

Cipramil®

(SIP-ra-mil)

Citalopram hydrobromide (sigh-TALO-pram high-dro-BRO-mide)

Consumer Medicine Information (CMI)

What is in this leaflet

This leaflet contains answers to some common questions about Cipramil.

It does not contain all the information that is known about Cipramil. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risk of you using this medicine against the benefits he/she expects it will have for you.

If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine.

You may need to read it again.

What Cipramil is used for

Cipramil is used to treat depression.

It belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs). They are thought to work by their actions on brain chemicals called amines which are involved in controlling mood.

Depression is longer lasting or more severe than the "low moods" everyone has from time to time due to the stress of everyday life. It is thought to be caused by a chemical imbalance in parts of the brain. This imbalance affects your whole body and can cause emotional and physical symptoms such as feeling low in spirit, loss of interest in activities, being unable to enjoy life, poor

appetite or overeating, disturbed sleep, often waking up early, loss of sex drive, lack of energy and feeling guilty over nothing.

Cipramil corrects this chemical imbalance and may help relieve the symptoms of depression.

Your doctor, however, may prescribe it for another purpose.

Ask your doctor if you have any questions about why it has been prescribed for you.

This medicine is only available with a doctor's prescription.

Cipramil is not addictive. However, if you suddenly stop taking it, you may get side effects.

Tell your doctor if you get any side effects after stopping Cipramil.

Before you take it

When you must not take it

Do not take Cipramil if you are allergic to it or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include shortness of breath, wheezing or difficulty breathing, swelling of the face, lips, tongue or other parts of the body, or rash, itching or hives on the skin.

Do not take Cipramil at the same time as the following other medicines:

- pimozide, a medicine used to treat mental disorders

monoamine oxidase inhibitors (MAOIs), such as phenelzine, tranylcypromine and moclobemide, which are also used for the treatment of depression, and linezolid (an antibiotic). One day must elapse after you have finished taking moclobemide before you start taking Cipramil. If you have taken any other MAOI you will need to wait 14 days. After stopping Cipramil you must allow 14 days before taking any MAOI including moclobemide.

Taking Cipramil with MAOIs may cause a serious reaction with a sudden increase in body temperature, extremely high blood pressure and severe convulsions. Your doctor will know when it is safe to start Cipramil after the MAOI has been stopped.

Do not take it after the expiry date printed on the pack.

If you take it after the expiry date has passed, it may not work as well. The expiry date refers to the last day of the month.

Do not take it if the packaging is torn or shows signs of tampering.

Before you start to take it

Tell your doctor if:

1. **you have allergies to any other substances such as foods, preservatives or dyes.**
2. **you are pregnant or intend to become pregnant.**

Citalopram 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.

Do not take Cipramil if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

Make sure your doctor and/or midwife know you are on Cipramil.

When taken during pregnancy, particularly in the last three months of pregnancy, medicines like Cipramil may affect the general condition of your newborn baby and may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breathe faster and appear bluish.

These symptoms usually begin during the first 24 hours after the baby is born. If this happens to your baby, you should contact your doctor and/or midwife immediately.

If used during pregnancy Cipramil should never be stopped abruptly.

Ask your doctor or pharmacist for advice before taking any medicine.

3. you are breast-feeding or planning to breast-feed.

Do not take Cipramil if you are breast-feeding unless you and your doctor have discussed the risks and benefits involved. It is not recommended that you breast-feed while taking Cipramil as it is excreted in breast milk.

4. you have, or have had, the following medical conditions:

- a tendency to bleed or bruise easily
- diabetes
- heart disease, especially long QT syndrome or other conduction disorders
- conditions causing changes in the levels of potassium or magnesium in the blood (electrolytes)
- kidney disease
- liver disease

- bipolar disorder (manic depression)
- a history of seizures or fits
- restlessness and/or a need to move often

5. you are receiving electroconvulsive therapy.

6. you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

If you have any of the above medical conditions, your doctor may perform additional tests, such as an ECG to check your heart and blood tests to check potassium and/or magnesium levels.

If you are lactose intolerant, contact your doctor before taking Cipramil.

Cipramil tablets contain lactose.

Do not give Cipramil to a child or adolescent.

