XP-069-22-20-13402

Package leaflet: Information for the user

Cipram®
20 mg film-coated tablets

Citalopram (as hydrobromide)

Read all of 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.
- 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.
- If you get any side effects, talk to you doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet

1. What Cipram is and what it is used for

How does Cipram work
Cipram belongs to a group of antidepressants called Selective Serotonin Reuptake Inhibitors (SSRIs). These medicines act on the serotonin-system in the brain by increasing the serotonin level. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

What is Cipram used for
Cipram contains citalopram and is used to treat depression and when you feel better, to help prevent these symptoms recurring.
Further, Cipram is used for long-term treatment to prevent the occurrence of new depressive episodes in patients who have recurrent depressions.
Cipram is also beneficial in relieving symptoms in patients prone to panic attacks.

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.

2. What you need to know before you take Cipram

Do not take Cipram:
- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6).
- 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, selegiline (used in the treatment of Parkinson´s disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic).
- at the same time as taking pimozide.
- 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.

Warnings and precautions

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 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 4 “Possible 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.
- 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 or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

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

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.

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.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away.**
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.

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.

Special information relating to your disease
As with other medicines used to treat depression or related diseases, the improvement is not achieved immediately. After the start of Cipram 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 increased anxiety, which will disappear 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. 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. under 25 years of age and you have not used antidepressive medicines before.

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 of 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.

Other medicines and Cipram
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:

- ”Non-selective monoamine oxidase inhibitors (MAOIs)”, containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active substance. If you have taken any of these medicines you will need to wait 14 days before you start taking Cipram. After stopping Cipram you must allow 7 days before taking any of these medicines.
- “Reversible, selective MAO-A inhibitors”, containing moclobemide (used to treat depression).
- The antibiotic linezolid.
- Lithium (used in the prophylaxis and treatment of manic-depressive disorder) and tryptophan.
- Imipramine and desipramine (both used to treat depression).
- “Irreversible MAO-B inhibitors”, containing selegiline (used to treat Parkinson's disease); these increase the risk of side effects. The dose of selegiline must not exceed 10 mg per day.
- 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) these increase the risk of side effects; if you get any unusual symptoms when using this combination you should see your doctor.
- Cimetidine, when used in high doses (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, tricyclic antidepressants, acetylsalicylic acid (used as pain killers), non-steroidal anti-inflammatory drugs (used for arthritis)); slightly 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) and tramadol (used to treat severe pain) due to a possible risk of a lowered threshold for seizures.
- Neuroleptics (medicines to treat schizophrenia, psychosis) due to a possible risk of a lowered threshold for seizures, and antidepressants.
- Class IA and III antiarrhytmics, antipsychotics (e.g. fentiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarian treatment particularly holofantrine), certain antihistamines (astemizole, mizolastine).
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life threatening heart rhythm disorder.

Cipram with food, drink and alcohol
Cipram can be taken with or without food (see section 3 “How to take Cipram”).

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

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.

If you take Cipram during the last 3 months of your pregnancy and until the date of birth you should be aware that the following effects may be seen in your newborn: trouble with breathing, blue-ish 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. If your newborn baby has any of these symptoms, please contact your doctor immediately.

Make sure your midwife and/or doctor know you are on Cipram. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Cipram 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 midwife and/or doctor immediately.

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.

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.

Important information about some of the ingredients of Cipram
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take Cipram

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

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.

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.
Elderly patients should not usually receive more than 20 mg per day.

Patients with special risks
Patients with liver complaints should not receive more than 20 mg per day.

Children and adolescents (< 18 years)
Cipram should not be given to children or adolescents. For further information please see section 2 "What you need to know before you take Cipram".

How and when to take Cipram
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. Do not chew them (they have a bitter taste).

Duration of treatment
Like other medicines for depression and panic disorder, these tablets 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 the tablets 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.

If you take more Cipram than you should
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 heart beat, convulsion, change in heart rhythm, drowsiness, coma, vomiting, tremor, decreased blood pressure, increased blood pressure, nausea (feeling sick), serotonin syndrome (see section 4), agitation, dizziness, dilated pupils of the eye, sweating, bluish skin, hyperventilation.

If you forget to take Cipram
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 stop taking Cipram
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.

Abrupt cessation of the medication may cause mild and transient discontinuation symptoms such as dizziness, feelings like pins and needles, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling sick (nausea), vomiting, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

When you have completed your course of treatment it is therefore advised that the dose of Cipram is gradually reduced over a couple of weeks rather than stopped abruptly.

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

4. Possible 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, agitation, confusion, trembling and abrupt contractions of muscles; this may be signs of a rare condition called serotonin syndrome which has been reported with the combined use of antidepressants.
- 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.

The following side effects are often mild and usually disappear after a few days' treatment. Be aware that several of the below mentioned effects also can be symptoms of your illness and therefore wanes when you start to get better.

If side effects are troublesome or last for more than a few days tell your doctor.

Dry mouth increases the risk of caries. Therefore you should brush your teeth more often than usual.

Very common (may affect more than 1 in 10 people):
Sleepiness
Difficulty in sleeping
Increased sweating
Dry mouth
Nausea (feeling sick)
Headache

Common (may affect up to 1 in 10 people):
Decreased appetite
Agitation
Decreased sexual drive
Anxiety
Nervousness
Confusional state
Abnormal dreams
Tremor
Tingling or numbness in the hands or feet
Dizziness
Disturbance in attention
Ringing in the ears (tinnitus)
Yawning
Diarrhoea
Vomiting
Constipation
Itching
Pain in muscle and joints
Men may experience problems with ejaculation and erection
Women may experience failure to achieve an orgasm
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
Depersonalization
Hallucination
Mania
Fainting
Enlarged pupils
Fast heart beat
Slow heart beat
Nettle rash
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 section "Warnings and precautions"
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
Flow 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. This includes any possible side effects not listed in this leaflet.

5. How to store Cipram

Keep this medicine out of the sight and reach of children.

Store below 30°C.

Do not use this medicine after the expiry date which is stated on the label or carton. The expiry date refers to the last day of that month.

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

6. Contents of the pack and other information

What Cipram contains
The active substance is citalopram (as hydrobromide).
Cipram film-coated tablets contain 20 mg citalopram (as citalopram hydrobromide).
The other ingredients are maize starch, lactose monohydrate, microcrystalline cellulose, copovidone, glycerol 85%, croscarmellose sodium, magnesium stearate.
Coating: Hypromellose 5, macrogol 400.
Colour: Titanium dioxide (E 171).

What Cipram looks like and contents of the pack
Cipram is presented as 20 mg film-coated tablets and are available in blister packs or polypropylene containers.

Description of Cipram tablets
The 20 mg tablets are oval, white, scored, film-coated, marked with "C" and "N".

Cipram is available in the following packs:
20 mg: 14, 20, 28, 50, 56, 98, and 100 tablets in blister packs, 100, 250 and 500 tablets in polypropylene containers.

Not all pack sizes may be marketed.

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