

Citalopram 10 mg and 20 mg 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.

What is in this leaflet:

1. What Citalopram Tablets are and what they are used for
2. What you need to know before you take Citalopram Tablets
3. How to take Citalopram Tablets
4. Possible side effects
5. How to store Citalopram Tablets
6. Contents of the pack and other information

1. What Citalopram Tablets are and what they are used for

Citalopram is one of a group of medicines called antidepressants, and known as a Selective Serotonin Re-Uptake Inhibitor or SSRI. These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness. It works by relieving the symptoms of depression (mood disorders).

Citalopram is also beneficial in relieving symptoms in patients prone to panic attacks and fear of open spaces.

2. What you need to know before you take Citalopram Tablets

Do not take Citalopram Tablets:

- If you are allergic (hypersensitive) to citalopram or any of the other ingredients of this medicine (listed in section 6).
- If you suffer from uncontrolled epilepsy.
- If you are taking medicines containing the following active ingredients: sumatriptan (used for migraine), tramadol (a pain killer), pimozide (an antipsychotic medicine) or linezolid (an antibiotic).
- At the same time as taking antidepressant medicines called monoamine oxidase inhibitors (MAOIs):
 - You must wait two weeks after stopping treatment with an irreversible MAOI (e.g. phenelzine, iproniazid, isocarboxacid) before starting to take your Citalopram Tablets.
 - You must wait one day after stopping treatment with a reversible MAOI (e.g. moclobemide) before starting to take your Citalopram Tablets.
 - If you are currently being treated with citalopram, you must allow at least seven days to elapse between stopping your citalopram treatment and starting to take any MAOIs.
 - If you are taking a selective MAOI called selegiline (used to treat Parkinson's disease).
- 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 are taking medicines for heart rhythm problems or that may affect the heart's rhythm, e.g. such as Class IA and II antiarrhythmics (see also 'Taking other medicines').

Warnings and Precautions

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

- have problems with your kidneys or liver.
- are elderly (over 65 years).
- suffer from diabetes, as your doctor may need to adjust the dosage of your diabetic medication.
- suffer from epilepsy controlled by medication.
- are receiving electroconvulsive therapy (ECT) for depression.
- suffer from mania (periods of extreme excitability).
- are taking a type of medication known as a neuroleptic (used to treat schizophrenia).
- have problems with your eyes, such as certain kinds of glaucoma (high pressure within the eyeball possibly leading to blindness).
- suffer or have suffered from the heart problems or have recently had a heart attack.
- 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).
- experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.
- are taking medication that can affect platelet function (the ability of the blood to clot) or are receiving treatment for a bleeding disorder, as citalopram may increase the risk of haemorrhage.

Patients who are prone to panic attacks may actually notice a temporary increase in their levels of anxiety after starting to take their medicine, however this usually passes during the first two weeks of treatment.

Thoughts of suicide and worsening of your depression or anxiety disorder

If you are depressed and/or have anxiety disorders, you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks, but sometimes longer.

You may be more likely to think like this:

- if you have previously had thoughts about killing or harming yourself.
- if you are a young adult. Information from clinical trials has shown an increased risk of suicidal behaviour in young adults (less than 25 years old) with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time,

contact your doctor or go to the emergency department at 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.

Children and adolescents

Citalopram 10 mg and 20 mg Tablets should normally not be used by 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 Tablets

Please tell your doctor if you are taking any of the following medicines before you take Citalopram Tablets (also see **Do not take Citalopram Tablets**):

- Monoamine oxidase inhibitors (MAOIs) – should not be taken at the same time as Citalopram Tablets (see section 2 - Do not take Citalopram Tablets) .
- The herbal remedy St. John's Wort (*Hypericum perforatum*) - should not be taken at the same time as Citalopram Tablets as the side effects may increase.
- Medicines to treat mental illness (such as chlorpromazine, thioridazine, risperidone, haloperidol, phenothiazine derivatives and fluphenazine).
- Tricyclic anti-depressants to treat depression (such as desipramine and clomipramine), and sedatives to calm you (examples are diazepam, buspirone, chlordiazepoxide and oxazepam).
- Medicines known to thin your blood, or other medicines which can cause bleeding, such as aspirin, dipyridamole, ticlopidine or non-steroidal anti-inflammatory drugs (NSAIDs, e.g. ibuprofen).
- Lithium (for attacks of mania) or tryptophan (for depression).
- Medicines to treat malaria (such as mefloquine and halofantrine).
- Neuroleptics used to treat schizophrenia.
- Cimetidine, omeprazole, esomeprazole, lansoprazole to treat stomach ulcers.
- Other SSRIs such as fluvoxamine.
- Metoprolol, flecainade or propofenone to treat heart conditions.
- Antimicrobial agents (such as sparfloxacin, moxifloxacin, erythromycin IV, pentamidine).
- Antihistamines (such as astemizole and mizolastine).
- Medicines inducing low blood levels of potassium/magnesium which can cause muscle weakness, twitching or abnormal heart rhythm and also increases the risk of abnormal heart beat.

