Package leaflet: Information for the patient

Ciprager 40 mg Film-coated tablets
citalopram

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 only. 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. See section 4.

What is in this leaflet

1. What Ciprager is and what it is used for

Ciprager belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs), also known as antidepressants. These medicines act on the serotonin-system in the brain by increasing the levels of a substance called serotonin. Disturbances in the serotonin-system are considered an important factor in the development of depression and related diseases.

Ciprager is used to treat:
- depression (major depressive episodes)
- panic disorder (panic attacks), including those caused by agoraphobia, which is a fear of leaving the house, entering shops or of public places

2. What you need to know before you take Ciprager

Do not take Ciprager
- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6)
- if you are taking MAO (monoamine oxidase) inhibitors e.g.:
  - moclobemide (an antidepressant),
  - linezolid (an antibiotic medicine), unless you are under close observation with monitoring of blood pressure.
  - irreversible MAO-inhibitors (other antidepressants) within the last two weeks or if you have taken a reversible MAO-inhibitor (RIMA) within the time prescribed in the relevant patient information leaflet of the RIMA (see "Taking other medicines").
  - selegiline (medicine for Parkinson's disease) in daily doses higher than 10 mg per day (see "Taking other medicines").

  After stopping Ciprager, you have to wait for at least 7 days before starting to take any MAO-inhibitors (see "Taking other medicines")
- if you are taking pimozide (to treat mental illnesses)
- if you are taking sumatriptan (5-HT agonist) used to treat migraine, or a similar medicine (see section 'Other medicines and Ciprager').
- if you were 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. Also refer to the section "Other medicines and Ciprager" below

Warnings and precautions
Talk to your doctor or pharmacist before taking Ciprager:
- if you are diabetic, as your doctor may need to adjust the dose of insulin or other medicine used to lower your blood sugar
- if you suffer from epilepsy, as your doctor will monitor you closely. Ciprager treatment should be stopped if you have a fit or suffer from more fits than usual (see section 4)
- if you are having 'electro-convulsive' therapy
- if you suffer from manic phases characterised by overactive behaviour or thoughts. If you enter into a manic phase, contact your doctor immediately
- if you have a history of mental illness as your psychotic symptoms may increase
- if you have or have had problems with your eyes such as certain kinds of glaucoma
- if you have a history of bleeding disorders or are using medicines that affect blood clotting or increase the risk of bleeding (see section 'Other medicines and Ciprager'), or if you are pregnant (see 'Pregnancy, breast-feeding and fertility')
- if you suffer from liver or kidney problems, as your doctor may need to adjust your dose. Your doctor should monitor your liver function. Caution and extra careful dosing is advised if you have severe liver or kidney problems
- if you have an abnormal heart rhythm or have low levels of salts (potassium, magnesium) in the blood. Your doctor may treat you to correct these symptoms before starting your treatment with citalopram.
- 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)

During treatment
Talk to your doctor or pharmacist:
- if you start to feel agitated, confused, body temperature above 38°C, notice trembling and abrupt contractions of the muscles, including the muscles that control movement of the eye, exaggeration of reflexes, increased muscle tension, hallucinations, coma, and excessive sweating, you may be suffering from a rare condition called serotonin syndrome, **tell your doctor straight away**. **Do not** suddenly stop Ciprager treatment as you may suffer from withdrawal effects (see section 3).
- if you get symptoms such as restlessness, agitation or difficulty remaining still during first few weeks of treatment. Your doctor may adjust your dose.
- if you suffer from increased anxiety at the start of your treatment.
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.
- Ciprager can reduce sodium levels in the blood making you feel weak, confused or have aching stiff muscles. Tell your doctor if you experience these symptoms.

Medicines like Ciprager (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 under 18 years of age
Ciprager should not normally be used to treat children and adolescents under 18 years of age. Patients under 18 have an increased risk of side effects such as suicide attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Ciprager for patients under 18 years because he/she decides that this is in their best interests. If your doctor has prescribed Ciprager for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of the symptoms listed above develop or worsen when patients under 18 are taking Ciprager. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Ciprager in this age group have not yet been demonstrated.

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.

