

Package leaflet: Information for the user

Citalopram 10mg, 20mg & 40mg Tablets

Citalopram hydrobromide

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you

Citalopram Tablets treat depression and anxiety disorders but they will not work straight away. Like all medicines, it can have side-effects. It is important that you and your doctor talk about the benefits and the possible unwanted effects of the medicine before you start taking it.

- Citalopram Tablets must be taken with care by children or teenagers under 18. (See Section 2 on page 3).
- Citalopram Tablets will not work straight away. You may feel worse before feeling better after starting the medicine. Your doctor should ask to see you again 2 or 3 weeks after you first start taking the medicine. Tell your doctor if you feel no better. (See Section 3 on page 5).

- Some people with depression or anxiety think of harming or killing themselves. If you have any of these thoughts, see your doctor or go to a hospital straight away. (See Section 2 on page 2).
- If you feel restless or feel like you cannot keep still, go to your doctor. If you keep on taking more Citalopram Tablets each day, it may make these feelings worse. (See Section 4 on page 6).
- Talk to your doctor before you stop taking Citalopram Tablets.

If you stop taking it suddenly or miss a dose you may get unwanted effects. (See Section 4 on page 6).

- Taking some other medicines with Citalopram Tablets can cause problems. You may need to talk to your doctor first. (See Section 2 on page 2).

- If you are pregnant or planning to get pregnant, talk to your doctor before taking Citalopram Tablets. (See Section 2 on page 2).

Keep this leaflet. You may need to read it again. If you have further questions, please ask your doctor or pharmacist or nurse.

This medicine has been prescribed for you. Do not pass it to others. It may harm them, even if their sign of illness are the same as yours. If you get any of the side effects talk to your doctor or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet:

- What Citalopram Tablets are and what they are used for
- What you need to know before you take Citalopram Tablets
- How to take Citalopram Tablets
- Possible side effects
- How to store Citalopram Tablets
- Contents of the pack and other information

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

Citalopram Tablets belong to a group of antidepressants called SSRIs (selective serotonin reuptake inhibitors).

Citalopram Tablets are used to treat:

- major depression or anxiety disorders in adults
- panic disorders with or without fear of wide open spaces, crowds, or uncontrolled social conditions.

Other medicines or psychotherapy can also treat these conditions. Treating your depression or anxiety properly is important to help you get better. Without treatment your condition may get worse and be more difficult to treat.

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

Do not take Citalopram Tablets:

- if you are allergic (hypersensitive) to citalopram or to any of the other ingredients of Citalopram tablets (see What Citalopram tablets contains, section 6).

Consult your doctor if you think you might be.

- if you are also taking a medicine containing pimozone.

Talk to your doctor.

- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs). MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine and moclobemide (used for the treatment of depression), selegiline (used in the treatment of Parkinson's disease) and linezolid (an antibiotic).

If Citalopram Tablets are taken with a MAOI or if a MAOI is started very soon after stopping Citalopram Tablets, serious reactions, which on occasions have been fatal, may occur. Symptoms such as agitation, tremor, stiffness, muscle spasm, rigidity, confusion, irritability, fever, delirium and coma have been seen.

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 taking your Citalopram tablets. One day must elapse after you have finished taking moclobemide. After stopping Citalopram tablets you must allow 1 week before taking any MAOI.

- if you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)

- if you take medicines for heart rhythm problems or that may affect the heart's rhythm. (see Taking other medicines, below).

Warnings and precautions

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

- you have kidney or liver disease
- you have epilepsy or have ever had a history of seizures or fit
- you have increased pressure in the eye (glaucoma)
- you have diabetes (you may need an adjustment of your antidiabetic therapy).
- you have or have ever had overactive behaviour or thoughts (mania) or panic disorder.
- you have bleeding disorder or have ever suffered from bleeding in the stomach or intestine.
- you have low blood levels of sodium
- you are pregnant (see 'Pregnancy, breast-feeding and fertility')
- you are on ECT (electro-convulsive treatment)
- you suffer or have suffered from heart problems or have recently had a heart attack
- 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)
- you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate
- especially if you are elderly

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

Please consult your doctor, even if these statements were applicable to you at any time in the past.

