

PACKAGE LEAFLET: INFORMATION FOR THE PATIENT

Citalopram 20mg 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 Citalopram is and what it is used for
2. What you need to know before you take Citalopram
3. How to take Citalopram
4. Possible side effects
5. How to store Citalopram
6. Contents of the pack and other information

1. WHAT CITALOPRAM IS AND WHAT IT IS USED FOR

- Citalopram belongs to a group of antidepressants known as selective serotonin reuptake inhibitors (SSRIs).
- Citalopram is used for the treatment of depression (major depressive episodes).

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE CITALOPRAM

Do not take Citalopram

- If you are allergic to citalopram or any of the other ingredients of Citalopram (listed in section 6).
- If you are taking, or have taken in the last 2 weeks an antidepressant medicine of the type called monoamine oxidase inhibitors (MAOIs) e.g. selegiline or moclobemide.
- If you are treated with linezolid (an antibiotic medicine) unless you are under close observation and monitoring of blood pressure.
- 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. Also refer to the section “Other medicines and Citalopram” below.

Warnings and precautions

Talk to your doctor or pharmacist before taking Citalopram if you:

- Suffer from diabetes, treatment with Citalopram may alter control of your sugar levels.
- Suffer from epilepsy or seizures, as seizures are a potential risk with antidepressant drugs.
- Receive electro-convulsive therapy.
- Have a history of mania/hypomania, Citalopram should be used with caution and should be discontinued when you enter a manic phase.
- Have kidney or liver problems. Citalopram is not recommended for use in patients with severe kidney problems.
- Have a bleeding disorder, Citalopram may cause bleeding.
- Are using medicinal products that effect the clotting of blood (see section “Other medicines and Citalopram”).
- Have a stomach ulcer or have had any bleeding in the stomach or intestine in the past.
- Suffer from low blood potassium or magnesium levels.
- Suffer from psychosis with depressive episodes.
- Experience „serotonin syndrome“. A combination of symptoms, such as agitation, tremor, muscle contractions and hyperthermia may indicate the development of this condition. Treatment with Citalopram should be discontinued immediately.
- 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 problems with your eyes, such as certain kinds of glaucoma.
- During the first few weeks of treatment symptoms such as restlessness, and an inability to sit or stand still may develop in patients taking anti-depressants. In patients who develop these symptoms, increasing the dose could be harmful.
- Citalopram should be discontinued in any patients who develop fits (epilepsy) or if their frequency of fits increase. Citalopram should be avoided in patients with unstable (uncontrolled) epilepsy. Patients with controlled epilepsy should be carefully monitored.
- Citalopram should not be used at the same time as medicines which have a serotonergic effect including pain killers and medicines used to treat migraines (see “Other medicines and Citalopram”).
- Citalopram should be used with caution in patients with low sodium levels.

You should not discontinue treatment with Citalopram abruptly due to the withdrawal effects that might occur (see section 3).

Thoughts of suicide and worsening of your depression:

If you are depressed 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, and ask them to read this leaflet. You might ask them to tell you if they think your depression is getting worse, or if they are worried about changes in your behaviour.

Children and adolescents

Citalopram 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 attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behaviour and anger) when they take this class of medicines. Despite this, your doctor may prescribe Citalopram for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Citalopram 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 Citalopram. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Citalopram in this age group have not yet been demonstrated.

Other medicines and Citalopram

DO NOT TAKE Citalopram

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

- 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. phenothiazine 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.

- If you take monoamine oxidase inhibitors (MAOIs), e.g. phenelzine, isocarboxazid or tranlycypromine do not take Citalopram for 14 days after discontinuation of treatment with a so called irreversible MAOI. Do not take Citalopram for the time specified after discontinuation of treatment with a reversible MAOI (e.g. moclobemide), as stated in the patient information leaflet of the reversible MAOI. Do not take MAOIs for 7 days after discontinuation of treatment with Citalopram. Do not use Citalopram if you are taking more than 10 mg/day of the MAO selegiline.
- If you take pimozide (an antipsychotic medicine). Citalopram must not be taken together with pimozide due to the influence of this combination to the heart function.
- Medicines containing selegiline (used to treat Parkinson’s disease).

