Package leaflet: Information for the user

Cipramil 40 mg/ml oral drops, solution
Citalopram (as hydrochloride)

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 your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

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.

What is Cipramil used for
Cipramil contains citalopram and is used for the treatment of depression and when you feel better, to help prevent these symptoms recurring.

Further, Cipramil is used for long-term treatment to prevent the occurrence of new depressive episodes in patients who have recurrent depression.

Cipramil is also beneficial in relieving symptoms in patients prone to panic attacks.

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

2. What you need to know before you take Cipramil

Do not take Cipramil:
- 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 belong 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)
- 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)
- if you take medicines for heart rhythm problems or that may affect the heart's rhythm (see "Other medicines and Cipramil")

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

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 Cipramil may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted
- if you have epilepsy. Treatment with Cipramil 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 disorder, or if you are pregnant (see ‘Pregnancy, breast-feeding and fertility’).
- 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 a problem with dilatation of the pupil of the eye (mydriasis) or if you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).
- if you have so-called psychosis with depressive episodes. Cipramil might make your psychotic symptoms worse.

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.

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

Children and adolescents
Cipramil 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 Cipramil for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Cipramil 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 Cipramil. Also, the long term safety effects concerning growth, maturation and cognitive and behavioural development of Cipramil in this age group have not yet been demonstrated.

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 Cipramil 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.

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 behavior.

Tell your doctor immediately or contact the nearest hospital if you have disturbing thoughts or experiences or if any of the above-mentioned symptoms occurs during the treatment.

Other medicines and Cipramil

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 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. Dose adjustment may be required.
- Sumatriptan and similar medicines (used to treat migraine) and 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, 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 may cause increased blood levels of citalopram.
- Drugs known to affect the platelet function (e.g. some antipsychotic drugs, 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 to treat 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) and antidepressants (SSRIs) due to a possible risk of a lowered threshold for seizures
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life-threatening heart rhythm disorder.

Do not take Cipramil if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. Class IA and III antiarrhythmics, antipsychotics (e.g. fentiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Cipramil with food, drink and alcohol

Cipramil can be taken with or without food (see section 3 "How to take Cipramil").

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

Pregnancy, breast-feeding and fertility

Inform your doctor if you are pregnant or planning to become pregnant. Pregnant women should not usually 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, 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 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 blue-ish. 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 Cipramil 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 Cipramil 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.

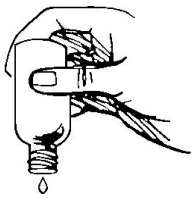
Important information about some of the ingredients in Cipramil Oral Drops
Cipramil Oral drops contain propyl parahydroxybenzoate (E216) and methyl parahydroxybenzoate (E218), which may cause allergic reactions (possibly delayed).

This medicine contains 76 mg of alcohol (ethanol 96%) in each ml which is equivalent to 9.0 % v/v. The amount in 1 ml of this medicine is equivalent to less than 2 ml of beer or 1 ml of wine. The small amount of alcohol in this medicine will not have any noticeable effects.

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 not sure.

Turn the bottle completely upside down. If no drops come out, tap the bottle lightly to start the flow.



Adults
Depression
The usual dose is 16 mg (8 drops) daily. The dose may be increased by your doctor to a maximum of 32 mg (16 drops) daily.

Panic disorder
The starting dose is 8 mg (4 drops) daily for the first week before increasing the dose to 16-24 mg (8-12 drops) daily. The dose may be increased by your doctor to a maximum of 32 mg (16 drops) daily.

Elderly patients (above 65 years of age)
The starting dose should be decreased to half of the recommended dose, e.g. 8-16 mg (4-8 drops) daily.
Elderly patients should not usually receive more than 16 mg (8 drops) daily.

Patients with special risks
Patients with liver complaints should not receive more than 16 mg (8 drops) daily.

Children and adolescents (< 18 years)
Cipramil should not be given to children or adolescents. For further information please see section 2 "What you need to know before you 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.
The drops can be taken in water, orange juice or apple juice.

Count the required number of drops into your drink (water, orange juice or apple juice), stir it briefly and then drink all of it.

If you have previously received Cipramil tablets, you may find that the dose of your medicine in mg given as drops is a bit lower than that of tablets. However, because the drops are more easily absorbed than the tablets, your body will receive the same amount of medicine.

The doses of tablets correspond to doses of drops as follows:

Tablets	Drops
10 mg	8 mg (4 drops)
20 mg	16 mg (8 drops)
30 mg	24 mg (12 drops)
40 mg	32 mg (16 drops)

Duration of treatment
Like other medicines for depression and panic disorder these oral drops 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 oral drops 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
If you think that you or anyone else may have taken too much Cipramil contact your doctor or nearest hospital emergency department immediately. 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 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, blue-ish skin, hyperventilation.

If you forget to take Cipramil

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 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.

If you stop taking Cipramil too quickly, you may experience discontinuation symptoms. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Cipramil, please contact your doctor.

Discontinuation symptoms include: 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

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

If you experience any of the following symptoms contact your doctor or go to the hospital straight away:

Rare (may affect up to 1 in 1,000 people):

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

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

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

- Swelling of skin, tongue, lips, or face, feeling dizzy or having difficulties breathing or swallowing (serious allergic reaction).

- Unusual bleeds, including gastrointestinal bleeds.

- Fast, irregular heartbeat, fainting, which could be symptoms of a life-threatening condition known as Torsade de Pointes.

The majority of the side effects listed below are mild. 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.

Very common (may affect more than 1 in 10 people):

- Sleepiness

- Difficulty in sleeping
- Increased sweating
- Dry mouth (as dry mouth may increase the risk of tooth decay it is advisable to brush your teeth more often).
- 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):

- Purpura: red or purple patches/spots (smaller than 1cm) of the skin caused by bleeding underneath
- Increased appetite
- Aggression
- Depersonalisation (feeling detached from yourself)
- Hallucination
- Mania (feeling excessively elated, impulsive, irritable, or irrational)
- Fainting
- Enlarged pupils
- Fast heart beat
- Slow heart beat
- Nettle rash
- Loss of hair
- Rash
- Light sensitivity
- Difficulties urinating (urinary hesitation, decreased urination)
- 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 "Warnings and precautions"
- Reduction in blood platelets, which increases risk of bleeding or bruising
- Hypersensitivity (rash)
- Disruption to the hormones affecting urine production
- 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
- Ecchymosis: blue or purplish patches (bigger than 1cm) of the skin caused by bleeding underneath
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding 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 these types of medicines
- Alteration of the heart rhythm (called "prolongation of QT interval", seen on ECG, a trace of the electrical activity of the heart).

Reporting of side effects
If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Cipramil

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

Store below 25°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.

After opening, the drops should be used within 16 weeks and stored below 25°C in the dark.

Keep the bottle in the outer carton in order to protect from light.

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 Cipramil Oral drops, solution contains
The active substance is citalopram (as hydrochloride).

Each ml of Cipramil Oral drops, solution contains 40 mg citalopram (as citalopram hydrochloride). 1 ml = 20 drops, 1 drop = 2 mg citalopram.

The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethanol, hydroxyethylcellulose, purified water. The drops contain 9.0 % v/v alcohol (76 mg/ml).

What Cipramil Oral drops, solution looks like and contents of the pack
Cipramil oral drops, solution are presented as a 40 mg/ml solution in a dropper bottle of 15 ml.

Clear, nearly colourless to yellowish solution with a bitter taste.

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Manufacturer
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