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 in sitting or standing still can also occur during the first weeks of the treatment. Tell your doctor immediately if you experience these symptoms.

Children and adolescents

Citalopram Tablets 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 Tablets for patients under 18 because he/she decides that this is in their best interest. If your doctor has prescribed Citalopram Tablets 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 Tablets.

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 Citalopram treatment it may take several weeks before you experience any improvement. In the beginning of the treatment certain patients may experience increased anxiety, which will disappear during 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.

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.

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 Citalopram tablets

Medicines may affect the action of other medicines and this can sometimes cause serious adverse reactions. Please tell your doctor or pharmacist if you are taking or have taken any other medicines (including those purchased without prescription) during the last 14 days. This includes other medicines for depression (see Do not take Citalopram tablets above).

- The herbal remedy St John's wort (Hypericum perforatum). This should not be taken at the same time as Citalopram tablets.

- Monoamine oxidase inhibitors (MAOIs). These should not be taken at the same time as Citalopram tablets (see Do not take Citalopram tablets above). Tell your doctor or pharmacist if you are taking, have recently taken or might take any of these medicines:

- Linezolid (an antibiotic)
- other medicines for depression (SSRIs, tricyclic antidepressants, such as clomipramine, nortriptyline and desipramine, bupropion and medicines containing tryptophan)
- some medicines for mental illness (such as perphenazine, risperidone and lithium)
- medicines for epilepsy (such as phenytoin, sodium valproate, phenobarbital or carbamazepine)
- Medicines known to affect the blood platelets (e.g. anticoagulant drugs used to treat or prevent blood clots; aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and diclofenac used as painkillers and some antipsychotic drugs and tricyclic antidepressants).
- Sumatriptan (used to treat migraine) or tramadol (a pain killer). If you feel unwell when using these medicines with Citalopram tablets you should see your doctor.
- Pimozide (a neuroleptic). This should not be taken at the same time as Citalopram tablets (see Do not take Citalopram tablets above).
- Medicines containing selegiline (used to treat Parkinson's disease)
- some medicines to treat problems with heartbeat (such as propafenone and flecainide)
- metoprolol (a beta blocker used to treat migraine, high blood pressure and heart problems)
- Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of citalopram.
- Mefloquine (used to treat malaria).

DO NOT TAKE CITALOPRAM TABLETS 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. fenflanzine 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. Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without prescription.

Citalopram Tablets with food and drink:

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

As with all antidepressants, it is sensible to avoid drinking alcohol whilst receiving treatment although Citalopram tablets has not been shown to increase the effects of alcohol.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you might be pregnant, or are planning to have baby,

ask your doctor or pharmacist for advice before taking this medicine. Do not take Citalopram tablets if you are pregnant unless you and your doctor have discussed the risks and benefits involved.

If you take Citalopram tablets 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 Citalopram tablets so they can advise you. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram tablets may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the newborn (PPHN), making the baby breath 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. Also, if you take Citalopram tablets 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: fits, being too hot or cold, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, overactive reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness or sleeping difficulties. If your newborn baby gets any of these symptoms please contact your midwife and/or doctor immediately.

Breast-feeding

Ask your doctor or pharmacist for advice before taking any medicine. If you are breast-feeding, ask your doctor for advice. You should not breast-feed your baby when taking Citalopram tablets because small amounts of the medicine can pass into the breast milk.

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.

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

Driving and using machines:

Citalopram Tablets do not usually affect the ability to carry out normal daily activities. However, if you feel dizzy or sleepy when you start to take this medicine, must not be driving, operating machinery or performing jobs that need you to be alert until these effects wear off.