There is no experience with its use in children or adolescents under 18 years old.

Cipramil can be given to elderly patients over 65 years of age with a reduced dose.

The effects of Cipramil in elderly patients are similar to that in other patients.

If you have not told your doctor about any of the above, tell them before you use Cipramil.

Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines and Cipramil may interfere with each other. These include:

- bupropion, a medicine helping to treat nicotine dependence
- medicines used to treat reflux and ulcers, such as cimetidine, omeprazole, esomeprazole and lansoprazole

- medicines known to prolong bleeding, e.g. aspirin or other non-steroidal anti-inflammatory drugs (NSAIDs)
- ticlopidine and warfarin, medicines used to prevent blood clots
- mefloquine, an anti-malaria medicine
- sumatriptan, used to treat migraines
- tramadol, used to relieve pain
- carbamazepine, a medicine used to treat convulsions
- medicines that reduce the level of potassium or magnesium in the blood, e.g. diuretics ('fluid tablets')
- some heart medications, such as beta-blockers (e.g. metoprolol, sotalol) or antiarrhythmics (e.g. amiodarone, disopyramide)
- Antifungal medicines e.g. fluconazole, voriconazole
- Some antibiotics, e.g. azithromycin, clarithromycin, erythromycin, roxithromycin, amphotericin, gentamicin
- Antihistamine medicines, used to relieve the symptoms of allergy (such as hay fever) or colds and 'flu, e.g. terfenadine, loratadine, diphenhydramine
- selegiline, a medicine used to treat Parkinson's disease
- tryptophan, an amino-acid
- lithium, used to treat mood swings and some types of depression
- linezolid, an antibiotic
- antipsychotics, a class of medicines used to treat certain mental and emotional conditions e.g. risperidone, thioridazine and haloperidol
- tricyclic antidepressants, e.g. imipramine, desipramine
- St John's Wort (Hypericum perforatum), a herbal remedy
- any other medicines for depression, anxiety, obsessive-

compulsive disorder or pre-menstrual dysphoric disorder.

These medicines may be affected by Cipramil or may affect how well it works. You may need to use different amounts of your medicines or take different medicines. Your doctor will advise you.

Some combinations of medicines may increase the risk of serious side effects and are potentially life threatening.

Drugs that are known to affect the way the heart beats (for example some heart medicines, antibiotics, asthma medicines, antihistamines) should be avoided while taking Cipramil. If it is necessary for you to be on these medicines at the same time as Cipramil, your doctor may perform an ECG test to check your heart rate and rhythm.

Your doctor or pharmacist has more information on medicines to be careful with or avoid while taking Cipramil.

How to take it

How much to take

Your doctor will decide what dose you will receive.

The standard dose for adults for this medicine is between 20 mg and 40 mg (one to two tablets) per day.

The recommended starting dose in elderly patients is 10 mg (half a tablet) per day but may be increased to a maximum of 20 mg (one tablet) per day by your doctor if needed.

If you have liver problems, or are taking medicines such as cimetidine and omeprazole, the recommended starting dose is 10mg (half a tablet) per day. The dose can be increased to a maximum of 20mg (one tablet) per day.

Your doctor may have prescribed a different dose. If you have been prescribed or are currently taking doses of Cipramil greater than

40mg, talk to your doctor about reducing the dose.

Ask your doctor or pharmacist if you are unsure of the correct dose for you.

They will tell you exactly how much to take.

Follow the instructions they give you.

If you take the wrong dose, Cipramil may not work as well and your condition may not improve.

How to take it

Swallow the tablets whole with a full glass of water.

Do not chew them.

When to take it

Take Cipramil as a single dose either in the morning or in the evening.

Take Cipramil with or without food.

How long to take it

Continue to take Cipramil even if it takes some time before you feel any improvement in your condition.

As with other medicines for the treatment of these conditions it may take a few weeks before you feel any improvement.

Individuals will vary greatly in their response to Cipramil. Your doctor will check your progress at regular intervals.

The duration of treatment may vary for each individual but is usually at least 6 months.

In some cases, the doctor may decide that longer treatment is necessary.

Continue taking your medicine for as long as your doctor tells you, 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.

Do not stop taking this medicine suddenly.

