor may decrease the dose to 5 mg daily or increase it up to a maximum of 20 mg daily, depending on your response to treatment.

Generalized anxiety disorder:
The usual recommended dose of Sipralexa is 10 mg once daily. Your doctor may increase the dose up to a maximum of 20 mg daily.

Obsessive-compulsive disorder:
The usual recommended dose of Sipralexa is 10 mg once daily. Your doctor may increase the dose up to a maximum of 20 mg daily.

For people over 65 years of age,
the recommended starting dose is 5 mg once daily. Your doctor may increase the dose up to 10 mg daily.

Use in children and adolescents:
Sipralexa should not normally be given to children and adolescents. For further information, see section 2 " *Warnings and precautions* ".

Reduced kidney function:
Caution is advised in patients with severely reduced kidney function. Take as prescribed by your doctor.

Reduced liver function:
Patients with liver problems should not receive more than 10 mg per day. Take as prescribed by your doctor.

Patients known to be poor metabolizers of the CYP2C19 enzyme
should not receive more than 10 mg per day. Take as prescribed by your doctor.

How to take the tablets?
You can take Sipralexa with or between meals. Swallow the tablets with a little water. Do not chew them; they have a bitter taste.

If it is necessary to break the 10, 15 and 20 mg tablet, place it on a flat surface with the score line above and then apply pressure with both index fingers on either side of the line, as shown in the diagram below.

The 10, 15 and 20 mg tablets can be divided into 2 equal doses.

Treatment duration:
It may take approximately two weeks before you start to feel better. Continue taking Sipralexa even if you do not feel better for a long time.

Do not change the dosage of your medication without first speaking with your doctor.

Continue taking Sipralexa for as long as your doctor recommends. If you stop treatment too soon, your symptoms may return. It is recommended to continue treatment for at least six months from the time you feel well again.

If you have taken more Sipralexa than you should have

If you have taken more Sipralexa than prescribed, contact your doctor, pharmacist, the Poison Control Center (070/245.245), or the nearest hospital emergency department immediately. Do this even if you are not experiencing any unpleasant effects. Some signs of an overdose may include dizziness, tremors, agitation, seizures, coma, nausea, vomiting, irregular heartbeat, low blood pressure, and changes in body fluid composition. Take the Sipralexa pack/blister pack with you if you go to the doctor or hospital.

If you forget to take Sipralexa

Do not take a double dose to make up for a missed dose. If you miss a dose and remember before going to bed, take it immediately. Continue as usual the next day. If you only remember during the night or the following day, skip the missed dose and continue as usual.

If you stop taking Sipralexa

Do not stop taking Sipralexa without consulting your doctor. At the end of your treatment, it is generally recommended to gradually reduce the dose of Sipralexa over several weeks.

When you stop taking Sipralexa, especially if you stop abruptly, you may experience withdrawal symptoms. These symptoms are common when stopping Sipralexa. The risk is higher if Sipralexa has been used for a long time, at high doses, or if the dose is reduced too quickly. In most patients, these symptoms are mild and disappear spontaneously within 2 weeks. However, in some patients, they may be severe or last for a long time (2 to 3 months or more). If you experience severe symptoms when stopping Sipralexa, please contact your doctor. He or she may then advise you to restart your treatment and reduce the dose more gradually.

Symptoms that may occur when treatment is stopped include: dizziness (instability or imbalance), tingling or prickling sensations, burning sensations

and (less frequently) electric shock sensations, including in the head, sleep disturbances (restless dreams, nightmares, inability to sleep), feeling anxious, headache, nausea, sweating (including night sweats), feeling restless, tremors (shaking), feeling confused or disoriented, feeling emotional or irritable, diarrhea (loose stools), visual disturbances, exaggerated perception of heartbeats (palpitations).

If you have any further questions about the use of this medicine, ask your doctor or pharmacist for more information.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

Like all medicines, this medicine can cause side effects, although not everybody gets them.

