Cipramil

Notice: user information

Cipramil 40 mg/ml solution for dilution for infusion
citalopram

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you. Do not give it to others. It may harm them, even if their signs of illness are the same as yours.
- If you experience any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

Que contient cette notice ?

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

What is Cipramil ?
Cipramil is an antidepressant whose active ingredient is citalopram. It belongs to the group of selective serotonin reuptake inhibitors (SSRIs).

Serotonin is a substance present in everyone's brain. People who are depressed have lower serotonin levels than others. Cipramil and other SSRIs act on the serotonin system in the brain and help increase serotonin levels in the brain.

What is Cipramil used for ?
Cipramil contains citalopram and is used to treat major depressive episodes.
Your doctor may have prescribed Cipramil for other reasons. Contact your doctor if you have any questions about why you should take Cipramil.

2. WHAT YOU NEED TO KNOW BEFORE TAKING CIPRAMIL?

Never take Cipramil

- If you are allergic to the active substance or to any of the other ingredients of this medicine listed in section 6.

- If you are taking other medicines used to treat depression, called non-selective monoamine oxidase inhibitors (MAOIs), including phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, moclobemide (a treatment for depression) and linezolid (an antibiotic). If you have taken any of these medicines, you should wait 14 days before starting Cipramil. One day after stopping moclobemide treatment may be sufficient.

After stopping treatment with Cipramil, you must wait 7 days before taking any of these medicines.

- If you have had or were born with an episode of heart rhythm disturbance (seen on an ECG, a test performed to assess how your heart is working).
- If you are taking treatments for heart rhythm disorders or treatments that could affect your heart rhythm (see section “Other medicines and Cipramil”).

Warnings and precautions
Talk to your doctor or pharmacist before using Cipramil.
Tell your doctor about any other illnesses or medical history you may have, as they may need to be taken into account. In particular, tell your doctor:

- In case of a manic episode or panic disorder. Some manic-depressive patients may develop a manic phase. It is characterized by unusual and rapidly changing ideas, inappropriate joy, and excessive physical activity. If you experience this, contact your doctor.
- If you have liver disease or kidney disease, your doctor may need to adjust your medication doses.
- If you have diabetes. Treatment with Cipramil may alter your blood sugar levels. Adjustment of insulin and/or oral antidiabetic doses may be necessary.
- If you suffer from epilepsy. Treatment with Cipramil should be discontinued if epilepsy develops or if seizures increase in frequency (see section 4 “Possible side effects”).
- If you have any conditions that may cause bleeding, or if you are pregnant (see “Pregnancy, breastfeeding and fertility”).
- If your blood level of sodium, potassium or magnesium is too low.
- In case of electroshock treatment.
- In case of heart rhythm disorders. Such a disorder can be hereditary or appear spontaneously.
- If you have or have had heart problems or have recently had a heart attack.
- If you have a slow resting heart rate and/or know you are at risk of mineral deficiency due to severe and prolonged diarrhea or vomiting or taking diuretic medication.
- If you experience a rapid or irregular heartbeat, fainting, discomfort, or dizziness when standing up, as this may indicate an abnormal heart rhythm.
- If you have or have ever had eye problems, such as certain types of glaucoma (increased pressure inside the eye).
- If you are taking other medicines, please see the section "Other medicines and Cipramil".

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

Symptoms such as restlessness or difficulty sitting or standing still (akathisia) may also occur during the first few weeks of treatment. Consult your doctor immediately in this case.

Suicidal thoughts and worsening of your depression or anxiety disorder
If you suffer from depression and/or anxiety disorders, you may have thoughts of harming yourself or killing yourself. These thoughts may be reinforced when you first start antidepressant treatment because these medications all take time to work, usually about two weeks, but sometimes longer.
The likelihood of having such thoughts is greater:

- If you have previously had suicidal thoughts or thoughts of harming yourself.
- If you are a young adult. Information from clinical trials has shown an increased risk of suicidal behavior in adults under 25 years of age with psychiatric disorders who were treated with an antidepressant.

If you have persistent suicidal thoughts or thoughts of harming yourself, **contact your doctor or go to the hospital directly. You may find it helpful to tell a family member or friend** that you are suffering from depression or an anxiety disorder, and ask them to read this leaflet. You could ask them to alert you if they think your depression or anxiety is getting worse, or if changes in your behavior worry them.