Talk to your doctor or pharmacist if you are taking, or have previously taken any of the following:

- Other medicinal products with serotonergic effects such as sumatriptan, other triptans or tryptophan (see „Take special care with Citalopram”).
- An anticoagulant (to prevent blood clotting), e.g. warfarin, aspirin (acetylsalicylic acid), dipyridamole or ticlopidine.
- Medicines that lower the seizure threshold i.e. neuroleptics, mefloquine or bupropion.
- Herbal preparations containing St John’s wort (*Hypericum perforatum*).
- Pain-relief and inflammation medicines called non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, ketoprofen or diclofenac.
- Medicines used to treat pain, such as tramadol (see “Warnings and precautions”).
- Medicines used to treat depression, e.g. fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine.
- Medicines used to treat migraine, e.g. sumatriptan and other triptans (see “Warnings and precautions”).
- Medicines used to treat heart failure, e.g. metoprolol.
- Medicines for psychiatric illness, e.g. lithium, risperidone or chlorpromazine.
- Medicines for stomach ulcers, e.g. omeprazole, esomeprazole, lansoprazole or cimetidine.
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life-threatening heart rhythm disorder (QT prolongation, Torsades de Pointes).
- Linezolid (an antibiotic medicine).

Citalopram with food, drink and alcohol

You are advised not to drink alcohol whilst taking Citalopram.

Citalopram can be taken with or without food..

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 medicine.

There is only limited experience concerning the use of Citalopram during pregnancy. Do not take Citalopram if you are pregnant or planning to become pregnant, unless your doctor considers it absolutely necessary. Make sure your midwife and/or doctor know you are on Citalopram. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram 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.

You should not discontinue treatment with Citalopram abruptly. If you are taking Citalopram in the last 3 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 bluish skin or being too hot or cold, being sick, crying a lot, stiff or floppy muscles, lethargy, tremors, jitters or fits. If your baby has any of these symptoms when it is born, contact your doctor who will be able to advise you.

Ask your doctor or pharmacist for advice before taking this medicine.

Breast-feeding

Citalopram passes into breast milk in small amounts. There is a risk of an effect on the baby. If you are taking Citalopram, talk to your doctor before you start breast-feeding.

Ask your doctor or pharmacist for advice before taking any medicine.

Fertility

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

Citalopram may affect your ability to drive a car or use machines. Do not drive or use machines until you know how Citalopram affects you. Please ask your doctor or pharmacist if you are unsure about anything.

Citalopram contains lactose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE CITALOPRAM

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

Citalopram should be taken as a single dose, either in the morning or the evening. The tablets can be taken with or without food. The tablets should be swallowed with a drink of water or other fluid. Citalopram does not work immediately. An antidepressant effect should not be expected for at least 2 weeks. Treatment should continue until you are free of symptoms for 4-6 months. Citalopram should be withdrawn slowly. It is advised that the dose is gradually reduced over a 1-2 week period. Do not stop taking Citalopram even if you begin to feel better, unless you are told to do so by the doctor. Never change the dose of your medicine without talking to your doctor first.

The usual dose is:

Adults

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

Elderly patients (> 65 years of age)

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

Use in Children and adolescents

Citalopram should not be used in the treatment of children and adolescents under 18 years of age. (See ‘Warnings and precautions’)

Liver problems

Patients with mild to moderate liver problems should receive a starting dose of 10 mg per day. Patients with liver complaints should not receive more than 20 mg per day. Such patients should be clinically monitored. Caution and extra careful dosing is advised in patients with severe liver problems.

Kidney problems

In patients with mild to moderate kidney problems no dosage adjustment is required. The use of Citalopram in patients with severe kidney problem is not recommended as no information is available in these patients.

Withdrawal symptoms seen on discontinuation

Abrupt discontinuation should be avoided. When stopping treatment with Citalopram the dose should be gradually reduced over a 1-2 week period in order to reduce the risk of withdrawal reactions (see section „If you stop taking Citalopram” and „Possible side effects”).

If intolerable symptoms occur following a decrease in the dose upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, your doctor may continue decreasing the dose, but at a more gradual rate.

