

PACKAGE LEAFLET: INFORMATION FOR THE USER

Cipramil® 20mg Film-coated Tablets Citalopram (as hydrobromide)

Read all of this leaflet carefully before you start taking this medicine

- 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 symptoms are the same as yours.
- 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.

In this leaflet:

- What Cipramil is and what it is used for
- Before you take Cipramil
- How to take Cipramil
- Possible side effects
- How to store Cipramil
- Further information

1. WHAT CIPRAMIL IS AND WHAT IT IS USED FOR

How does Cipramil work

Cipramil is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to correct certain chemical imbalances in the brain which are causing the symptoms of your illness.

What is Cipramil used for

Cipramil 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.

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

2. BEFORE YOU TAKE CIPRAMIL

Do not take Cipramil

- if you are allergic (hypersensitive) to citalopram or any of the other ingredients of Cipramil
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs)
- at the same time as taking pimozide
- if you were born with or have 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. Also refer to the section "Taking other medicines" below.

MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine and moclobemide which are also used for the treatment of depression.

Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine you will need to wait 2 weeks before you start getting your Cipramil treatment.

One day must elapse after you have finished taking moclobemide.

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

Take special care with Cipramil

- If you have episodes of mania or panic disorder
- If you have a severe liver disease
- If you have a severe kidney disease
- If you have diabetes (you may need an adjustment of your antidiabetic therapy)
- If you have epilepsy or a history of seizures or fits
- If you have some kind of bleeding disorder
- If you have a decreased level of sodium in the blood
- If you are receiving electroconvulsive treatment
- If you experience restlessness and/or a need to move often (akathisia)
- 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 heart beat, fainting, collapse, or dizziness on standing up which may indicate abnormal functioning of the heart rate.

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 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 adults aged less than 25 years 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 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.

Some patients with manic-depressive illness may enter into a manic phase. This is characterised 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.

Tell your doctor immediately if any of the above-mentioned symptoms occurs during the treatment.

Taking other medicines

DO NOT TAKE CIPRAMIL if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. such as 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-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

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

When using Cipramil with the following medicines, caution should be exercised:

- lithium (used in the prophylaxis and treatment of manic-depressive disorder) and tryptophan; if you get high fever and abrupt contractions of muscles, feel agitated and confused you must see your doctor immediately.
- selegiline (used for Parkinson's disease); the dose of selegiline must not exceed 10mg 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); 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.
- 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*) - concomitant intake with Cipramil may increase the risk of side effects.

Taking Cipramil with food and drink

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 and breast-feeding

Pregnant women should not usually take Cipramil nor should mothers breast-feed their babies while taking this medicine.

If you take one medicine from this group of medicines (antidepressants) 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 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.

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 of Cipramil

Cipramil contains **lactose**. 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 CIPRAMIL

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

Panic disorder

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

Obsessive-compulsive disorder (OCD)

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

Elderly patients (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g. 10-20mg per day. Elderly patients should not usually receive more than 20mg per day.

Patients with special risks

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

Children and adolescents (< 18 years)

Cipramil should not be given to children or adolescents. For further information please see section 2.

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

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

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 depression 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 casualty 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.

Symptoms of overdosage may include:

- convulsion
- heart rhythm change/arrhythmia/failure
- 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.

If you forget to take Cipramil

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cipramil

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

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

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; these 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
- fast, irregular heart beat, fainting which could be symptoms of a life threatening condition known as Torsades de Pointes.

Rare but serious side effects (in more than 1 out of 10,000 patients and in less than 1 out of 1,000 patients)

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

- feeling sick and unwell with weak muscles or confused; this may be signs of a rare condition called hyponatraemia (abnormally low level of sodium in the blood) which may develop with these type of antidepressants (SSRIs), especially in elderly female patients.

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 side effects (in more than 1 out of 10 persons) may include:

Feeling sleepy
Sleeplessness
Increased sweating
Dry mouth
Nausea (feeling sick)

Common side effects (in more than 1 but less than 10 out of 100 patients) may include:

Decreased appetite
Agitation
Ringing in the ears (tinnitus)
Yawning
Diarrhoea
Vomiting
Itching
Pain in muscle and joints
Men may experience problems with ejaculation and erection
For females, failure to achieve an orgasm
Fatigue
Prickling of the skin
Decreased weigh

Uncommon (in more than 1 out of 1,000 patients and in less than 1 out of 100 patients) may include:

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
Difficulties urinating
Vaginal bleeding
Swelling of the arms or legs
Increased weight

Rare (in more than 1 out of 10,000 patients and in less than 1 out of 1,000 patients) may include:

Convulsions
Involuntary movements
Hepatitis

Some patients have reported (frequency not known):

Thoughts of harming yourself or thoughts of killing yourself, see also section "Take special care with Cipramil"

Skin and mucous bleeding and low level of blood platelets

Hypersensitivity (rash)

Increase in the amount of urine excreted

Panic attack

Grinding one's teeth

Restlessness

Unusual muscle movements or stiffness

Akathisia (involuntary movements of the muscles)

Sudden swelling of skin or mucosa

Painful erections

Flow of milk in women that are not nursing

Abnormal liver function test

An increased risk of bone fractures has been observed in patients taking these types of medicines.