Children and Adolescents
Cipramil should not be used in children and adolescents under 18 years of age. In addition, you should be aware that patients under 18 years of age, treated with this class of medication, have an increased risk of suicide attempts, suicidal thoughts and hostility (mainly aggression, rebellious behavior and anger). However, your doctor may prescribe Cipramil for patients under 18 years of age if he/she judges it to be in their best interest. If your doctor has prescribed Cipramil for a patient under 18 years of age and you wish to discuss this, do not hesitate to contact your doctor. You should inform your doctor if any of the above-mentioned symptoms appear or worsen in a patient under 18 years of age, treated with Cipramil. Long-term safety in relation to growth, maturation and mental and behavioral development has not been evaluated in this age group.

Specific information about your condition
As with other medications used to treat depression or related illnesses, improvement in your condition is not achieved immediately. Several weeks may pass before you feel any improvement. In cases of panic disorder, improvement generally requires 2 to 4 weeks of treatment. In the first few days of treatment, some patients experience an increase in anxiety, which disappears with continued treatment. It is therefore imperative to follow your doctor's advice. Do not stop treatment or change the dose without first speaking to your doctor.

Talk to your doctor, pharmacist or nurse before taking Cipramil.

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

Some medications can affect each other, which can sometimes cause serious side effects.
Tell your doctor if you are taking any of the following medications:

- **MAO inhibitors** (another group of drugs used to treat depression or Parkinson's disease) such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, linezolid (an antibiotic), and moclobemide. If you have been taking any of these drugs, you should wait 14 days

before starting treatment with Cipramil. You should wait one day after stopping treatment with moclobemide before starting treatment with Cipramil. After stopping treatment with Cipramil, you should wait 7 days before taking any of these drugs.

- Medicines containing selegiline **(** irreversible MAO-B inhibitors) because the risk of side effects is increased. The dose of selegiline should not exceed 10 mg per day. Selegiline is used in the treatment of Parkinson's disease.
- Lithium (used in the treatment of manic- depressive disorders) and **tryptophan .**
- Imipramine and **desipramine** (medicines used to treat depression) **.**
- Metoprolol (used for high blood pressure and/or heart problems). Blood levels of metoprolol may increase, although no increase in therapeutic effects or adverse effects related to metoprolol has been reported **.**
- Sumatriptan and similar drugs (used to treat migraines) and **tramadol and similar drugs (opioids used** as strong painkillers). These increase the risk of side effects. Consult your doctor if you experience any unusual symptoms while taking this combination.
- **Cimetidine, lansoprazole, and omeprazole** (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine (antidepressant), and ticlopidine (used to reduce the risk of stroke). These medicines may increase blood levels of citalopram.
- All **medications that can affect blood clotting** , both as a therapeutic effect and as an adverse effect (e.g., some antipsychotics, acetylsalicylic acid (used as a painkiller), nonsteroidal anti-inflammatory drugs (used for arthritis), ticlopidine, and dipyridamole). These may slightly increase the risk of bleeding.
- St. **John's wort** (*Hypericum perforatum* – a herbal preparation for depressed mood). Combining Cipramil with herbal preparations containing St. John's wort may increase the risk of side effects.
- Mefloquine (used to treat malaria), **bupropion** (used to treat depression), and **tramadol (** used to treat severe pain) due to a possible risk of lowering the seizure threshold.
- Neuroleptics (drugs used in the treatment of schizophrenia and psychoses) due to a possible risk of lowering the seizure threshold, and **antidepressants .**
- Do not take Cipramil if you are taking medicines used to treat heart rhythm disorders or that may disrupt the heart rhythm, such as class IA and III **antiarrhythmic drugs, antipsychotics** (e.g., phenothiazine derivatives, pimozide, haloperidol), **tricyclic antidepressants** , certain antimicrobial agents (e.g., sparfloxacin, moxifloxacin, IV erythromycin, pentamidine, antimalarial treatments, especially halofantrine), **certain antihistamines** (astemizole, mizolastine). Contact your doctor or pharmacist if you have any questions about this.
- Drugs **that decrease blood levels of potassium or magnesium** , as these combinations increase the risk of potentially fatal arrhythmias.

Cipramil with food, drinks, and alcohol
You can take Cipramil with or without food. Cipramil does not enhance the effects of alcohol. However, it is advisable not to consume alcohol while taking Cipramil.

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.

