

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

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

- Feeling sick (nausea), dry mouth
- Headache
- Increased sweating
- Sleepiness, difficulty sleeping, changes in your sleeping pattern
- Loss of body strength, weakness

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

- Tremor, dizziness
- Migraine
- Decreased appetite, decreased weight, weight loss (anorexia)
- Agitation, anxiety, nervousness, confusion
- Decreased sex drive (libido)
- Sensation of tingling, pricking or numbness in skin (paraesthesia)
- Problems with concentration
- Ringing in ears (tinnitus)
- Quick or irregular heartbeat (palpitations)
- Diarrhoea, vomiting, constipation, indigestion (dyspepsia), stomach pain, wind (flatulence), increased saliva
- Muscle pain (myalgia), joint pain (arthralgia)
- Itching (pruritus)
- Tiredness, yawning
- Blocked or runny nose (rhinitis)
- Inability in women to achieve orgasm, menstrual pain, impotence, ejaculation failure
- Abnormal dreams, memory loss (amnesia), absence of emotion or enthusiasm

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

- Slow heart beat
- Fast heart beat
- Increased appetite, increased weight
- Aggression, feeling detached from yourself (depersonalisation), hallucinations, mania (feeling highly excited, being over-active and easily irritated or distracted), euphoria (a state of optimism, cheerfulness and well-being), increased sex drive (libido)
- Fainting (syncope)
- Dilated pupils (mydriasis)
- Hives (urticaria)
- Rash
- Hair loss (alopecia)
- Redness or red spots on the skin (purpura)
- Photosensitivity (skin rash caused by exposure to sunlight)
- Problems passing urine (urinary retention)
- Heavy menstrual period (menorrhagia)
- Oedema (generalised swelling)

**Rare** (may affect up to 1 in 1,000 people):

- Bleeding (e.g. vaginal, gastrointestinal, skin and soft tissue bleeding)
- A major fit ('grand mal convulsion'), involuntary movements (dyskinesia)
- Taste disturbances
- Liver inflammation (hepatitis)
- Fever (pyrexia)
- Coughing
- Feeling unwell (malaise)

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

- Reduced number of blood platelets (thrombocytopenia)
- Abnormality of the rhythm or rate of the heart beat (arrhythmia)
- Allergy (hypersensitivity)
- Condition known as SIADH (syndrome of inappropriate secretion of antidiuretic hormone) predominantly in the elderly
- Low levels of potassium in the blood
- Panic attacks, teeth grinding (bruxism), restlessness
- Extrapyrimal disorder (e.g. involuntary movements, shaking, muscle rigidity and muscle contractions)
- Feeling of restlessness and not being able to keep still (akathisia)

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- Movement disturbance
- Vision disturbance
- Heart condition called QT-prolongation (irregular heartbeat recognisable on ECG)
- Dizziness when standing up fast caused by low blood pressure (orthostatic hypotension)
- Nosebleed
- Blood in the stools (gastrointestinal or rectal haemorrhage)
- Abnormal liver function test
- Bruising (ecchymosis)
- Abnormal milk secretion from the breasts in men (galactorrhoea)
- Painful prolonged erection (priapism)
- Irregular menstrual bleeding (metrorrhagia)
- An increased risk of bone fractures has been observed in patients taking this type of medicine
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding and fertility' in section 2 for more information.

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.

#### 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](http://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. Do not use this medicine after the expiry date which is stated on the carton/tablet container and the blister after EXP. This medicinal product does not require any special storage conditions.

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

#### 6 Contents of the pack and other information What Citalopram Tablets contain

- The active substance is citalopram (as hydrobromide). Each tablet contains 10, 20 or 40 mg citalopram.
- The tablet core contains mannitol (E421), microcrystalline cellulose (E460), colloidal silica anhydrous, magnesium stearate.
- The film-coating contains hypromellose (E464), macrogol, titanium dioxide (E171).

#### What Citalopram Tablets look like and contents of the pack

Citalopram 10mg Tablets are round, white tablets with a diameter of 6mm.

Citalopram 20mg Tablets are round, white tablets with a score line with side-scores and a diameter of 8mm. The tablet can be divided into two equal doses.

Citalopram 40mg Tablets are round, white tablets with a score-line with side-scores and a diameter of 10mm. The tablet can be divided into two equal doses.

Pack size of 28.

**Marketing Authorisation holder and Manufacturer**  
Accord, Barnstaple, EX32 8NS, UK

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Package leaflet: Information for the patient

# Citalopram 10mg, 20mg and 40mg film-coated tablets

**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 of the 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 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 belongs to a group of antidepressants called selective serotonin reuptake inhibitors (SSRIs). Citalopram is used for the treatment of depression and, when you feel better, to help prevent these symptoms recurring. Citalopram is also used for long-term treatment to prevent the occurrence of new episodes of depression if you have recurrent depression.

Citalopram is also beneficial in relieving symptoms if you tend to suffer from panic attacks.