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.

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.

5. HOW TO STORE CIPRAMIL

As with all medicines, keep Cipramil out of the reach and sight of children - a locked cupboard or medicine cabinet is often best.

Do not store your Cipramil tablets above 25°C.

Do not take the tablets after the expiry date (EXP) which is printed on the carton and blister label.

If your doctor tells you to stop taking your medicine you can

return any left-over medicine to the pharmacist (for safe disposal), unless the doctor tells you to keep it at home.

If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.

6. FURTHER INFORMATION

What Cipramil contains

Each film-coated tablet contains 20mg citalopram (as hydrobromide) as the active ingredient.

The other ingredients in the tablets are maize starch, lactose monohydrate, copovidone, magnesium stearate, glycerol, microcrystalline cellulose, croscarmellose sodium, hypromellose, macrogol and titanium dioxide (E171).

What Cipramil looks like and contents of the pack

Cipramil 20mg are white, oval tablets, deeply scored on one face with the letters 'C' and 'N' on either side of the score and plain on the reverse.

Cipramil are available in blister packs containing 28 tablets.

Manufacturer

Cipramil tablets are manufactured by: H. Lundbeck A/S, Ottiliavej 9, DK-2500 Copenhagen, Denmark.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK. Distributed by: Eurodrug Ltd, Santry, Dublin 9.

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1. WHAT CIPRAMIL IS AND WHAT IT IS USED FOR

How does Cipramil work

Cipramil is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to correct certain chemical imbalances in the brain which are causing the symptoms of your illness.

What is Cipramil used for

Cipramil 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.

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

2. BEFORE YOU TAKE CIPRAMIL

Do not take Cipramil

- if you are allergic (hypersensitive) to citalopram or any of the other ingredients of Cipramil
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs)
- at the same time as taking pimozone.
- if you were born with or have 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. Also refer to the section "Taking other medicines" below.

MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine and moclobemide which are also used for the treatment of depression.

Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine you will need to wait 2 weeks before you start getting your Cipramil treatment.

One day must elapse after you have finished taking moclobemide.

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

Take special care with Cipramil

- If you have episodes of mania or panic disorder
- If you have a severe liver disease
- If you have a severe kidney disease
- If you have diabetes (you may need an adjustment of your antidiabetic therapy)
- If you have epilepsy or a history of seizures or fits
- If you have some kind of bleeding disorder
- If you have a decreased level of sodium in the blood
- If you are receiving electroconvulsive treatment
- If you experience restlessness and/or a need to move often (akathisia)
- 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 heart beat, fainting, collapse, or dizziness on standing up which may indicate abnormal functioning of the heart rate.

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 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 adults aged less than 25 years 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 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.

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.

Tell your doctor immediately if any of the above-mentioned symptoms occurs during the treatment.

Taking other medicines

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

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

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

When using Cipramil with the following medicines, caution should be exercised:

- lithium (used in the prophylaxis and treatment of manic-depressive disorder) and tryptophan; if you get high fever and abrupt contractions of muscles, feel agitated and confused you must see your doctor immediately.
- selegiline (used for Parkinson's disease); 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); 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.
- 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*) - concomitant intake with Cipramil may increase the risk of side effects.

Taking Cipramil with food and drink

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 and breast-feeding

Pregnant women should not usually take Cipramil nor should mothers breast-feed their babies while taking this medicine.

If you take one medicine from this group of medicines (antidepressants) 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 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.

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 of Cipramil

Cipramil contains **lactose**. 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 CIPRAMIL

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

Panic disorder

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

Obsessive-compulsive disorder (OCD)

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

Elderly patients (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g. 10-20mg per day. Elderly patients should not usually receive more than 20mg per day.

Patients with special risks

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

Children and adolescents (< 18 years)

Cipramil should not be given to children or adolescents. For further information please see section 2.

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

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

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 depression 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 casualty 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.