Pregnancy
Do not use Cipramil if you are pregnant unless your doctor considers it absolutely necessary.
If you have taken Cipramil during the last three months of your pregnancy and up until delivery, the following effects may occur in the newborn: breathing problems, blue skin discoloration, seizures, changes in body temperature, feeding difficulties, vomiting, low blood sugar, muscle contraction or relaxation, quick reflexes, tremors, irritability, lethargy, constant crying, drowsiness and sleep disturbances. If the newborn shows any of these symptoms, please contact your doctor immediately.
Inform your doctor or midwife that you are being treated with Cipramil. When used during pregnancy, particularly in the last 3 months of pregnancy, medicines such as Cipramil may increase the risk of a serious condition in newborns called persistent pulmonary hypertension of the newborn (PPHN), which causes the newborn to breathe faster and appear blue. These symptoms usually appear within the first 24 hours after birth. If this happens to your newborn, contact your midwife and/or doctor immediately.

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

Breastfeeding
Breastfeeding is not recommended during treatment with Cipramil.

Fertility
In animal studies, citalopram has been shown to reduce sperm quality. Theoretically, this could affect fertility, however, no impact on human fertility has been observed to date.

Driving and using machines
Cipramil does not normally cause drowsiness. If you experience dizziness or drowsiness at the start of treatment, you should avoid driving or operating machinery until these symptoms have subsided.

Cipramil contains sodium
This medicine contains less than 1 mmol (23 mg) sodium per dose, that is to say essentially 'sodium-free'.

3. HOW TO TAKE CIPRAMIL?

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are unsure.

Your doctor will determine your dose. Dosage can vary greatly from person to person.

The recommended dose is:

Adults
The one milliliter vial of concentrate for solution for infusion containing 40 mg/ml will always be diluted in 250 ml of sterile physiological saline or sterile 5% glucose solution. This diluted solution will be administered by infusion into a vein, usually at a rate of one hour per 20 mg of citalopram.

Elderly patients (over 65 years)
The recommended starting dose is half the usual daily dose. Elderly patients should not receive more than 20 mg per day.

Patients at specific risk
Patients with liver failure will not receive more than 20 mg per day.

Use in children and adolescents
Do not give Cipramil to children or adolescents under 18 years of age. For further information, see section 'Warnings and precautions'.

Method and route of administration
The solution to be diluted for infusion is intended only, after dilution, for intravenous administration. This treatment is mainly applied in a hospital setting. The solution to be diluted for intravenous infusion will always be diluted in sterile physiological saline or in sterile 5% glucose solution.

Duration of treatment
The duration is usually 10 to 14 days. Afterwards, the treatment will be continued orally.

If you take more Cipramil than you should
This medicine is administered by your doctor or healthcare staff. An overdose is therefore unlikely.
If you take too much Cipramil, contact your doctor, pharmacist, or the nearest Poison Control Center (070/245.245) or hospital emergency department immediately. Do this even if you do not feel any discomfort. Take the Cipramil pack with you if you go to the doctor or hospital. Some of the signs of overdose can be life-threatening.
Symptoms of overdose may include nausea, vomiting, sweating, agitation, tremors, drowsiness, dizziness, convulsions, coma, serotonin syndrome (see section 4 "Possible side effects?"), low or high blood pressure, fast or slow pulse, heart rhythm disturbances, rapid breathing (hyperventilation), dilated pupils, blue skin discoloration.

If you forget to take Cipramil
It is unlikely that you will be given Cipramil. However, if you think you have missed a dose, tell your doctor or nurse.

If you stop taking Cipramil
Do not stop your treatment without contacting your doctor. The usual duration of treatment with Cipramil concentrate for solution for infusion is 10 to 14 days. Afterwards, you will continue your treatment with Cipramil tablets or a similar treatment.
It may take some time before you feel better. This is normal. Continue treatment as prescribed by your doctor.
Abruptly stopping this type of medicine may cause withdrawal symptoms. These are usually mild and transient.
Dizziness, tingling sensations, tremors, sleep disturbances (nightmares, insomnia, or intense dreams), agitation or anxiety, nausea and/or vomiting, confusion, sweating, headache, diarrhea, palpitations, feeling emotional, irritability, and visual disturbances. For this reason, it is generally recommended to gradually reduce the dose of Cipramil over several weeks. Contact your doctor if you wish to stop treatment.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. WHAT ARE THE POSSIBLE SIDE EFFECTS?

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

Some patients have reported the following severe side effects:
Warning! If you experience any of the following side effects, you should stop treatment and contact your doctor immediately:

- High fever, agitation, confusion, tremors, and sudden muscle twitching. These may be signs of a rare disorder called serotonin syndrome. This syndrome has been reported with several antidepressant medications.
- If you experience swelling of the skin, tongue, lips or face or if you have difficulty breathing or swallowing (a severe allergic reaction).
- Abnormal bleeding, including gastrointestinal bleeding.