Other medicines and Ciprager
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Do not take Ciprager 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. phenothiazine derivatives, pimozide, haloperidol, risperidone), tricyclic antidepressants (e.g. imipramine, desipramine, clomipramine, nortriptyline), 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.
- take sumatriptan and similar medicines used to treat migraine.
- take opoids (e.g. buprenorphine) used for pain relief.
- take linezolid (an antibiotic) (see section 'Do not take Ciprager')
- take medicines for Parkinson's disease or depression called MAOIs e.g. selegiline (more than 10 mg per day) or moclobemide (see section 'Do not take Ciprager'). Ciprager must not be administered until 14 days after an irreversible MAO inhibitor was discontinued. If you stop taking Ciprager' you must allow 7 days before you start taking any MAOI medicine

Tell your doctor if you are taking or have taken any of the following medicines:
- tryptophan and oxitriptan (used for depression) and tramadol (to treat severe pain), as these medicines can increase the risk of side effects
- other antidepressants e.g. fluvoxamine
- lithium (to treat mental illness)
- medicine to treat stomach ulcers e.g. cimetidine, omeprazole, esomeprazole, lansoprazole
- fluconazole (used to treat fungal infections)
- medicine to thin your blood (anticoagulants) e.g. warfarin, acetylsalicylic acid (aspirin)
- medicine to prevent blood clots e.g. ticlopidine, dipyridamole
- any medicine that can reduce the amount of potassium or magnesium in the blood, as these conditions increase the risk of life-threatening heart rhythm disorder (QT-prolongation, Torsades de Pointes)
- metoprolol (for e.g. heart disease), propafenone or flecainide (to treat irregular heartbeat). An increase in the blood level of these medicines has been reported or may be possible and a dose adjustment may be needed.
- bupropion (to help stop smoking) or mefloquin (for prevention and treatment of malaria) as there is a risk of possible lowered seizure threshold
- the herbal remedy St John's wort (*Hypericum perforatum*)
- medicines known as non-steroidal anti-inflammatory drugs (NSAIDs) e.g. ibuprofen

Ciprager with alcohol
It is recommended not to drink alcohol while taking this medicine.

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicinal product.

Pregnancy
Ciprager is not recommended if you are pregnant or planning to become pregnant, unless your doctor considers it absolutely necessary. There is only limited experience on the use of Ciprager during pregnancy.

You **should not** stop Ciprager treatment abruptly during pregnancy. If you are taking Ciprager in the last three months of pregnancy, let your doctor know as your baby might have some symptoms when it is born. These symptoms usually begin during the first 24 hours after the baby is born. They include not being able to sleep or feed properly, trouble with breathing, a blue-ish skin or being too hot or cold, being sick, crying a lot, stiff or floppy muscles, lethargy, tremors, drowsiness, irritability, decreased blood sugar, jitters or fits. If your baby has any of these symptoms when it is born, contact your doctor immediately who will be able to advise you.

Make sure your midwife and/or doctor know you are on Ciprager. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Ciprager 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 Ciprager 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 Ciprager so they can advise you.

Breast-feeding
Ciprager passes into breast milk in small amounts. There is a risk of an effect on the baby. Speak to your doctor first before you start breast-feeding. Your doctor may ask you to stop feeding your baby if the treatment with this medicine is considered necessary for you.

Fertility
Ciprager 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
Ciprager may decrease your ability to perform tasks requiring precision or close attention. **Do not** drive or use any tools or machinery until you know how you are affected by this medicine. If you are not sure, talk your doctor.

Ciprager 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 Ciprager

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

How much to take

Adults
Depression
The recommended dose is 20 mg taken once daily. After 3 to 4 weeks of starting treatment your doctor may review your treatment and may decrease or increase the dose of your medicine. This may be increased to a maximum of 40 mg per day.

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

Elderly patients (above 65 years of age)
The recommended starting dose is 10 mg per day. Elderly patients should not usually receive more than 20 mg per day.

Patients with special risks
The recommended starting dose for patients with liver problems is 10 mg per day for first two weeks after which it may be increased to a maximum of 20 mg per day.

