PATIENT INFORMATION LEAFLET

Scheduling status:

S5

Cipramil 20 mg Tablets

Citalopram

Contains sugar: Lactose monohydrate 23,1 mg per tablet

Read all of this leaflet carefully before you start taking Cipramil

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- Cipramil has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

1. What Cipramil is and what it is used for:

How does Cipramil work:

Cipramil 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 Cipramil used for:

Cipramil is used to treat depression and when you feel better, to help prevent these symptoms recurring.

Cipramil is also beneficial in relieving symptoms in patients prone to panic attacks and in patients with obsessive-compulsive disorder (OCD).

2. What you need to know before you take Cipramil:

Do not take Cipramil

- if you are allergic (hypersensitive) to citalopram or any of the other ingredients of Cipramil (see **What Cipramil contains**)
- if you take other medicines which belongs to a group called monoamine oxidase inhibitors (MAOIs). MAOIs include medicines such as phenelzine, 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 suffer from severely impaired kidney function (creatinine clearance less than 30 ml/min)
- 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) (QT prolongation)
- if you are under the age of 18 years
- if taking other medicine that prolong the QT interval

Even if you have finished taking MAOIs you will need to wait 2 weeks before you start getting your Cipramil treatment.

After stopping Cipramil you must allow 1 week before taking any MAOI

Warnings and precautions

Take special care with Cipramil

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 anxiety
- if you suffer from reduced liver or kidney function. Your doctor may need to adjust your dosage
- if you have diabetes. Treatment with Cipramil may alter glycaemic control. Insulin and/or oral hypoglycaemic (anti-diabetic) dosage may need to be adjusted.
- if you have epilepsy. Treatment with Cipramil should be stopped if seizures (fits) occur or if there is an increase in the seizure frequency (see also **Possible Side effects**)
- if you have bleeding disorders, or if you are pregnant (see **Pregnancy, breastfeeding and fertility**)
- if you have a decreased level of sodium in the blood
- if you are receiving electroconvulsive treatment (ECT)
- 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.

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 Cipramil, since it takes 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.

Use in children and adolescents under 18 years of age

Cipramil should not be used for children and adolescents under 18 years. 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.

Special information relating to your disease

Improvement is not achieved immediately. After the start of Cipramil treatment it may take several weeks before you experience any improvement.

In the treatment of panic disorder it usually takes 3 months 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 Cipramil

Always tell your healthcare provider if you are taking any other medicine. (This includes complementary or traditional 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 Cipramil. After stopping Cipramil 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), tramadol and similar medicines (opioids, 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 Cipramil may be increased but increased side effects of Cipramil have not been recorded
- medicines known to affect the platelet function (e.g. some antipsychotic medicines, tricyclic antidepressants, aspirin (used as pain killers), non-steroidal anti-inflammatory medicines (used for arthritis)); slightly increased risk of bleeding abnormalities
- St John's wort (hypericum perforatum) (a herbal remedy used for depression) - concomitant intake with Cipramil 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 (fits), and antidepressants
- Class IA and III antidysrhytmics (medicines taken for irregular heartbeats), antipsychotics (e.g. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly holofantrine), certain antihistamines (astemizole, mizolastine)

Cipramil with food, drink and alcohol

Cipramil can be taken with or without food.

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

Pregnancy, breastfeeding and fertility

Safe use of Cipramil in pregnancy and lactation has not been demonstrated.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking Cipramil.

Pregnant women should not take Cipramil 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 Cipramil 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, bluish 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 Cipramil. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Cipramil 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.

If you take Cipralex near the end of your pregnancy there may be an increased risk of heavy vaginal bleeding shortly after birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Cipralex so they can advise you.

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

Cipramil 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.

Cipramil contains lactose

Important information about some of the ingredients of Cipramil

If you have been told by your doctor that you have an intolerance to some sugars such as lactose, contact your doctor before taking Cipramil.

3. How to take Cipramil:

Do not share medicines prescribed for you with any other person.

Always take Cipramil exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure or need further information.

Adults

Depression

The usual dose is 20 mg per day. The dose 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. 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 receive more than 20 mg per day.

Patients with special risks

For patients with liver complaints, the starting dose should be 10mg daily for the first two weeks of treatment. The dose may be increased by your doctor to a maximum of 20 mg per day.

Children and adolescents (< 18 years)

Cipramil should not be given to children or adolescents. For further information please see **Contraindications - Do not take Cipramil**.

How and when to take Cipramil:

Cipramil is taken every day as a single daily dose.

Cipramil 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:

For depression, panic disorder and OCD these tablets may take a few weeks before you feel any improvement. Continue to take Cipramil 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 Cipramil than you should:

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.
Do this even if there are no signs of discomfort or poisoning. Take the Cipramil 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, convulsion, change in heart rhythm, drowsiness, coma, vomiting, tremor, decreased blood pressure, increased blood pressure, nausea (feeling sick), Serotonin syndrome (see **Possible Side effects**), agitation, dizziness, dilated pupils of the eye, sweating, blue-ish skin, hyperventilation.

If you forget to take Cipramil:

Do not take a double dose to make up for forgotten doses. 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 Cipramil:

Do not stop taking Cipramil until your doctor tells you to do so. When you have completed your course of treatment, it is generally advised that the dose of Cipramil 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 Cipramil 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:

Cipramil can cause side effects.

Not all side effects reported for Cipramil are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking Cipramil, please consult your health care provider for advice.

Some patients have reported the following serious side effects.

If you get any of the following symptoms you should stop taking Cipramil 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.
- If you experience swelling of skin, tongue, lips, or face, or have difficulties breathing or swallowing (allergic reaction).
- Unusual bleeds, including gastrointestinal bleeds

If you get any of the following symptoms you should stop taking Cipramil 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.

Frequent side effects:

- Sleepiness
- Difficulty in sleeping
- Increased sweating
- Dry mouth
- Nausea (feeling sick)
- 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
- For females, failure to achieve an orgasm
- Fatigue
- Fever
- Prickling of the skin
- Decreased weight

Less frequent side effects:

- 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
- Vaginal bleeding
- Swelling of the arms or legs
- Increased weight
- Convulsions
- Involuntary movements
- Taste disturbance
- Bleeding
- Hepatitis

Some patients have reported (frequency not known):

- Thoughts of harming yourself or thoughts of killing yourself, see **Warnings and precautions**: **Take special care with Cipramil.**
- 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)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see **Pregnancy, breastfeeding and fertility** in section 2 for more information
- Sudden swelling of skin or mucosa
- Painful erections
- Increased blood levels of the hormone prolactin
- 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 any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of Cipramil.

5. How to store Cipramil

Store at or below 25 ºC.

Store all medicines out of reach of children.

Do not use Cipramil after the expiry date, which is stated on the blister and or carton.

The expiry date refers to the last day of the month.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Cipramil contains:

Each tablet contains: citalopram hydrobromide corresponding to 20 mg citalopram;

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

Coating: hypromellose 5, macrogol 400.

Colour: titanium dioxide (E 171).

What Cipramil looks like and contents of the pack

Cipramil is presented as blister packs containing 28 tablets.

Identification of Cipramil:

Cipramil 20 mg Tablets:

Oval (8 x 5.5 mm), white, scored, film-coated and marked “C” and “N” symmetrically around the score.

Holder of Certificate of Registration:

Adcock Ingram Limited

1 New Road

Erand Gardens

Midrand, 1685

Customer Care: 0860 ADCOCK / 232625

PATIENT INFORMATION LEAFLET

This leaflet was last revised in

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