

Package leaflet: Information for the patient
Citalopram 10mg, 20mg and 40mg
film-coated Tablets

Important things you need to know about citalopram

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

Citalopram treats depression and panic disorders but it 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 should not be taken by children or teenagers under 18 (see section 6).
- Citalopram 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).
- 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 (see section 2).
- If you feel restless or feel like you cannot keep still, go to your doctor. If you keep on taking more citalopram each day, it may make these feelings worse (see section 5).
- Talk to your doctor before you stop taking citalopram. If you stop taking it suddenly or miss a dose you may get unwanted effects (see section 4).
- Taking some other medicines with citalopram can cause problems. You may need to talk to your doctor first (see section 2).
- If you are pregnant or planning to get pregnant, talk to your doctor before taking citalopram (see section 2).

Read the rest 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. Stopping citalopram
5. Possible side effects
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1. What citalopram is and what it is used for

Citalopram belongs to a group of antidepressants called SSRIs (selective serotonin reuptake inhibitors). Citalopram is used to treat:

- Depression
- Panic disorders including fear of wide open spaces (agoraphobia) or crowds

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

2. What you need to know before you take citalopram

Do not take citalopram if:

- you are allergic (hypersensitive) to citalopram or any of the other ingredients in this medicine (see Section 8: Contents of the pack and other information). Signs of an allergic reaction include: a rash, swallowing or breathing problems, swelling of your lips, face, throat or tongue.
- you are taking a MAOI (monoamine oxidase inhibitor) medicine, or have taken them in the last 2 weeks. Examples of MAOIs include: tranylcypromine, phenelzine and isocarboxazid (for depression) or selegiline (for Parkinson's disease).
- you are taking a medicine called moclobemide, or have taken it in the last 24 hours.
- you are taking pimozide (an antipsychotic medicine).
- you are taking linezolid (an antibiotic medicine used to treat pneumonia and infections in skin).
- 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).
- 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.
- you are taking the herbal remedy St John's wort (*Hypericum perforatum*).

Do not take this medicine if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking citalopram.

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**. 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.

Warnings and precautions

Talk to your doctor or pharmacist before taking citalopram if:

- you have epilepsy or have ever had a fit
- you have diabetes
- you have or have ever had a history of overactive behaviour or thoughts (mania)
- you are having ECT (electro-convulsive treatment).
- you have bleeding disorders or have ever suffered from bleeding in the stomach or intestine or use anticoagulants (for thinning the blood)
- you are pregnant (see "Pregnancy")
- you are taking this medicine for a panic disorder. You may need to be started on a lower dose.
- you have problems with your eyes, such as certain kinds of glaucoma or you have in history of glaucoma.
- you have liver disease.
- you have severe kidney disease
- 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 be signs of an abnormal heart rate.
- you have low levels of sodium in your blood.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

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.

A combination of symptoms such as feeling restless (agitation), shaking, with brief, involuntary twitching of a muscle, including the muscles that control movement of the eye (myoclonus), hallucinations, coma, excessive sweating, exaggeration of reflexes, increased muscle tension and elevated body temperature due to failed thermoregulation (hyperthermia) may indicate development of a severe condition called Serotonin syndrome. You should tell your doctor immediately, if these signs occur.

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

Other medicines and citalopram

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

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

Tell your doctor if you are taking any of the following:

- Other medicines for depression (SSRIs, tricyclic antidepressants, such as clomipramine, nortriptyline, imipramine and desipramine, and medicines containing bupropion, oxitriptan, tryptophan, tramadol, buprenorphine). This combination can lead to serotonin syndrome, a potentially life-threatening condition.
- Some medicines for mental illness (such as perphenazine, risperidone and lithium)
- Medicines for epilepsy (such as phenytoin, sodium valproate, phenobarbital or carbamazepine)
- Painkillers containing acetylsalicylic acid (such as aspirin) or non-steroidal anti-inflammatory medicines (NSAID's) such as ibuprofen
- Medicines for migraine such as sumatriptan (triptans), tramadol (strong pain killer), oxitriptan and tryptophan (substances that may influence the level of serotonin in the brain), buprenorphine (strong pain killer). These combination may cause serotonin syndrome (see section "Warnings and precautions").
- Herbal products containing St John's Wort
- Medicines for pain such as tramadol
- 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).
- Metoprolol, a beta blocker used to treat migraine, some heart conditions and high blood pressure.
- Medicines for early-stage Parkinson's disease such as selegiline
- Lithium (used to prevent and treat mania) and tryptophan (an antidepressant)
- Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), flvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of citalopram.
- Antibiotics such as Linezolid
- Mefloquine (used to treat malaria)
- Neuroleptics (used in the treatment of schizophrenia)

Citalopram with food, drink and alcohol

Citalopram can be taken with or without food.

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

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.

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 doctor know you are taking 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. Also, if you take citalopram during the last 3 months of your pregnancy and until the date of birth you should be aware that the following effects may be seen in your newborn: trouble with breathing, stiff or loose muscles, jitteriness, a bluish skin or being too hot or cold. If your newborn baby gets any of these symptoms please contact your midwife and/or doctor immediately.