Rare but serious side effect (affects less than 1 in 1,000 people)
Warning! If you experience any of the following side effects, you must stop treatment and contact your doctor immediately:

- Hyponatremia: Decreased sodium concentration in the blood with feelings of fatigue, confusion and muscle contractions.
- Rapid or irregular heartbeat, fainting which could be signs of Torsade de Pointes (a life-threatening event).

Side effects are generally mild and usually subside after a few days of treatment. Be aware that some of these effects may also be symptoms of your

illness and will therefore diminish as you begin to feel better.
Tell your doctor if you experience any bothersome side effects or if they last more than two weeks.

Very common (affects more than 1 in 10 people)

- Dry mouth. A dry mouth increases the risk of tooth decay. In this case, it is advisable to brush your teeth more than usual.
- Insomnia
- Drowsiness
- Nausea (feeling unwell)
- Excessive sweating
- Headaches

Common (affects less than 1 in 10 people)

- Hustle
- Decreased appetite, weight loss
- Yawning, fatigue
- Diarrhea, constipation
- Vomiting
- Dizzying sensations
- Tingling sensations in the feet and/or hands
- Itching
- Decreased libido
- Anxiety
- Nervousness
- Confusion, abnormal dreams, attention disorders
- Tremors
- Fever
- Hearing a repetitive sound
- Muscle and/or joint pain
- In men: impotence, ejaculation disorders
- In women: difficulty reaching orgasm

Uncommon (affects less than 1 in 100 people)

- Increased appetite, weight gain
- Aggressiveness
- Depersonalization
- Hallucination
- Mania
- Syncope
- Enlarged pupil
- Fast or slow heart rate
- Hair loss
- Rash
- Urticarial rash (hives), hypersensitivity to light
- Dark spots under the skin (bruise sensitivity)
- Unexpected vaginal bleeding
- Difficulty urinating (urinary retention)
- Swelling of the arms or legs
- Urinary hesitancy, decreased urination

Rare (affects less than 1 in 1,000 people)

- Convulsions
- Involuntary movements
- Taste disorders
- Bleeding
- Hepatitis
- Blood sodium level too low

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

- Allergic reactions including skin rash
- Involuntary muscle movements or muscle stiffness
- Decrease in the number of platelets in the blood (risk of bleeding and bruising)

- Nosebleeds, gastrointestinal bleeding
- Severe allergic reaction with difficulty breathing and dizziness
- Increased urine volume (insufficient secretion of ADH)
- Hypokalemia: decreased potassium concentration in the blood with muscle weakness
- Muscle contractions
- Akathisia: involuntary movements
- Minor subcutaneous bleeding and bleeding from mucous membranes (bruising)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breastfeeding and fertility' in section 2 for further information
- Panic attacks
- Hustle
- Grinding of teeth
- Vision problems
- Blood pressure drops when standing up
- Sudden swelling of the skin and mucous membranes
- Painful erections
- Increased blood levels of the hormone prolactin
- Liver test disturbances
- Suicidal thoughts and suicidal behaviors, see “Warnings and precautions” section
- Milk flow in men and non-breastfeeding women
- Irregularity of the menstrual cycle
- Change in heart rate, measured by electrocardiogram (QT prolongation)
- An increased risk of bone fractures has been observed in patients taking this class of drugs.

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 via:

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

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

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

5. HOW TO STORE CIPRAMIL?

Keep out of sight and reach of children.
Store in the original outer packaging away from light. Once diluted, the solution should be used within 6 hours.

Do not use this medicine after the expiry date which is stated on the label and packaging after "EXP". The expiry date refers to the last day of that month.

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

6. CONTENTS OF THE PACKAGE AND OTHER INFORMATION

What Cipramil contains
The active substance is citalopram in the form of hydrochloride. 1 ml contains 40 mg of citalopram in the form of hydrochloride.

Other ingredients are: sodium chloride, water for injection.

What Cipramil looks like and what it contains
Clear, almost colourless solution.

Cipramil is available in 1 ml colorless ampoules. Boxes of 10 ampoules.

Marketing Authorisation Holder and Manufacturer
Marketing Authorisation Holder
Lundbeck sa - Stephanie Square Centre - Avenue Louise 65/11 – 1050 Brussels

Manufacturer
H. Lundbeck A/S – Ottiliavej 9 – 2500 Valby – Denmark

Conditions of dispensing
Medication subject to medical prescription.

Marketing authorization number:
BE: BE151164
LU: 1997114274

The last date this notice was approved is 01/2025.