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

**Do not take Citalopram Tablets if you:**

- are **allergic** to citalopram or any of the other ingredients of this medicine (listed in section 6).
- are taking **monoamine oxidase inhibitors (MAOIs)** (medicines used for treatment of depression or Parkinson's disease). The MAOI called selegiline may be used in combination with citalopram, but only at doses of less than 10mg per day.
- have **recently taken MAOIs**. Depending on the type of MAOI you used to use, you may have to wait for up to 14 days after stopping the MAOI before starting with Citalopram. If you stop taking Citalopram and want to start taking MAOIs, you have to wait for at least 7 days. Please ask your doctor for advice.
- are taking **linezolid** unless you are under close medical supervision and monitored on blood pressure.
- are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)
- take medicines for heart rhythm problems or that may affect the heart's rhythm. Also refer to the section 'Other medicines and Citalopram Tablets' below.

#### Children and adolescents under 18 years

Citalopram 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, confrontational behaviour and anger) when they take this class of medicine. Despite this, your doctor may prescribe Citalopram for patients under 18 because they decide that this is in their best interest. 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 this medicine. 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.

#### 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.
- 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 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 Tablets. Citalopram Tablets should be taken with caution if you:

- have **diabetes** (as your doctor may need to adjust the dose of your antidiabetic medicine).
- have had **seizures or have epilepsy**. You will be carefully monitored by your doctor. Treatment with Citalopram should be stopped if seizures occur or if you start having more seizures than usual.
- are receiving electro-convulsive treatment (**ECT**).
- have or have had **episodes of mania** (overactive behaviour or thoughts) or **panic disorder**.
- have a history of **bleeding disorders** or are using **medicines that affect blood clotting** or increase the risk of bleeding, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility').
- suffer from **psychosis** with depressive episodes, because the psychotic symptoms may increase.
- have **impaired kidney or liver function** (your doctor may need to reduce the dose of Citalopram and you also check your liver function).
- have or are prone to **heart rhythm disorders** (QT-interval prolongation or have suspected congenital QT-syndrome).
- suffer or have suffered from **heart problems** or have recently had a **heart attack**.

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- have a **low resting heart rate** and/or 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.
- suffer from **low blood levels of potassium or magnesium** (hypokalaemia/hypomagnesaemia).
- suffer from angle closure glaucoma or have a history of glaucoma.
- suffer from **low blood sodium** (hyponatraemia) or **SIADH** (inappropriate secretion of the anti-diuretic hormone which regulates the water balance in the body). These disorders have been reported rarely when taking Citalopram (mainly in the elderly) and generally they stabilise on stopping treatment.

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.

#### Other warnings

- If whilst taking Citalopram, you develop symptoms such as restlessness, confusion, trembling, excitation, fever, shivering, hallucinations, muscle cramps, rapid heart beat, tell your doctor at once. These may be a first sign of a condition called **serotonin syndrome**. They will stop your treatment with Citalopram immediately.
- If you start feeling restless and are no longer able to stand or sit still, please inform your doctor, since you may be suffering from a side effect called **akathisia**.
- At the start of treatment, sleeplessness and intense excitation can occur. Patients with panic disorder may experience intensified anxiety symptoms in the first 2 weeks of treatment. In both cases, the doctor may adjust the dose accordingly.
- After discontinuation of therapy, withdrawal symptoms may appear: dizziness, sleep disturbance, agitation, anxiety, nausea and/or vomiting, tremor or headache are the most common symptoms. They usually occur within the first few days, and last for about 14 days. It is advised to gradually stop treatment by lowering the dose over a period of several weeks. Please consult your doctor before discontinuing treatment.

#### Other medicines and Citalopram Tablets

**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. 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.

Buprenorphine/ opioids. These medicines may interact with citalopram and you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation, hallucinations, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C. Contact your doctor when experiencing such symptoms.

#### The following medicinal products must not be used together with Citalopram Tablets:

- MAOIs. This applies both to irreversible MAOIs like phenelzine and to reversible MAOIs like moclobemide. The MAOI called selegiline may be used in combination with citalopram, but only at doses of less than 10mg per day.
- If you have recently taken MAOIs. Depending on the type of MAOI you used to use, you may have to wait for up to 14 days after stopping the MAOI before starting with Citalopram. If you stop taking Citalopram and want to start using MAOIs, you have to wait for at least 7 days. Please ask your doctor for advice.

Linezolid. Citalopram may be used together if you are under close medical supervision and monitored on blood pressure.

#### Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes other medicines for depression (see Do not take Citalopram Tablets):

- 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.
- Buprenorphine (a type of opioid medicine). The use of these medicines together with citalopram can lead to serotonin syndrome, a potentially life-threatening condition (see 'Other medicines and Citalopram Tablets').