If you take citalopram 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 so they can advise you.

Citalopram may get into breast milk in very small amounts and may affect your baby. Talk to your doctor before you start breast-feeding.

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 has a minor or moderate influence on the ability to drive and use machines. You should be careful when driving, operating machinery or performing jobs that need you to be alert. Do not drive or use machines if you feel you are affected.

3. How to take citalopram

Always take this medicine exactly as your doctor or pharmacist has told you. 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 this medicine. 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.

Taking citalopram:

- Take your medicine at the same time every day
- Swallow the tablets with a glass of water

How much to take:

Depression

- The recommended dose is 20 mg per day. This may be increased by your doctor to a maximum of 40 mg per day.
- The exact dose will depend on how your condition responds to treatment
- You will normally be asked to keep taking this medicine for at least 6 months

Panic disorder (panic attacks):

- The starting dose is 10 mg per day for the first week before increasing to 20-30 mg per day. The dose may be increased by your doctor to a maximum of 40 mg per day.
- The exact dose will depend on how your condition responds to treatment.

Elderly (above 65 years of age)

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

People with liver problems

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

If you take more citalopram than you should

If you think that you or anyone else may have taken too many citalopram tablets, contact your

doctor or go to the nearest hospital straight away. Do this even if there are no signs of discomfort or poisoning. Signs could include: feeling sick (nausea), being sick (vomiting), dizziness, sweating, fits, being very sleepy, passing out or going into a coma, tremor, having a blue colour to the skin, fast short breathing, changes in blood pressure, a staring or fixed look on the face, changes in heart rhythm, a fast or irregular heartbeat, agitation, enlarged eye pupils or serotonin syndrome (see Section 4) Take the carton and any tablets left with you. This is so that the doctor knows what you have taken.

If you forget to take citalopram

- 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 question on the use of this product, ask your doctor or pharmacist.

4. Stopping citalopram

Do not stop taking citalopram until your doctor tells you to.

When stopping citalopram, your doctor will help you to gradually take less of the medicine. This will be over a period of weeks or months. As you take less citalopram you may notice some side effects. If you notice any effects when you are stopping citalopram, tell your doctor. Your doctor may then ask you to start taking it again and reduce the dose more slowly.

Possible effects when stopping: feeling dizzy, feelings like pins and needles, feeling sick (nausea) or vomiting, feeling agitated or being anxious or having headaches, difficulty in falling asleep or staying asleep, vivid dreams, nightmares, tremor, confusion or disorientation, sweating, diarrhoea, palpitations, emotional instability, irritability and visual disturbances.

5. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them. Several of the effects listed below can also be symptoms of your illness and may disappear as you start to get better.

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

- you have difficulty breathing
- you get swelling of the hands, feet, ankles, face, lips or throat which may cause difficulty in swallowing or breathing. You could also notice an itchy, lumpy rash (hives) or nettle rash (urticaria). This may mean you are having an allergic reaction to citalopram. This affects less than 1 in every 100 people who take citalopram.
- you have thoughts of harming or killing yourself
- you have a fit (seizure). This affects less than 1 in every 1000 people who take citalopram
- you have a fast, irregular heartbeat or fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

Talk to a doctor straight away if:

- you have unpleasant or distressing restlessness accompanied by inability to sit or stand.
- you feel confused, restless, agitated, sweaty, shaky, shiver, high fever, confusion, see or hear things which are not there (hallucinations), jerking muscles, muscle spasm (which may also affect the jaw and tongue) or a fast heartbeat. You may have something called serotonin syndrome. This happens in only a very few people who take this medicine.
- you notice changes in the way your heart beats, it may beat much faster or slower than normal
- you have unusual bruising or bleeding. This affects less than 1 in 1000 people who take citalopram
- you notice blood in your vomit or stools (motions)
- you cannot pass water
- you notice yellowing or your skin or eyes and your urine becomes darker in colour. This could be a liver problem, such as jaundice or hepatitis
- you notice any of the following symptoms: trembling, muscle stiffness or spasm, slow movement, producing more saliva than usual or feeling restless. This affects less than 1 in every 100 people who take citalopram.
- you start having fits for the first time or fits that you have suffered from in the past become more frequent
- your behaviour changes because you feel elated or over excited
- you experience tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium (hyponatraemia).