If you take more Citalopram than you should

If you have taken more Citalopram than you should, talk to a doctor or pharmacist immediately. Symptoms of an overdose include: sleepiness, a condition of near unconsciousness with apparent mental inactivity, reduced ability to respond to stimulation or coma, seizures, ECG changes (e.g. prolonged QT interval), irregular heart beat, feeling sick, vomiting, discolouration of the skin, sweating, hyperventilation. Features of serotonin syndrome may occur (see „Possible side effects“), particularly when other substances are co-ingested.

If you forget to take Citalopram

If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you stop taking Citalopram

Do not stop taking Citalopram unless you are told to do so by your doctor. Since withdrawal reactions may occur when the treatment is stopped, it is advised to reduce the dose gradually at intervals of 1-2 weeks.

Withdrawal reactions include: dizziness, pins and needles, electric shock sensations, numbness, sleeplessness, intense dreams, agitation, anxiety, feeling sick or being sick, shaking, confusion, sweating, headache, diarrhoea, faster heartbeat (palpitations), emotional instability, irritability and visual disturbances. Most of the withdrawal reactions are mild and self-limiting in nature but may be severe in some patients.

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. A few people may develop a severe allergic reaction. This is a very rare but serious side effect. **If you experience any of the following symptoms stop taking Citalopram and tell your doctor immediately or go to your nearest casualty department:**

- Swelling of the lips, face and neck (allergic reaction) leading to severe difficulty in swallowing or breathing.
- Shock (strong decrease of blood pressure, paleness, agitation, weak and fast pulse, clammy skin, decreased consciousness) caused by a sudden strong vascular dilatation as a result of severe allergy to certain substances (anaphylactic reactions).
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

Serotonin syndrome has been reported in patients treated with this type of antidepressant (SSRI).

Tell your doctor if you experience high fever, trembling, muscle twitches and anxiety because these symptoms may indicate the development of this condition. **Treatment with Citalopram should be discontinued immediately.**

Cases of thoughts/behaviours of harming or killing yourself have been reported during Citalopram therapy or early after treatment has been stopped (see section 2 “Warnings and precautions”). If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

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

The following side effects have been reported at the approximate frequencies shown:

Very common: may affect more than 1 in 10 people

- sleepiness, difficulty sleeping
- headache
- feeling your heart beat
- feeling sick, dry mouth
- increased sweating
- feeling of weakness (asthenia)

Common: may affect up to 1 in 10 people

- reduction in weight, loss of appetite
- agitation, problems with concentration, abnormal dreaming (unusual and intense dreams), memory loss, anxiety, decreased sex drive, absence of emotion or enthusiasm, confusion, nervousness
- pins and needles or numbness
- tremor, dizziness, ringing in the ears (tinnitus), pain in muscles and joints
- runny and itchy nose, inflammation of the sinuses (pain and pressure in your face, which is worse when you lean forwards, blocked nose, sore throat and cough, headache, fever, earache, toothache or pain in your upper jaw)
- indigestion/heart burn, being sick, stomach pain, wind, increased saliva, diarrhoea, constipation • problems with urination (e.g. controlling urination)
- inability to achieve orgasm in women, impotence (inability to get or maintain an erection), ejaculation failure
- itching
- fatigue, yawning

Uncommon: may affect up to 1 in 100 people

- increase in weight, increase in appetite, absence of appetite
- a state of optimism, cheerfulness and well-being (euphoria), aggression, reduced emotions, indifference, hallucinations, mania, general feeling of discomfort or uneasiness
- fainting
- slowing of the heart beat, fast heart beat
- coughing
- nettle rash, hair loss, rash, bruising easily, sensitivity to sunlight, dilatation of the pupil
- problems passing urine
- swelling of the arms and legs
- abnormally heavy and prolonged menstrual period

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

- bleeding, e.g. from the vagina, stomach, skin and mucous membranes (the lubricated inner lining of the mouth, nasal passages, vagina and urethra)
- convulsions, involuntary movements, taste abnormalities
- unintentional and purposeless motions
- inflammation of the liver (hepatitis)
- lower amount of blood sodium, predominantly in the elderly (which causes hallucinations, confusion, fits, lack of energy and muscle cramps or weakness)
- fever