These side effects usually subside after a few weeks of treatment. Please note that some of these effects may also be symptoms related to your illness, which will improve as you begin to feel better.

If you experience the following side effects, you should contact your doctor or go to the hospital immediately:

Uncommon (may affect up to 1 in 100 patients):

- Abnormal bleeding, including gastrointestinal bleeding.

Rare (may affect up to 1 in 1,000 patients):

- Swelling of the skin, tongue, lips, pharynx or face, hives or difficulty breathing or swallowing (severe allergic reaction).
- High fever, agitation, confusion, tremors and sudden muscle contractions can be signs of a rare condition called serotonin syndrome.

Frequency not known (cannot be estimated from the available data):

- Difficulty urinating.
- Convulsions (seizures), see also section “Warnings and precautions”.
- Yellowing of the skin and whites of the eyes are signs of liver dysfunction/hepatitis.
- Rapid, irregular heartbeat, fainting spells which could be signs of torsades de pointes (a potentially life-threatening event).
- For thoughts of self-harm or suicidal ideation, see also the section "Warnings and precautions".
- Sudden swelling of the skin or mucous membranes (angioedema).

In addition, the following adverse effects have been reported:

Very common (may affect more than 1 in 10 patients):

- Feeling sick (nausea).
- Headaches.

Frequent (may affect up to 1 in 10 patients):

- Blocked nose or runny nose (sinusitis).
- Loss or increase of appetite.
- Anxiety, agitation, abnormal dreams, difficulty falling asleep, drowsiness, dizziness, yawning, trembling, tingling of the skin.
- Diarrhea, constipation, vomiting, dry mouth.
- Excessive sweating.
- Muscle and joint pain (arthralgia and myalgia).
- Sexual disorders (delayed ejaculation, erectile dysfunction, decreased libido, female orgasmic disorders).
- Fatigue, fever.
- Weight gain.

Uncommon (may affect up to 1 in 100 patients):

- Urticarial eruption (urticaria), skin rash, itching (pruritus).
- Teeth grinding, agitation, nervousness, panic attacks, confusion.
- Sleep disturbances, taste disturbances, fainting (syncope).
- Dilated pupil (mydriasis), visual disturbances, ringing in the ears (tinnitus).
- Hair loss.
- Excessive menstrual bleeding.
- Irregular menstruation.
- Weight loss.
- Accelerated heart rate.
- Swelling of the arms or legs.
- Nosebleeds.

Rare (may affect up to 1 in 1,000 patients):

- Aggression, depersonalization, hallucinations.
- Slowing of the heart rate.

Frequency not known (cannot be estimated from the available data):

- Decrease in the amount of sodium in the blood (symptoms are "feeling sick" - nausea - and a general feeling of being unwell with muscle weakness or confusion).
- Dizziness upon standing up, due to a drop in blood pressure (orthostatic hypotension).
- Disruption of liver function tests (increased blood concentrations of liver enzymes).
- Abnormal movements (involuntary movements).
- Painful erections (priapism).
- Signs of abnormal bleeding, particularly on the skin and mucous membranes (bruising), and low blood platelet count (thrombocytopenia).
- Increased secretion of a hormone, called HAD, which causes water retention in the body and blood dilution, decreasing the amount of sodium (inappropriate secretion of HAD).
- Increased blood levels of the hormone prolactin
- Milk discharge in men and women outside of breastfeeding.
- Mania.
- An increased risk of bone fractures has been observed in patients taking this type of medication.
- Heart rhythm disorder (called "prolonged QT interval", observed on ECG, a test that measures the electrical activity of the heart).
- Heavy vaginal bleeding shortly after birth (postpartum hemorrhage), see "Pregnancy, breastfeeding and fertility" in section 2 for more information.

In addition, a number of side effects are known to occur with medications that work in the same way as escitalopram (the active ingredient in Sipralexa). These include:

- Motor agitation (akathisia).
- Loss of appetite.