Other side effects

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

- Feeling sick (nausea),
- Being sleepy or drowsy, or finding it difficult to sleep
- Headaches, dry mouth (a dry mouth increases the risk of tooth decay, so be sure to clean your teeth more often than usual)
- Feeling weak, dizzy or shaky
- Sweating more than usual
- Changes in your sleeping pattern

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

- Diarrhoea, constipation
- Feeling agitated or nervous
- Feeling anxious
- Feeling shaky or dizziness
- Ringing in your ears (Tinnitus)
- Strange or vivid dreams
- Finding it hard to concentrate, forgetting things or feeling confused
- Decreased or loss of appetite (anorexia), or losing weight
- Becoming less interested or bothered by things
- Lowered sex drive
- Migraines
- Muscles pain
- Joint pain
- Unusual skin sensations such as numbness, tingling, pricking, burning or creeping on the skin (paraesthesia), 'pins and needles'. These could be signs of paraesthesia
- Indigestion, being sick (vomiting), stomach ache, passing wind, or having more saliva than usual
- Problems passing water or passing water more often than usual
- A runny or itchy nose, blocked or painful sinuses
- A rash or itching
- Feeling tired or yawning
- Painful period cramps
- Sexual problems including being unable to get an erection, having delayed or no ejaculation, or being unable to have an orgasm, abnormal orgasm (female)
- Very fast, uneven or forceful heartbeat (palpitations)
- Loss of memory (amnesia)
- Loss of weight
- Tremor

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

- Feeling unusually happy (euphoria)
- Increased appetite, putting on weight
- Feeling detached from yourself (depersonalisation)
- Seeing or hearing things that aren't there (hallucinations)
- Overactive behaviour or thoughts (mania)
- Being more sensitive to sunlight
- Aggression
- Fainting
- Menstrual periods which are heavier or last longer than usual
- Water retention which may cause swollen arms or legs (Oedema)
- Large pupils (the dark centre of eye)
- Severe itching of the skin (with raised lumps)
- Loss of hair, balding
- Redness of the skin with blood spots
- Bruising easily
- Fast or slow heartbeat
- Rash
- Difficulties urinating

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

- Tired, weak, confused and have muscles that ache, are stiff or do not work well. This may be due to low sodium levels in your blood
- Increased sex drive
- Changes in the way things taste
- Fits or seizure
- Coughing
- Fever
- Bleeding under skin or mucous membrane
- Involuntary movements
- Hepatitis
- Feeling generally unwell

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

- Panic attacks
- Abnormal production of breast milk in men and women
- Feeling dizzy when you stand up (postural hypotension)
- Blurred vision
- Clenching or grinding the teeth (Bruxism)
- You may bruise more easily than usual. This could be because of a blood disorder (thrombocytopenia)
- Liver problems shown by blood tests
- An increased risk of bone fractures has been observed in patients taking this type of medicines.
- Feeling unwell, confused or weak, feeling sick (nausea), loss of appetite, feeling irritable. This could be an illness called 'syndrome of inappropriate anti-diuretic hormone secretion' (SIADH). This rare side effect is more likely to happen if you are elderly.
- Tiredness, confusion, and muscle weakness and muscle cramps. This may be due to low levels of potassium in your body (hypokalaemia)
- Nose bleed (Epistaxis)
- Wide spreading of bruising (Ecchymosis)
- Bleeding between menstrual periods
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see "Pregnancy" in section 2 for more information.
- A persistent or painful erection that lasts for several hours (priapism).
- Rash (hypersensitivity)
- Restlessness
- Unusual movements or stiffness
- Involuntary movements of the muscles (akathisia)
- Low blood pressure
- Sudden swelling of skin or mucosa
- Abnormal heart rhythm
- Increase in a hormone called prolactin in the blood

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 this medicine, please tell your doctor.

Additional side effects in children and adolescents

You should inform your doctor if any of the symptoms listed below start or get worse when patients under 18 are taking citalopram.

Among children and teenagers under 18 given citalopram, these side effects are common:

- Increased thoughts about suicide and suicide attempts
- Being hostile, aggressive or unfriendly
- Being agitated

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.

6. Children and adolescents under 18

Use in children and adolescents under 18 years of age

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 and suicidal behaviour when they take this type of medicine. 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 below start or get worse 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.

Among children and teenagers under 18 given citalopram, these side effects are common

- Increased thoughts about suicide and suicide attempts
- Being hostile, aggressive or unfriendly
- Being agitated

7. How to store citalopram

- Keep this medicine out of the sight and reach of children.
- Store in the original packaging
- Do not use after the expiry date which is stated on the carton. The expiry date refers to the last day of that month.
- 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 to protect the environment.

8. Contents of the pack and other information

What Citalopram 10mg, 20mg and 40mg film-coated Tablets contains

The active substance is citalopram hydrobromide
Citalopram tablets contain 10 mg, 20 mg or 40 mg of citalopram (as citalopram hydrobromide).
The other ingredients are mannitol, microcrystalline cellulose, colloidal anhydrous silica, magnesium stearate. The film-coating contains hypromellose, titanium dioxide (E171) and macrogol 6000.

What Citalopram Tablets look like and contents of the pack:

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

- Citalopram 10 mg tablets are round, biconvex, white film coated tablets, diameter 6 mm.
- Citalopram 20 mg tablets are round biconvex, white film coated tablets, diameter 8 mm, with a score line.
- Citalopram 40 mg tablets are round biconvex, white film coated tablets, diameter 10 mm, with a score line.

Marketing Authorisation Holder

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