Use in children and adolescents under 18 years
Ciprager **should not** be normally given to children and adolescents under 18 years of age (see section 'Warning and precautions').

Method of administration
- Swallow the tablets with a glass of water.
- Try to take the tablets at the same time every day, with or without food, either in the morning or evening.
- Ciprager 40 mg tablets can be divided into equal doses.
- For doses not realisable with this strength, other strengths of this medicine are available

Duration of treatment
Like other medicines for depression and panic disorder, these tablets may take a few weeks before you feel any improvement. Continue to take Ciprager even if it takes some time before you feel any improvement in your condition. 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.
Never change the dose of the medicine without talking to your doctor first.

If you take more Ciprager than you should
Contact your doctor or nearest hospital emergency department **immediately**. Take the container and any remaining tablets with you. Symptoms of overdose may include drowsiness, dizziness, increase or decrease in blood pressure, widening of the black of the eye, coma, fits or shaking, feeling agitated, lack of consciousness, sweating, blue colouration of skin, increased rate of breathing, fever, change in mental status, restlessness, inability to sit or stand still, muscle wasting, feeling or being sick and changes in heart rate or heart rhythm (which can be seen in tests such as ECG).

If you forget to take Ciprager
If you have forgotten to take a dose, take it as soon as you remember. However, if it is nearly time for the next dose, miss the forgotten dose altogether and continue with the rest of the tablets as normal. **Do not** take a double dose to make up for a forgotten dose.

If you stop taking Ciprager
Do not suddenly stop taking your medicine as you may experience withdrawal symptoms (see section 4 'Withdrawal Symptoms'). If you need to stop taking your medicine, the doctor will reduce your dose slowly over at least one or two weeks.

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

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. The very common side effects are most likely in the first two weeks of treatment.

If you get any of the following symptoms you should see your doctor immediately:

Common: may affect up to 1 in 10 people
- inability to urinate

Uncommon: may affect up to 1 in 100 people
- feeling excited leading to unusual behaviour (mania)
- a fit (seizure), or if you are epileptic, you may notice an increase in the number of fits you are having

Rare: may affect up to 1 in 1,000 people
- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (hepatitis)
- generally heavy bleeding or bleeding of the gut or rectum
- high fever, feel agitated or confused, trembling, sudden muscle movements. These symptoms may be a sign of a rare condition called serotonin syndrome
- restlessness or difficulty to sit or stand still. These effects are more likely during the first weeks of treatment. Tell your doctor straight away if you notice these symptoms
- overproduction of a hormone causing fluid retention, resulting in weakness, tiredness or confusion

Not known: frequency cannot be estimated from the available data
- a severe allergic reaction causing swelling of the face or the throat, tightness in the chest, difficulty breathing or swallowing
- fast, irregular heart beat, changes in heart rhythm which may be seen as prolonged QT interval in electocardiogram, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes

Thoughts of suicide and worsening of your depression or anxiety disorder
Thoughts of suicide or self-harm may occur or may increase in the first few weeks of treatment for depression, until the antidepressant effect becomes apparent. Tell your doctor immediately if you have any distressing thoughts or experiences. Patients who are prone to panic attacks may actually experience a temporary period of heightened anxiety after starting treatment. This generally resolves during the first two weeks (see also section 2 ‘Thoughts of suicide and worsening of your depression or anxiety disorder’).

Other side effects

Very common: may affect more than 1 in 10 people
- drowsiness
- sleep problems
- sleepiness
- difficulty sleeping
- headache
- light-headedness
- feeling agitated
- feeling nervous
- shaking
- fast, irregular heartbeats or thumping in your chest (palpitations)
- constipation
- feeling sick
- dry mouth
- increased sweating
- a feeling of weakness

Common: may affect up to 1 in 10 people
- weight loss, lack of appetite
- memory loss
- difficulty concentrating
- strange dreams
- feeling anxious