If Cipramil is stopped suddenly you may experience mild, but usually temporary, symptoms such as dizziness, pins and needles, sleep disturbances (vivid dreams, inability to sleep), feeling anxious or agitated, headaches, feeling sick (nausea), vomiting, sweating, tremor (shaking), feeling confused, feeling emotional or irritable, diarrhoea, visual disturbances, or fast or irregular heartbeats.

When you have completed your course of treatment, the dose of Cipramil is gradually reduced over a couple of weeks rather than stopped abruptly.

Your doctor will tell you how to reduce the dosage so that you do not get these unwanted effects.

If you forget to take it

If you miss a dose and remember in less than 12 hours, take it straight away, and then go back to taking it as you would normally.

Otherwise, if it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Do not take a double dose to make up for the dose you have missed.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for hints.

If you take too much (overdose)

Immediately telephone your doctor, or the Poisons Information Centre (Tel: 0800 764 766 or go to Accident and Emergency at your nearest hospital, if you think you or anyone else may have taken too much Cipramil.

Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

Symptoms of an overdose may include nausea (feeling sick), vomiting, dizziness, fast or slow heart beat or change in heart rhythm, decreased or increased blood pressure, tremor (shaking), agitation, dilated pupils of the eyes, drowsiness and sleepiness. Convulsions or coma may occur. A condition called serotonin syndrome may occur with high fever, agitation, confusion, trembling and abrupt contractions of muscles.

While you are taking it

Things you must do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking Cipramil.

Tell any other doctors, dentists and pharmacists who treat you that you are taking this medicine.

If you become pregnant while taking Cipramil, tell your doctor immediately.

Persons taking Cipramil may be more likely to think about killing themselves or actually trying to do so, especially when Cipramil is first started or the dose is changed. Tell your doctor immediately if you have thoughts about killing yourself or if you are close to or care for someone using Cipramil who talks about or shows signs of killing him or herself.

All mentions of suicide or violence must be taken seriously.

Occasionally, the symptoms of depression may include thoughts of suicide or self-harm. It is possible that these symptoms continue or get worse until the full antidepressant effect of the medicine becomes apparent. This is more likely to occur if you are a young adult, i.e. 18 to 24

years of age, and you have not used antidepressant medicines before.

Patients and care givers should pay attention for any of the following warning signs of suicide-related behaviour while taking Cipramil. Tell your doctor immediately, or even go to the nearest hospital for treatment:

- thoughts or talk of death or suicide
- thoughts or talk of self-harm or harm to others
- any recent attempts of self-harm
- increase in aggressive behaviour, irritability or agitation.

Do not stop taking this medicine or change the dose without consulting your doctor, even if you experience increased anxiety at the beginning of treatment.

At the beginning of treatment, some patients may experience increased anxiety which will disappear during continued treatment.

Tell your doctor immediately if you experience symptoms such as restlessness or difficulty in sitting or standing still.

These symptoms can occur during the first weeks of treatment.

Contact your doctor as soon as possible if you suddenly experience an episode of mania.

Some patients with bipolar disorder (manic depression) may enter into a manic phase. This is characterised by profuse and rapidly changing ideas, exaggerated gaiety and excessive physical activity.

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 behaviour.

Medicines like Cipramil may cause symptoms of sexual dysfunction (see section "Side effects").

In some cases, these symptoms have continued after stopping treatment.

Things you must not do

Do not give the tablets to anyone else, even if they have the same condition as you.

Do not take Cipramil to treat any other complaints unless your doctor tells you to.

Do not stop taking Cipramil, or lower the dosage, without checking with your doctor.

Do not let yourself run out of medicine over the weekend or on holidays.

Suddenly stopping Cipramil may cause unwanted discontinuation symptoms such as dizziness, headache and nausea. Your doctor will tell you when and how Cipramil should be discontinued. Your doctor will gradually reduce the amount you are using, usually over a period of one to two weeks, before stopping completely.

Things to be careful of

Be careful driving or operating machinery until you know how Cipramil affects you.

It may cause nausea, fatigue and dizziness in some people, especially early in the treatment. If you have any of these symptoms, do not drive, operate machinery, or do anything else that could be dangerous.

Avoid alcohol while you are taking this medicine.