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

- Linezolid (an antibiotic).
- Sumatriptan (used to treat migraine) or tramadol (a pain killer). If you feel unwell when using these medicines with Citalopram you should see your doctor.
- Lithium (used to prevent and treat mania) and tryptophan (an antidepressant).
- Pimozide (a neuroleptic). This should not be taken at the same time as Citalopram Tablets.
- Imipramine and desipramine (used to treat depression).
- Medicines containing selegiline (used to treat Parkinson's disease).
- Cimetidine (used to treat stomach ulcers).
- Mefloquine (used to treat malaria).
- Bupropion (used to treat depression).
- 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. The effects of either drug could be increased, decreased or altered.
- Neuroleptics (used in the treatment of schizophrenia).
- Fluconazole (used to treat fungal infections).

#### Citalopram Tablets with food, drink and alcohol

You are advised NOT to drink alcohol with this medicine. Citalopram Tablets may 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.

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.

Data suggest that the use of Citalopram during pregnancy does not lead to problems with the foetus. Therefore, Citalopram may be used if you are pregnant or planning to become pregnant taking into account the following issues. If you are taking Citalopram during pregnancy, you should not stop treatment with Citalopram abruptly.

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.

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. Also, if you take Citalopram during the last 3 months of your pregnancy and until the date

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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.

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 this medicine.

#### Driving and using machines

Citalopram Tablets may affect your ability to make judgements and to react to emergencies. Make sure you are not affected in this way before you drive or operate machinery. If you are affected in any way, you should NOT drive or operate machinery.

### 3 How to take Citalopram Tablets

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

Swallow the tablets with liquid once daily in the morning or in the evening. The tablets may be taken with or without food.

Citalopram 20 mg Tablets and Citalopram 40 mg Tablets can be divided into equal doses.

#### Adults

##### Depression

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

##### Panic disorder

The starting dose is 10mg per day for the first week before increasing the dose to 20-30mg per day. The dose may be increased by your doctor to a maximum of 40mg 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.

##### Children and adolescents (less than 18 years of age)

Citalopram should not be given to children or adolescents (see 'Children and adolescents under 18 years').

#### Kidney Disease

If you suffer from a mild to moderate decrease in kidney function, you can use the normal dose for adults. If you suffer from severe kidney problems, use of citalopram is not recommended, as no information is available on use in these patients.

#### Liver Disease

A starting dose of 10mg daily for the first two weeks is recommended in patients with mild to moderate liver disease. Patients with liver complaints should not receive more than 20mg per day. If you suffer from severe liver disease, your doctor will be extra careful with increasing the dose. Your doctor will check your liver function whilst taking citalopram.

#### How long should you take Citalopram Tablets

Your doctor will decide on the duration of treatment. An improvement in depressive symptoms can take at least 2 weeks after starting treatment. Treatment should be continued for at least 4-6 months. If you don't start to feel better after a couple of weeks, go back to your doctor who will advise you.

### If you take more Citalopram Tablets than you should

If you have taken or think anyone else may have taken too many Citalopram Tablets, contact your doctor or nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the box/container with you if you go to a doctor or hospital. Some of the signs of an overdose could be life-threatening. Symptoms of possible overdose include feeling sick (nausea), vomiting, sweating, dizziness, sleepiness, agitation, coma, seizures, enlarged eye pupils, bluish skin, fast heart beat, rapid breathing (hyperventilation), irregular heart beat, increased body temperature, changes in heart rhythm, changes in blood pressure and serotonin syndrome (see Section 4).

#### If you forget to take Citalopram Tablets

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

#### If you stop taking Citalopram

Do not stop taking Citalopram Tablets until your doctor tells you to, even if you feel better. Stopping treatment (particularly suddenly) commonly leads to withdrawal symptoms such as feeling dizzy, sensory disturbances (numbness or 'pins and needles'), sleep disturbances (including insomnia and intense dreams), feeling agitated or anxious, nausea and/or vomiting, shakiness of the arms and legs (tremor), confusion, sweating, headache, diarrhoea, fluttering or pounding heartbeat (palpitations), emotional instability, irritability, and visual disturbances.

To reduce the possibility of withdrawal effects, your doctor will help you to reduce your dose slowly over a number of weeks or months.

Most people find that any withdrawal symptoms are mild and go away on their own within two weeks. For some people, these symptoms may be more severe, or go on for longer. If you get severe withdrawal effects when you stop taking Citalopram, please see your doctor. They may ask you to start taking your tablets again and come off them more slowly. If you do get withdrawal effects, you will still be able to stop Citalopram. Please see your doctor if you are worried about withdrawal effects when stopping Citalopram.

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. Several of the effects listed below can also be symptoms of your illness and may disappear as you start to get better.

#### If you experience one of the following side effects you should stop taking Citalopram and seek immediate medical advice:

- **Difficulty breathing**
- **Swelling of the face, lips, tongue or throat that causes difficulty in swallowing or breathing**
- **Severe itching of the skin (with raised lumps)**
- **Fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.**

If you notice any of the following symptoms you should contact your doctor immediately as your dose may need to be reduced or stopped:

- 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 high fever, agitation, confusion, trembling or abrupt contractions of muscles. These may be signs of a rare condition called serotonin syndrome
- Tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium (hyponatraemia).

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

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