Symptoms of overdosage may include:

- convulsion
- heart rhythm change/arrhythmia/failure
- 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.

If you forget to take Cipramil

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cipramil

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

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

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; these 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
- fast, irregular heart beat, fainting which could be symptoms of a life threatening condition known as Torsades de Pointes.

Rare but serious side effects (in more than 1 out of 10,000 patients and in less than 1 out of 1,000 patients)

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

- feeling sick and unwell with weak muscles or confused; this may be signs of a rare condition called hyponatraemia (abnormally low level of sodium in the blood) which may develop with these type of antidepressants (SSRIs), especially in elderly female patients.

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 side effects (in more than 1 out of 10 persons) may include:

Feeling sleepy
Sleeplessness
Increased sweating
Dry mouth
Nausea (feeling sick)

Common side effects (in more than 1 but less than 10 out of 100 patients) may include:

Decreased appetite
Agitation
Decreased sex drive
Anxiety
Nervousness
Confusion state
Tremor
Ringing in the ears (tinnitus)
Yawning
Diarrhoea
Vomiting
Itching
Pain in muscle and joints
Men may experience problems with ejaculation and erection
For females, failure to achieve an orgasm
Fatigue
Prickling of the skin
Decreased weight

Uncommon (in more than 1 out of 1,000 patients and in less than 1 out of 100 patients) may include:

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
Difficulties urinating
Vaginal bleeding
Swelling of the arms or legs
Increased weight

Rare (in more than 1 out of 10,000 patients and in less than 1 out of 1,000 patients) may include:

Convulsions
Involuntary movements
Hepatitis

Some patients have reported (frequency not known):

Thoughts of harming yourself or thoughts of killing yourself, see also section "Take special care with Cipramil"

Skin and mucous bleeding and low level of blood platelets
Hypersensitivity (rash)
Increase in the amount of urine excreted
Panic attack
Grinding one's teeth
Restlessness
Unusual muscle movements or stiffness
Akathisia (involuntary movements of the muscles)
Sudden swelling of skin or mucosa
Painful erections
Flow of milk in women that are not nursing
Abnormal liver function test

An increased risk of bone fractures has been observed in patients taking these types of medicines.

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.

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.

5. HOW TO STORE CIPRAMIL

As with all medicines, keep Cipramil out of the reach and sight of children - a locked cupboard or medicine cabinet is often best. Do not store your Cipramil tablets above 25°C (room temperature).

Do not take the tablets after the expiry date (EXP) which is printed on the carton and blister label.

If your doctor tells you to stop taking your medicine you can return any left-over medicine to the pharmacist (for safe disposal), unless the doctor tells you to keep it at home. If your tablets appear to be discoloured, damaged or show any other signs of deterioration, please return them to your pharmacist who will advise you.

6. FURTHER INFORMATION

What Cipramil contains

Each film-coated tablet contains 20mg citalopram (as hydrobromide) as the active ingredient.

The other ingredients in the tablets are maize starch, lactose monohydrate, copovidone, magnesium stearate, glycerol, microcrystalline cellulose, croscarmellose sodium, hypromellose, macrogol and titanium dioxide (E171).

What Cipramil looks like and contents of the pack

Cipramil 20mg are white, oval tablets, deeply scored on one face with the letters 'C' and 'N' on either side of the score and plain on the reverse.

Cipramil are available in blister packs containing 28 tablets.

Manufacturer

Cipramil tablets are manufactured by: H. Lundbeck A/S, Otiliavej 9, DK-2500 Copenhagen, Denmark.

Procured from within the EU by the Parallel Product Authorisation holder: Imbat Ltd, Unit L2, North Ring Business Park, Santry, Dublin 9.

The product is repackaged by: Doncaster Pharmaceuticals Group Ltd, Kirk Sandall, Doncaster, South Yorkshire, DN3 1QR, UK. Distributed by: Eurodrug Ltd, Santry, Dublin 9.

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PACKAGE LEAFLET: INFORMATION FOR THE USER

Cipramil® 20mg Film-coated Tablets Citalopram (as hydrobromide)

Read all of this leaflet carefully before you start taking this medicine

- 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 symptoms are the same as yours.
- 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.

In this leaflet:

- What Cipramil is and what it is used for
- Before you take Cipramil
- How to take Cipramil
- Possible side effects
- How to store Cipramil
- Further information

1. WHAT CIPRAMIL IS AND WHAT IT IS USED FOR

How does Cipramil work

Cipramil is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to correct certain chemical imbalances in the brain which are causing the symptoms of your illness.

What is Cipramil used for

Cipramil 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.

