

# CIPRAM TABLETS

Citalopram (as hydrobromide) (20mg)

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## What Cipram is used for

Cipram is used to treat depression and to help prevent recurrent depression. Cipram is also beneficial in relieving symptoms in patients prone to panic attacks, and in patients with obsessive-compulsive disorder (OCD) [Persistent, obsessive thoughts (obsessions) that lead to uncontrollable, repetitive behaviour (compulsions)].

Your doctor, however, may prescribe Cipram for another purpose. Ask your doctor if you have any questions about why Cipram has been prescribed for you.

## How Cipram works

Cipram contains the active ingredient citalopram. Cipram belongs to a group of antidepressants called Selective Serotonin Reuptake Inhibitors (SSRIs). They are thought to help by increasing the amount of serotonin in your brain, which are involved in controlling mood.

## Before you use Cipram

### - *When you must not use it*

- if you are allergic to citalopram or any of the other ingredients of this medicine (see **Product Description**).
- if you take other medicines which belongs to a group called monoamine oxidase inhibitors (MAOIs). MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, moclobemide (used in the treatment of depression) and linezolid (an antibiotic). The MAO-inhibitor called selegiline (used in the treatment of Parkinson's disease) may be used in combination with citalopram, but only at doses of less than 10 mg per day.
- at the same time as taking pimozone.

- 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).

Even if you have finished taking MAOIs you will need to wait 2 weeks before you start getting your Cipram treatment. One day must elapse after you have finished taking moclobemide. After stopping Cipram you must allow 1 week before taking any MAOI.

### - *Before you start to use it*

Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor:

- if you have episodes of mania (feeling abnormally elated or over-excited, which causes unusual behaviour) or panic disorder.
- if you suffer from impaired liver or kidney function. Your doctor may need to adjust your dosage.
- if you have diabetes. Treatment with Cipram may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- if you have epilepsy. Treatment with Cipram should be stopped if seizures occur or if there is an increase in the seizure frequency (see also section **Side effects**).
- if you have some kind of bleeding disorders.
- if you have a decreased level of sodium in the blood.
- if you are receiving electroconvulsive treatment (ECT) for severe depression or other mental illnesses.
- if you suffer or have suffered from heart problems or have recently had a heart attack.
- if you have a low resting heart-rate 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 intolerance to some sugars (for example lactose)

Please consult your doctor, even if these statements were applicable to you at any time in the past.

### *Pregnancy, breast-feeding and fertility*

Inform your doctor if you are pregnant or planning to become pregnant. Pregnant women should not usually take Cipram nor should mothers breast-feed their babies while taking this medicine, unless you and your doctor have discussed the risks and benefits involved.

### - *Taking other medicines*

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

Some medicinal products may affect the action of another and this can sometimes cause serious adverse reactions.

Tell your doctor if you are taking any of the following medicines:

- MAOIs (see *When you must not use it*)
- Lithium (used for mental illness) and tryptophan (an amino acid).
- Imipramine and desipramine (both used to treat depression).
- Metoprolol (used for high blood pressure and/or heart disease); the blood levels of metoprolol are increased, but signs of increased effect or side effects of metoprolol have not been recorded.
- Sumatriptan and similar medicines (used to treat migraine) and tramadol (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 (used to treat stomach ulcers); blood levels of Cipram may be increased but increased side effects of Cipram have not been recorded.
- Drugs known to affect the platelet function (e.g. some antipsychotic drugs for mental illness, tricyclic antidepressants (TCAs), acetylsalicylic acid or aspirin (used as pain killers), non-steroidal anti-inflammatory drugs (NSAIDs, used for arthritis); increased risk of bleeding abnormalities.
- St John's wort (*Hypericum perforatum*) (a herbal remedy used for depression); concomitant intake with Cipram may increase the risk of side effects.
- Mefloquin (used to treat Malaria), bupropion (used to treat depression),

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tramadol (used to treat severe pain) and neuroleptics (medicines to treat schizophrenia, psychosis) due to a possible risk of a lowered threshold for seizures, and antidepressants

- Class IA and III antiarrhythmics for heart rhythm problems, antipsychotics (e.g. fentiazine derivatives, pimozide, haloperidol), TCAs, certain antimicrobial agents for infections (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarian treatment particularly holofantrine), certain antihistamines for cold and allergy (astemizole, mizolastine).
- Cipram has been shown not to increase the effects of alcohol. Nevertheless, it is recommended not to drink alcohol during treatment with Cipram.