Reporting of side effects:
If you experience any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via:

In Belgium:
Federal Agency for Medicines and Health Products
www.afmps.be
Vigilance Division:
Website: www.notifieruneffetindesirable.be
Email: adr@fagg-afmps.be

In Luxembourg:
Regional Pharmacovigilance Centre of Nancy or Pharmacy and Medicines Division of the Directorate of Health.
Website: www.guichet.lu/pharmacovigilance

By reporting side effects, you help provide more information on the safety of the medicine.

5. HOW TO STORE SIPRALEXA?

Keep out of the sight and reach of children.

Do not use this medicine after the expiry date shown on the blister and carton after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage precautions.

Do not dispose of any medication down the drain or in household waste. Ask your pharmacist how to dispose of medications you no longer use. These measures will help protect the environment.

6. PACKAGE CONTENTS AND OTHER INFORMATION

What does Sipralexa contain?

The active substance is escitalopram. Each tablet contains 5 mg, 10 mg, 15 mg or 20 mg of the active substance, escitalopram (as oxalate).

The other components are:
Core: silicified microcrystalline cellulose, talc, croscarmellose sodium and magnesium stearate.
Coating: hypromellose, macrogol 400 and titanium dioxide (E171).

Appearance of Sipralexa and contents of the outer packaging

Sipralexa is available in film-coated tablets of 5 mg, 10 mg, 15 mg and 20 mg, presented as follows:

5 mg: Film-coated tablet (6 mm), round, white, rounded on both sides and marked "EK" on one side.
10 mg: Film-coated tablet (8x5.5 mm), oval, white, scored and marked "E" and "L" on either side of the score line on one side.
15 mg: Film-coated tablet (9.8 x 6.3 mm), oval, white, scored and marked "E" and "M" on either side of the score line on one side.
20 mg: Film-coated tablet (11.5x7 mm), oval, white, scored and marked “E” and “N” on each side of the score line on one side.

The 10, 15 and 20 mg tablets can be divided into 2 equal doses.

Sipralexa is available in:

Blister packs in a cardboard box
5, 10, 15 and 20 mg: 14, 28, 56 and 98 tablets.

Unit Dose packaging
5, 10, 15 and 20 mg: 49x1, 56x1, 98x1, 100x1 and 500x1 tablets.

Not all presentations may be commercially available.

Marketing Authorisation Holder and Manufacturer

H. Lundbeck A/S, Ottiliavej 9, 2500 Valby, Denmark

Local representative:
Lundbeck, Stephanie Square Centre, Avenue Louise 65/11, 1050 Brussels, Belgium

Deliverance

Prescription required.

Marketing authorization number

Sipralexa 5 mg film-coated tablets: BE: BE238962, LU: 2007069294
Sipralexa 10 mg film-coated tablets: BE: BE238971, LU: 2007069295
Sipralexa 15 mg film-coated tablets: BE: BE238944, LU: 2007069296
Sipralexa 20 mg film-coated tablets: BE: BE238953, LU: 2007069297

This medicinal product is authorised in the Member States of the European Economic Area under the following names :

Germany	Cipralex
Austria	Cipralex
Belgium	Sipralexa
Bulgaria	Cipralex
Cyprus	Cipralex
Denmark	Cipralex
Spain	Cipralex
Estonia	Cipralex
Finland	Cipralex
France	Seroplex
Greece	Cipralex
Hungary	Cipralex
Ireland	Lexapro
Iceland	Cipralex
Italy	Cipralex
Latvia	Cipralex 10 mg film-coated tablets; Cipralex 20 mg film-coated tablets
Lithuania	Cipralex
Luxembourg	Sipralexa
Malta	Cipralex
Norway	Cipralex
The Netherlands	Lexapro
Poland	Cipralex
Portugal	Cipralex
Czech Republic	Cipralex
Romania	Cipralex
United Kingdom	Cipralex
Slovakia	Cipralex
Slovenia	Cipralex
Suede	Cipralex

The last date on which this leaflet was revised is 11/2024.