Important information about some of the ingredients in Citalopram Tablets:

Citalopram Tablets contain lactose which is a type of sugar, if you have been told by your doctor that you are intolerant of lactose,

contact your doctor before taking this medicine.

3. HOW TO TAKE CITALOPRAM TABLETS

Always take Citalopram Tablets exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

Your doctor will tell you how much to take when you first start taking it. Most people start to feel better after 2 to 3 weeks. If you do not feel any better after this time, talk to your doctor. He or she may tell you to take more of the medicine each day.

How much you take is decided by your doctor:

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. Treatment should be at least 6 months.

Panic disorder

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. Treatment should be at least 6 months.

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 patients (above 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.

Patients with special risks

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

Taking Citalopram Tablets:

- follow your doctor's advice on how and when to take the tablets.
- swallow the tablets whole with a glass of water, do not crush or chew your tablets.

Use in Children and adolescents

Citalopram Tablets should normally not be used for children and adolescents under 18 years.

If you take more Citalopram Tablets than you should:

If you think that you or anyone else may have taken too many Citalopram Tablets, contact your doctor or the nearest hospital casualty department immediately. Do this even if there are no signs of discomfort or poisoning.

Take the carton and any tablets left so that the doctor knows what you have taken.

Some of the signs of an overdose could be life-threatening.

Symptoms of overdose may include:

- Irregular heart beat
- Seizures
- Changes in heart rhythm
- Feeling sick (nausea)
- Vomiting
- Sweating
- Drowsiness
- Unconsciousness
- Fast heart beats
- Tremor
- Changes in blood pressure
- Serotonin syndrome (see Section 4)
- Agitation
- Dizziness
- Enlarged eye pupils
- Bluish skin
- Breathing too quickly

If you forget to take Citalopram Tablets:

- if you forget a tablet and you remember before you go to bed, take it straight away. Carry on as usual the next day.
- if you only remember during the night, or the next day, leave out the missed tablet. You may possibly feel different, but this should go away after you take your next tablet at the usual time.

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

If you stop taking Citalopram tablets

Stopping this medicine quickly may cause symptoms such as dizziness, nausea and numbness or tingling in hands or feet, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling or being sick, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations). These are usually non-serious and disappear within a few days.

When you have completed your course of treatment, the dose of Citalopram tablets is usually reduced gradually over a couple of weeks.

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

4. POSSIBLE SIDE EFFECTS

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

Stop taking Citalopram Tablets and see a doctor or go to a hospital straight away if:

- you have an allergic reaction. This may include a red and lumpy skin rash, swollen eyelids, face, lips, mouth or tongue, itching or difficulty breathing or swallowing
- you have unusual bruising or bleeding
- you notice blood in your vomit or stools (motions)
- you cannot pass water
- Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as torsades de pointes.
- you notice liver problems (e.g. hepatitis) that cause the skin or eyes to go yellow (jaundice)
- you get thoughts of suicide or self harm or they get worse (see Section 2 above)

Stop taking Citalopram Tablets and talk to your doctor if:

- You start having fits for the first time or fits that you have suffered from in the past become more frequent.
- you feel restless and cannot keep still (it may be something called akathisia). Taking more Citalopram Tablets may make these feelings worse.
- you are tired, weak or confused and have muscles that twitch, ache, are stiff or do not work well. This may be due to a low level of sodium in your blood. This is more likely to happen if you are elderly.
- you feel confused, restless, agitated, sweaty, shaky, shiver, have strange visions or sounds (hallucinations), jerking muscles, muscle spasm (which may affect the jaw and tongue) or a fast heartbeat. You may have serotonin syndrome.
- you have painful eyes and your vision is blurred or weakened.

If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

The following side effects are often mild and usually disappear after a few days' treatment.