- feeling confused
- decreased sexual drive
- lack of feeling
- migraine
- tingling or pins and needles
- dizziness
- attention difficulties
- change in taste
- problems with eyesight
- dilated pupils, which may even lead to visual disturbances due to increased pressure in your eye
- ringing in the ears (tinnitus)
- a fast heartbeat
- feeling faint or light-headed on standing up
- an itchy runny nose
- indigestion, stomach pain, discomfort
- being sick (vomiting)
- wind
- increased saliva
- diarrhoea
- itchy skin
- muscle pain, joint pain
- impaired sexual function in males (such as impotence, ejaculation problems)
- abnormal orgasm in females
- tiredness
- yawning

Uncommon: may affect up to 1 in 100 people
- increased appetite
- increased weight
- feeling high
- increased sexual drive
- aggression
- depersonalisation
- hallucinations
- fainting
- movement disorders
- a slow heart beat
- coughing
- abnormal results in liver function tests
- sensitivity of the skin to light
- hives (nettle rash)
- rash
- hair loss
- reddish spots on skin
- heavy periods
- feeling generally unwell
- swelling due to excessive fluid in the body

Rare: may affect up to 1 in 1,000 people
- uncontrollable twitching, jerking or writhing body movements and other movement disorders
- fever
- decreased levels of sodium in the blood
- bruising

Very rare: may affect up to 1 in 10,000 people
- abnormal milky discharge from the breast

Not known: frequency cannot be estimated from the available data
- reduction in blood platelets which increases risk of bleeding or bruising
- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- panic attack
- teeth grinding (when asleep)
- nose bleed
- persistent painful erection
- increased blood levels of the hormone prolactin
- irregular vaginal bleeding
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding, fertility in section 2 for more information

An increased risk of bone fractures has been observed in patients taking this type of medicines.

Withdrawal symptoms
When you stop taking Ciprager you may experience withdrawal symptoms. This is most likely if you stop taking your medicine suddenly. Some patients have experienced the following side effects within the first few days of discontinuing treatment:
- dizziness
- sensory disturbances (e.g. tingling or numbness in the hands and feet, electric shock sensations)
- sleep disturbances (e.g. difficulty in sleeping or strange dreams)
- agitation or anxiety
- feeling or being sick
- tremor
- dizziness
- confusion
- sweating
- headache
- diarrhoea
- palpitations
- emotional instability, irritability
- sight problems

These symptoms are usually mild to moderate and generally resolve within two weeks. However, in some patients these symptoms may be more severe, or go on for longer. If you need to stop taking your medicine, the doctor will reduce your dose slowly over a period of at least one or two weeks. If you get severe withdrawal effects when you stop taking Ciprager, please see your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. 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 Ciprager

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

Do not use Ciprager after the expiry date which is stated on the carton/label or blister after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

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 Ciprager contains
The active substance is citalopram. Each tablet contains 40 mg of citalopram (as citalopram hydrobromide). The other ingredients are lactose monohydrate (see section 2 'Ciprager contains lactose'), maize starch, cellulose microcrystalline, povidone, crospovidone and magnesium stearate. The film-coating also includes titanium dioxide (E171), macrogol and hypromellose and lactose monohydrate.

What Ciprager looks like and contents of the pack
Ciprager 40mg Film-coated tablets are white oval tablets marked 'CM' breakline '40' on one side and 'G' on the other side. The tablet can be divided into equal doses.

Ciprager 40 mg Film-coated tablets are available in blister packs of 7, 10, 14, 20, 28, 30, 50, 56, 60, 84, 90, 98 and 100 tablets, calendar blister packs of 28 tablets and plastic bottles of 100 tablets.
Not all pack sizes may be marketed.

Marketing Authorisation Holder
McDermott Laboratories Limited t/a Gerard Laboratories, 35/36 Baldoyle Industrial Estate, Grange Road, Dublin 13, Ireland.

Manufacturer
Mylan Hungary Kft., H-2900, Komarom, Mylan utca 1, Hungary.

This medicinal product is authorised in the member states of the EEA under the following names:

Belgium	Citalopram Viatris 40 mg, filmomhulde tabletten
Germany	Citalopram dura 40 mg filmtabletten
Ireland	Ciprager 40 mg film coated tablets
Italy	Citalopram Mylan Generics 40 mg compresse revestite con film
Luxembourg	Citalopram Viatris 40 mg comprimés pelliculé
United Kingdom	Citalopram 40 mg film coated tablets

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