It is not advisable to drink alcohol while you are being treated for depression.

Side effects

All medicines may have some unwanted side effects. Sometimes they are serious, but most of the time they are not. Your doctor has weighed the risks of using this medicine against the benefits he/she expects it will have for you.

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Cipramil.

It helps most people with depression, but it may have unwanted side effects in a few people.

The side effects of Cipramil are, in general, mild and disappear after a short period of time.

Tell your doctor if you notice any of the following and they worry you:

- itching
- ringing or other persistent noise in the ears
- aching muscles or joint pain
- flu-like symptoms, fever, runny or blocked nose, sneezing, facial pressure or pain, coughing or sore throat
- increased sweating
- increased saliva or dry mouth, taste disturbance
- loss of appetite or increased appetite, weight decrease or weight increase
- diarrhoea, constipation, flatulence, indigestion, stomach pain or discomfort
- dizziness
- nausea (feeling sick) or vomiting
- migraine, headache
- sleepiness or drowsiness, fatigue, yawning
- a sense of indifference to everything
- sexual disturbances (decreased sexual drive, problems with orgasm; problems with ejaculation or erection)
- problems with menstrual periods
- Restlessness or difficulty keeping still

Tell your doctor as soon as possible if you notice any of the following:

- chest pain
- a fast heart rate or decrease in heart rate or irregular heartbeat

- shortness of breath
- fainting
- dizziness when you stand up due to low blood pressure
- blurred vision
- low sodium levels in the blood (the symptoms are feeling sick and unwell with weak muscles or feeling confused) which may be caused by SSRI antidepressants, especially in elderly patients
- increased tendency to develop bruises
- unusual bleeding, including bleeding from the stomach or bowel
- passing more urine than normal or problems when urinating
- tingling or numbness of the hands or feet
- nervousness, confusion, problems with concentration, loss of memory
- agitation, anxiety, worsening of depression.

These may be serious side effects of Cipramil. You may need urgent medical attention.

Tell your doctor immediately, or go to Accident and Emergency at your nearest hospital, if you notice any of the following:

- thoughts of suicide
- serious allergic reaction
(symptoms of an allergic reaction may include swelling of the face, lips, mouth or throat which may cause difficulty in swallowing or breathing, or hives)
- high fever, agitation, confusion, trembling and abrupt contractions of muscles
(these symptoms may be signs of a rare condition called serotonin syndrome which has been reported with the combined use of antidepressants)
- tremors, movement disorders (involuntary movements of the muscles).

- fast, irregular heart beat with feelings of dizziness, faintness, loss of consciousness or difficulty breathing

These are very serious side effects. You may need urgent medical attention or hospitalisation.

Tell your doctor if you notice anything else that is making you feel unwell.

Other side effects not listed above may occur in some people.

An increased risk of bone fractures has been observed in patients taking medicines like Cipramil.

Do not be alarmed by this list of possible side effects.

You may not experience any of them.

After taking it

Storage

Keep Cipramil tablets in the blister pack until it is time to take them.

If you take the tablets out of the box or the blister pack, they may not keep well.

Keep Cipramil tablets in a cool dry place where the temperature stays below 25°C.

Do not store it or any other medicine in the bathroom, near a sink, or on a window-sill.

Do not leave it in the car.

Heat and damp can destroy some medicines.

Keep it where children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking the tablets, or the tablets have passed their expiry date, ask your pharmacist what to do with any that are left over.

Return any unused medicine to your pharmacist.

"Cipramil" is the registered trademark of H. Lundbeck A/S.

Product description

What it looks like

Cipramil 20 mg film-coated tablets are oval, white, scored and marked with "C" and "N".

A box contains 28 tablets.

Ingredients

Active ingredient(s):

- Cipramil 20 mg tablets - 20 mg citalopram (as hydrobromide) per tablet

Inactive ingredients:

- microcrystalline cellulose
- croscarmellose sodium
- glycerol
- hypromellose
- lactose monohydrate
- macrogol 400
- magnesium stearate
- copovidone
- maize starch
- titanium dioxide.

Cipramil does not contain gluten, sucrose, tartrazine or any other azo dyes.

Manufacturer/Sponsor

Cipramil is made by H. Lundbeck A/S, Denmark.

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