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

2. BEFORE YOU TAKE CIPRAMIL

Do not take Cipramil

- if you are allergic (hypersensitive) to citalopram or any of the other ingredients of Cipramil
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs)
- at the same time as taking pimozide
- if you were born with or have 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. Also refer to the section "Taking other medicines" below.

MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine and moclobemide which are also used for the treatment of depression.

Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine you will need to wait 2 weeks before you start getting your Cipramil treatment.

One day must elapse after you have finished taking moclobemide.

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

Take special care with Cipramil

- If you have episodes of mania or panic disorder
- If you have a severe liver disease
- If you have a severe kidney disease
- If you have diabetes (you may need an adjustment of your antidiabetic therapy)
- If you have epilepsy or a history of seizures or fits
- If you have some kind of bleeding disorder
- If you have a decreased level of sodium in the blood
- If you are receiving electroconvulsive treatment
- If you experience restlessness and/or a need to move often (akathisia)
- 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 heart beat, fainting, collapse, or dizziness on standing up which may indicate abnormal functioning of the heart rate.

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 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 adults aged less than 25 years 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 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.

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.

Tell your doctor immediately if any of the above-mentioned symptoms occurs during the treatment.

Taking other medicines

DO NOT TAKE CIPRAMIL if you take medicines for heart rhythm problems or medicines that may affect the heart's rhythm, e.g. such as 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-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

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

When using Cipramil with the following medicines, caution should be exercised:

- lithium (used in the prophylaxis and treatment of manic-depressive disorder) and tryptophan; if you get high fever and abrupt contractions of muscles, feel agitated and confused you must see your doctor immediately.

- selegiline (used for Parkinson's disease); 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); 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.
- 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*) - concomitant intake with Cipramil may increase the risk of side effects.

Taking Cipramil with food and drink

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 and breast-feeding

Pregnant women should not usually take Cipramil nor should mothers breast-feed their babies while taking this medicine.

If you take one medicine from this group of medicines (antidepressants) 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 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.

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 of Cipramil

Cipramil contains **lactose**. 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 CIPRAMIL

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

Panic disorder

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

Obsessive-compulsive disorder (OCD)

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

Elderly patients (above 65 years of age)

The starting dose should be decreased to half of the recommended dose, e.g. 10-20mg per day. Elderly patients should not usually receive more than 20mg per day.

Patients with special risks

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

Children and adolescents (< 18 years)

Cipramil should not be given to children or adolescents. For further information please see section 2.

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

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

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 depression 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 casualty 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.

Symptoms of overdosage may include:

- convulsion
- heart rhythm change/arrhythmia/failure
- 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.

If you forget to take Cipramil

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Cipramil

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

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

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; these 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
- fast, irregular heart beat, fainting which could be symptoms of a life threatening condition known as Torsades de Pointes.

Rare but serious side effects (in more than 1 out of 10,000 patients and in less than 1 out of 1,000 patients)

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

- feeling sick and unwell with weak muscles or confused; this may be signs of a rare condition called hyponatraemia (abnormally low level of sodium in the blood) which may develop with these type of antidepressants (SSRIs), especially in elderly female patients.

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 side effects (in more than 1 out of 10 persons)

may include:

Feeling sleepy
Sleeplessness
Increased sweating
Dry mouth
Nausea (feeling sick)

Common side effects (in more than 1 but less than 10 out of 100 patients) may include:

Decreased appetite
Agitation
Decreased sex drive
Anxiety
Nervousness
Confusion state
Tremor
Ringing in the ears (tinnitus)
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Itching
Pain in muscle and joints
Men may experience problems with ejaculation and erection
For females, failure to achieve an orgasm
Fatigue
Prickling of the skin
Decreased weight

Uncommon (in more than 1 out of 1,000 patients and in less than 1 out of 100 patients) may include:

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
Difficulties urinating
Vaginal bleeding
Swelling of the arms or legs
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Rare (in more than 1 out of 10,000 patients and in less than 1 out of 1,000 patients) may include:

Convulsions
Involuntary movements
Hepatitis

Some patients have reported (frequency not known):
Thoughts of harming yourself or thoughts of killing yourself, see also section "Take special care with Cipramil"
Skin and mucous bleeding and low level of blood platelets
Hypersensitivity (rash)
Increase in the amount of urine excreted
Panic attack
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An increased risk of bone fractures has been observed in patients taking these types of medicines.

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.

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.

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6. FURTHER INFORMATION

What Cipramil contains

Each film-coated Cipramil tablet contains 20mg citalopram (as hydrobromide) as the active ingredient.

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