## How to use Cipram

### - How much to use

Always take this medicine exactly as your doctor or pharmacist has told you.

### Adults

#### Depression

The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

#### Panic disorder

The starting dose is 10 mg per day for the first week before increasing the dose to 20-30 mg per day. The dose may be increased by your doctor to a maximum of 40 mg per day.

#### Obsessive-compulsive disorder (OCD)

The starting dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

#### Elderly patients (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g. 10-20 mg per day.

If you are elderly, you should receive a lower dose not more than 20 mg per day.

#### Patients with special risks

If you have liver problems, you should receive a lower dose not more than 20 mg per day.

### Children and adolescents (< 18 years)

Cipram should not be given to children or adolescents (see also Things to be careful of).

#### - When to use it

Cipram is taken every day as a single daily dose.

Cipram can be taken any time of the day with or without food.

Swallow the tablets with a drink of water.

#### - How long to use it

Like other medicines for depression, panic disorder and OCD these may take a few weeks before you feel any improvement.

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

Never change the dose of the medicine without talking to your doctor first.

The duration of treatment is individual, usually at least 6 months. Continue to take Cipram for as long as your doctor recommends. Do not stop taking them even if you begin to feel better, unless you are told to do so by your doctor. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return.

Patients who have recurrent depressions benefit from continued treatment, sometimes for several years, to prevent the occurrence of new depressive episodes.

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#### - If you forget to use it

Do not take a double dose to make up for a forgotten dose. If you 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 use too much (overdose)

If you think that you or anyone else may have taken too much Cipram, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the Cipram box/container with you if you go to a doctor or hospital.

Some of the signs of an overdose could be life-threatening irregular heartbeat, fits, drowsiness, coma, vomiting, trembling, decreased or increased blood pressure, nausea (feeling sick), serotonin syndrome

(see **Side effects**), restlessness, dizziness, dilated pupils of the eye, sweating, bluish skin, abnormally fast and deep breathing.

## While you are using it

### - Things you must do

Read this leaflet carefully before you start 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. If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

### - Things you must not do

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

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

### - Things to be careful of

#### Driving and using machines

Cipram generally does not cause drowsiness; however, if you feel dizzy or sleepy when you start to take this medicine, do not drive or work any tools or machinery until these effects wear off.

#### Children and adolescents under 18 years of age

Cipram should normally 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. Despite this, your doctor may prescribe Cipram for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Cipram for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any symptoms listed above develop or worsen when patients under 18 are taking Cipram.

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*Thoughts of suicide and worsening of your depression or anxiety disorder*

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself.
- if you are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant.

It is possible that these symptoms continue or get worse until the full antidepressant effect of the medicine becomes apparent. If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away**. 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.

**You may find it helpful to tell a relative or close friend**, that you are depressed or have an anxiety disorder, and ask them to read this leaflet. You might ask them to tell you if they think your depression or anxiety is getting worse, or if they are worried about changes in your behaviour.

*Please note:*

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 (akathisia) can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

## Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The side effects usually disappear after a few weeks of treatment. Please be aware that many of the effects may also be

symptoms of your illness and therefore will improve when you start to get better.

Some patients have reported the following serious side effects. If you get any of the following symptoms you should stop taking Cipram and see your doctor immediately:

- High fever, restlessness, confusion, trembling and abrupt contractions of muscles; these may be signs of a rare condition called **serotonin syndrome**
- If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction).
- Unusual bleeds, including gastrointestinal bleeds.