Very common side effects (likely to affect more than 1 in 10 people)

- Sleepiness
- Difficulty in sleeping
- Increased sweating
- Dry mouth (a dry mouth increases the risk of tooth decay, so be sure to clean your teeth more often than usual)
- Feeling sick (nausea)

Common side effects (likely to affect up to 1 in 10 people)

- Lack of appetite
- Agitation
- Decreased sex drive
- Anxiety

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- Anxiety
- Nervousness
- Confusion
- Abnormal dreams
- Tremor
- Tingling or numbness in the hands or feet
- Ringing in the ears (tinnitus)
- Yawning
- Diarrhoea
- Vomiting
- Constipation
- Itching
- Pain in muscles and joints
- For men, problems with ejaculation and erection
- For females, failing to reach an orgasm
- Tiredness
- Prickling of the skin
- Loss of weight

Uncommon (likely to affect up to 1 in every 100 people)

- Bruising easily
- Increased appetite
- Aggression
- Reduced emotions, indifference
- Hallucinations
- Mania
- Fainting
- Large pupils (the dark centre of the eye)
- Fast heart beat
- Slow heart beat
- Nettle rash
- Loss of hair
- Rash
- Sensitivity to sunlight
- Difficulties urinating
- Vaginal bleeding
- Swelling of the arms or legs
- Increased weight

Rare (likely to affect up to 1 in every 1000 people)

- Convulsions
- Involuntary movements
- Taste disturbances
- Bleeding
- Hepatitis
- Euphoria (an excessive feeling of happiness or excitement)

Some patients have reported (frequency not known)

- Thoughts of harming or killing themselves
- An increase in bleeding or bruising caused by a decrease in blood platelets
- Rash (hypersensitivity)
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythms
- Panic attack
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding and fertility' in section 2 for more information
- Grinding teeth
- Restlessness
- Unusual muscle movements or stiffness
- Involuntary movements of the muscles (akathisia)
- Low blood pressure
- Nosebleed
- Bleeding disorders including skin and mucosal bleeding (ecchymosis)
- Sudden swelling of skin or mucosa
- In men, painful erections
- Flow of breast milk in men or in women who are not breast-feeding (galactorrhoea)
- Abnormal liver function tests
- An increased risk of bone fractures has been observed in patients taking this type of medicines
- polyuria (frequent passing of urine)
- Disturbances of vision

SSRIs can, very rarely, increase the risk of bleeding, including stomach or intestinal bleeding. Let your doctor know if you vomit blood or develop black or blood stained stools.

Also let your doctor know if you continue to have other symptoms associated with your depression. This might include hallucinations, anxiety, mania or confusion.

Any side effects that do occur will usually disappear after a few days. If they are troublesome or persistent, or if you develop any other unusual side effects while taking Citalopram tablets, please tell your doctor.

If any of the side effects get serious, or if you notice any side effects not listed in the leaflet, please tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE CITALOPRAM TABLETS

- Keep this medicine out of the sight and reach of children.
 - Blister pack: Keep blister in the outer carton.
 - Do not use after the expiry date stated on the pack.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Citalopram Tablets contains:

The active substance is: Citalopram (as the hydrobromide). Citalopram Tablets contain 10mg, 20mg or 40mg of Citalopram. The other ingredients are: maize starch, lactose monohydrate, croscarmellose sodium, glycerol, copovidone, magnesium stearate and microcrystalline cellulose. The tablet coating contains the following other ingredients: hypromellose, macrogol 400 and titanium dioxide (E171).

What Citalopram Tablets look like and contents of the pack:

This medicine comes in blister packs of 28 film-coated tablets.

- Citalopram 10mg Tablets are round, biconvex, white to off-white film coated tablets, with 10 marked on one side.
- Citalopram 20mg Tablets are oval biconvex, white to off-white film coated tablets, scored on one side and 20 marked on the other side.
- Citalopram 40mg Tablets are oval biconvex, white to off-white film coated tablets, scored on one side and 40 marked on the other side.

Marketing Authorisation Holder and Manufacturer:

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This leaflet was last revised in 04/2021

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