Not known (cannot be estimated from the available data)

- low levels of platelets in your blood (thrombocytopenia) which can increase bleeding or bruising
- panic attacks, grinding teeth, restlessness
- inappropriate ADH secretion (characterised by an excessive production of urine)
- fits, impairment of voluntary movement, i.e. tremor, tics, changes in muscle tone, slowness of movement, involuntary and/or irregular muscle movements that occur in the facial area, restlessness of the arms and legs (akathisia)
- visual disturbance
- dizziness when suddenly standing up
- changes in electric recording heart (ECG QT interval prolonged)
- nosebleed
- bleeding in your stomach or intestine
- bleeding disorder including skin and mucosal bleeding (ecchymosis)

- sudden swelling of skin and mucosa
- abnormal liver function tests
- abnormal milk secretion from the breast (galactorrhoea)
- irregular menstrual bleeding
- painful erections in men
- low potassium levels in the blood

Since withdrawal reactions may occur when the treatment is stopped, it is advised to reduce the dose gradually at intervals of 1-2 weeks.

Withdrawal reactions include: dizziness, pins and needles, electric shock sensations, numbness, sleeplessness, intense dreams, agitation, anxiety, feeling sick or being sick, shaking, confusion, sweating, headache, diarrhoea, faster heartbeat (palpitations), emotional instability, irritability and visual disturbances. Most of the withdrawal reactions are mild and self limiting in nature.

Any side effects that do occur will usually disappear after a few days.

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 HPRC Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects, you can help provide more information on the safety of this medicine.

5. HOW TO STORE CITALOPRAM

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

Do not use Citalopram after the expiry date which is stated on the carton and container after EXP. The expiry date refers to the last day of that month.

Do not store above 25°C.

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

6. CONTENTS OF THE PACK AND OTHER INFORMATION

What Citalopram contains

The active substance is citalopram hydrobromide. Each tablet contains 20 mg of citalopram (as citalopram hydrobromide).

The other ingredients are:

Core: copovidone, croscarmellose sodium (E466), glycerol (E422), lactose monohydrate, magnesium stearate (E470b), maize starch, microcrystalline cellulose (E460i).

Coating: hypromellose (E464), microcrystalline cellulose (E460i), macrogol stearate 40 (E431) and titanium dioxide (E171).

What Citalopram looks like and contents of the pack

Citalopram 20mg Film-Coated Tablets are oval, white tablets. with a break-line on one side.

Citalopram is presented in blister packs of 28 tablets contained in a cardboard carton.

Product procured from within the EU, repackaged and distributed by:

PCO Manufacturing, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

Parallel Product Authorisation Holder;

WPR Healthcare Limited, Unit 10, Ashbourne Business Park, Rath, Ashbourne, Co. Meath.

PPA no: PPA 565/62/1

Manufacturer:

TEVA Pharmaceutical Works Company Limited, Hungary.

This medicinal product is authorised in the Member States of the EEA under the following names:

Belgium:	Citalopram Teva 10, 20 & 40 mg, filmomhulde tabletten
Czech Republic:	Citalopram Teva 10, 20 & 40 mg
Denmark:	Citalopram Teva 20 mg & 40mg
Estonia:	Citalopram-Teva 10, 20 & 40 mg
Ireland:	Citalopram Teva 10, 20 & 40 mg Film-coated Tablets
Latvia:	Citalopram Teva 10, 20 & 40 mg
Lithuania:	Citalopram-Teva 10, 20 & 40 mg plėvele dengtos tabletės
The Netherlands:	Citalopram 10, 20 & 40 PCH, filmomhulde tabletten 10, 20 & 40 mg
Norway:	Citalopram TEVA tabletti, filmdrasjert 10, 20 & 40 mg
Slovakia:	Citalopram Teva 10, 20 & 40 mg
Sweden:	Citalopram Teva, 10, 20 & 40 mg filmdragerad tablett
United Kingdom:	Citalopram 10, 20 & 40 mg tablets

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