*Rare but serious side effects (may affect up to 1 in 1,000 people):*

If you get any of the following symptoms you should stop taking Cipram and see your doctor immediately:

- Hyponatraemia: low blood levels of sodium which can cause tiredness, confusion, and muscle twitching.

*Very common (may affect more than 1 in 10 people):* Sleepiness, difficulty in sleeping, increased sweating, dry mouth, nausea (feeling sick). Dry mouth increases the risk of caries. Therefore you should brush your teeth more often than usual.

*Common (may affect up to 1 in 10 people):*

Decreased appetite, agitation, decreased sexual drive, anxiety, nervousness, confusional state, abnormal dreams, trembling, tingling or numbness in the hands or feet, dizziness, disturbance in attention, ringing in the ears (tinnitus), yawning, diarrhea, vomiting, constipation, itching, pain in muscle and joints, men may experience problems with ejaculation and erection, women may experience failure to achieve sexual pleasure, fatigue, fever, prickling of the skin, decreased weight

*Uncommon (may affect up to 1 in 100 people):*

Cutaneous bleeding disorder (easily bruising), increased appetite, aggression, depersonalisation (feelings of unreality and strangeness concerning oneself or the environment), hallucination (hearing voices or seeing things which are not there), mania, fainting, enlarged pupils, fast heart beat,

slow heart beat, hives, loss of hair, rash, light sensitiveness, difficulties urinating, excessive menstrual bleeding, swelling of the arms or legs, increased weight

*Rare (may affect up to 1 in 1,000 people):* Convulsions, involuntary movements, taste disturbance, bleeding, hepatitis

*Not known (frequency cannot be estimated from the available data):*

Thoughts of harming yourself or thoughts of killing yourself (see also *Things to be careful of*), reduction in blood platelets, which increases risk of bleeding or bruising, hypersensitivity (rash), serious allergic reaction which causes difficulty in breathing or dizziness, increase in the amount of urine excreted, hypokalaemia: low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm, panic attack, grinding one's teeth, restlessness, unusual muscle movements or stiffness, akathisia (involuntary movements of the muscles), visual disturbance, low blood pressure, nosebleed, bleeding disorders including skin and mucous bleeding (ecchymosis), sudden swelling of skin or mucosa, painful erections, slow of milk in men and in women that are not nursing, irregular menstrual period, abnormal liver function test, an increased risk of bone fractures has been observed in patients taking this type of medicines, abnormal heart rhythm

If you get any side effects, talk to your doctor or pharmacist. Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website [portal.bpfk.gov.my](http://portal.bpfk.gov.my) (Consumers → Reporting).

## Storage and Disposal of Cipram

- *Storage*

Keep this medicine out of the sight and reach of children. Store below 25°C.

- *Disposal*

Ask your pharmacist how to throw away medicines you no longer use.

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## Product Description

### - What it looks like

Cipram is presented as 20 mg film-coated tablets and are available in blister packs.

The tablets are round, white.

The 20 mg tablets are marked with “C” and “N”.

### - Ingredients

#### - Active ingredient:

Citalopram (as hydrobromide).

#### - Inactive ingredient:

maize starch, lactose monohydrate, microcrystalline cellulose, copovidone, glycerol 85%, croscarmellose sodium, magnesium stearate.

*Coating:* Hypromellose 5, macrogol 400.

*Colour:* Titanium dioxide (E 171).

### - MAL No.:

20mg: MAL19950394A

## Manufacturer

H. Lundbeck A/S,

Ottiliavej 9, 2500 Valby, Denmark

## Product Registration Holder

Lundbeck Malaysia Sdn. Bhd.

A-05-01, Oasis Square,

Jalan PJU 1A/7A, Ara Damansara,

47301 Petaling Jaya

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27/07/2015

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