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

Citalopram Tablets with food and drink

Citalopram Tablets can be taken with or without food. You are advised **NOT** to drink alcohol with this medicine.

Pregnancy, breast-feeding and fertility

Pregnancy

You should also tell your doctor before taking this medicine if you are pregnant, planning to become or think you may be pregnant or are breastfeeding. Do not take citalopram if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

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 new born (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.

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.

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 Tablets may affect your ability to make judgements and to react to emergencies. Make sure you are not affected before you drive or operate machinery. If you are affected, you should **NOT** drive or operate machines.

Citalopram Tablets contain 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 Citalopram Tablets

Always take this medicine exactly as your doctor has told you. Check with your doctor if you are not sure. The tablets should be swallowed with a drink of water. Do not chew the tablets. All the dose recommendations are a guideline only. Your doctor may prescribe a different dose, especially when you first start to take Citalopram Tablets.

Adults

Depression: The usual dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day. *Panic attacks:* The starting dose is 10 mg per day for the first week before increasing the dose to 20-30 mg per day. The dose may be increased by your doctor to a maximum of 40 mg per day. *Obsessive-compulsive disorder (OCD):* The starting dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.

Elderly (over 65 years)

Depression: The usual dose is between 10 mg and 20 mg per day. *Panic attacks:* The usual dose is between 10 mg and 20 mg per day. Elderly patients should not usually receive more than 20 mg per day.

Children and adolescents under 18 years of age

Citalopram Tablets are not recommended for use in children and adolescents (see Section 2, What you need to know before you take Citalopram Tablets).

Patients with liver disease

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

Patients with reduced kidney function

No dosage adjustment is necessary.

Duration of treatment

It may take several weeks before you feel any benefit from these tablets. This is normal for this type of medicine. Keep taking your medicine and do not stop taking it, even if you feel better, unless your doctor tells you to stop or you have an allergic reaction - see Section 4. For depression, a treatment period of at least 6 months is usually necessary. Continued treatment can protect against the likelihood of a future relapse. For panic disorders, a treatment period of several months or longer may be required, to ensure that you are free from symptoms.

If you take more Citalopram Tablets than you should

If you accidentally take more than your prescribed dose, contact your nearest hospital casualty department or tell your doctor immediately. If you go to the doctor/hospital, take your pack of Citalopram Tablets with you. Signs of an overdose may include: feeling or being sick, feeling drowsy, fits, sweating, coma, changes in heart beat and activity of heart muscles, agitation and restlessness, raised or lowered blood pressure, dizziness, blue discolouration around your lips, nails or cheeks, tremor, faster/rapid breathing, large pupils (the dark centre of the eye).

If you forget to take Citalopram Tablets

If you forget to take a dose, don't worry. Do not take the missed tablet(s) - just take the next dose when it is due and then go on as before.

If you stop taking Citalopram Tablets

Sometimes stopping your treatment suddenly can cause side effects. Common symptoms are headache, numbness or tingling in hands or feet, feeling or being sick, sleep disturbances (including difficulty falling and staying asleep, and intense dreams), feeling agitated or anxious, tremor, confusion, sweating, diarrhoea, pounding heart beat, mood swings, irritability, disturbances in your sight, and dizziness. Treatment should not therefore be stopped abruptly (unless you have an allergic reaction - see Section 4), but withdrawn slowly over a period of time advised by your doctor. Any side effects usually pass quickly.

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. Adverse effects associated with citalopram are usually short term and mild. They usually occur during the first two weeks of treatment and disappear as your depression improves. While taking this medicine, you may experience some of the following side effects:

Serious side effects:

- Stop taking Citalopram Tablets and seek emergency medical attention straight away if you experience any of the following:
- Allergic reaction (e.g. difficulty in breathing, swelling of the face, lips, tongue or throat causing difficulty in swallowing and breathing, severe itching of the skin (with raised lumps)).
 - Suicidal thoughts and behaviour
 - Mood changes
 - Serotonin syndrome (signs include high fever, agitation, confusion, trembling and abrupt muscle contractions)
 - Unusual bleeding, including gastrointestinal bleeding
 - Hyponatraemia (signs include feeling sick and unwell, with weak muscles or confusion)
 - Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

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

- Disturbed sleep, abnormal dreams, headache.

- Feeling sick, dry mouth.
- Increased sweating.

Common (may affect up to 1 in 10 people):

- Decrease in appetite and/or weight
- Agitation, confusion, anxiety, nervousness, poor concentration
- Tremor, tingling (pins and needles) in hands and feet, dizziness.
- Decreased sexual performance (impotence in men and problems reaching orgasm in women) and/or delayed ejaculation or failure to ejaculate.
- Being sick, diarrhoea, constipation.
- Tiredness, yawning.
- Ringing in the ears (tinnitus).
- Itching.
- Aches and pain in muscles and joints.

Uncommon (may affect up to 1 in 100 people):

- Increase in appetite and/or weight.
- Aggression, reduced emotions and indifference, seeing things that are not there (hallucinations), feeling over-excited (mania).
- Fainting, irregular heart beats/pulse rate.
- Large pupils (the dark centre of the eye).
- Skin rashes, itching, red/purple blotches on the skin , sensitivity to sunlight, hair loss.
- Problems passing water.
- Swelling of feet or ankles due to water retention.
- Females: heavy and prolonged menstrual periods.

Rare (may affect up to 1 in 1000 people):

- Low blood sodium levels (shown on blood tests).
- Convulsions, especially in those suffering from epilepsy, jerky movements of the arms and legs.
- Taste disturbance (food may taste slightly different).
- Unexplained bleeding or bruising.
- Inflamed liver.
- Fever.

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

- Thrombocytopenia.
- Changes which will be shown on blood tests – low blood potassium, changes the secretion of the hormone ADH, liver function tests appear abnormal.
- Panic attack, grinding of teeth , restlessness, suicidal thoughts and behaviour.
- Convulsions , serotonin syndrome (a condition caused by abnormally high levels of serotonin in the brain) – symptoms include confusion, agitation and anxiety.
- Movement disorders, including unable to move or unable to stop moving.
- Disturbance in sight.
- Changes in heart rate.
- Abnormal ECG heart tracing.
- Feeling faint (especially after standing up).
- Nose bleeds.
- Bleeding into the stomach or intestine which may cause you to vomit blood, or develop black or blood stained stools.
- Male: Continual erections, continuous discharge of milk from breast.
- An increased risk of bone fractures has been observed in patients taking this type of medicines.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store Citalopram Tablets

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the blister strip and carton after EXP. The expiry date refers to the last day of that month. Do not store above 30°C. 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 Citalopram Tablets contain

The active substance is citalopram (as hydrobromide). The other ingredients are: Tablet core: microcrystalline cellulose (E460(ii)), lactose anhydrous, maize starch, copovidone, magnesium stearate (E572), glycerol (E422), croscarmellose sodium. Tablet coating: hypromellose (E464), titanium dioxide (E171) and macrogol.

What Citalopram Tablets look like and contents of the pack

Citalopram 10 mg Tablets are white, round tablets, marked B on one side and 46 on the reverse. Each tablet contains 10 mg of the active ingredient citalopram (as hydrobromide). Citalopram 20 mg Tablets are white, oval tablets, embossed B above a breakline with 8 below on one side, and plain on the reverse. Each tablet contains 20 mg of the active ingredient citalopram (as hydrobromide).

The tablets are packed in blister strips and supplied as follows: 10 mg and 20 mg: 28 tablets.

Marketing Authorisation Holder:

Niche Generics Limited, 1 The Cam Centre, Wilbury Way, Hitchin, Herts, SG4 0TW, United Kingdom.

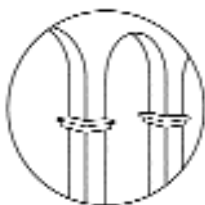
Manufacturer:

Niche Generics Limited, Unit 5, 151 Baldoyle Industrial Estate, Dublin, Ireland.

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

Ireland: Citalopram 10 mg/20 mg Tablets;
United Kingdom: Citalopram 10 mg/20 mg Tablets;

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Niche Generics Limited,
Unit 5, 151 Baldoyle Industrial Estate,
Baldoyle, Dublin 13, Ireland
Tel: +353 (0)18167300
e-mail: artwork@nichegenerics.ie

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Date of Origination:	16/1/04
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Component Code:	PM/20/241
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Software:	QuarkXpress 4.1
Version Number:	27
Revision Date:	04/04/2013
Reason for Revision:	SPC/PIL variation changes
Colours:	■ Black
Regulatory Approval Date:	
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