

PACKAGE LEAFLET

Package leaflet: Information for the user

Citalopram Viatris 10 mg, 20 mg, 30 mg, 40 mg Film-coated tablets

(citalopram)

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

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

1. What Citalopram Viatris is and what it is used for

Citalopram belongs to a group of medicines called selective serotonin reuptake inhibitors (SSRIs).. Citalopram Viatris increases the amount of serotonin. Citalopram Viatris is used to treat depression and to prevent relapse into depression. These tablets may also be used to treat a condition called panic disorder with or without agoraphobia (fear of public areas or situations).

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

Do not take Citalopram Viatris:

- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6).
- if you are currently taking a medicine of the type called monoamine oxidase (MAO)-inhibitors, used in the treatment of depression or Parkinson's disease. The MAO-inhibitor selegiline may be used in combination with Citalopram Viatris, albeit not more than 10 mg per day.
- if you have recently taken an MAO-inhibitor. Depending on the type of the MAO-inhibitor you were taking you may need to wait 14 days before you start taking Citalopram Viatris. Your doctor will let you know for how long you may need to wait after treatment with a MAO-inhibitor. After stopping Citalopram Viatris you must allow 7 days before taking any MAO-inhibitor.
- if you currently are taking a medicine called linezolid (used to treat infections). If your doctor decides that you can take Citalopram Viatris at the same time as linezolid, your blood pressure will be checked regularly.
- 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 section "Other medicines and Citalopram Viatris".

Warnings and precautions

Talk to your doctor or pharmacist before taking Citalopram Viatris:

- if you suffer from liver disease or severe kidney problems
- if you have a psychotic condition
- if you have previously suffered from mania. Citalopram should be discontinued if entering a manic phase.
- if you have a history of abnormal bleeding or a bleeding disorder (see 'Other medicines and Citalopram Viatris'), or if you are pregnant (see 'Pregnancy, breast-feeding and fertility')
- if you suffer from seizures (fits) or epilepsy
- if you are diabetic
- if you have a heart disease or an abnormal heart rhythm
- if you are having electro-convulsive therapy (ECT)
- if you have, or have had high pressure in your eyes (glaucoma)
- if you have a decreased level of sodium in your blood. Inform your doctor if you start feeling unwell with weak muscles or confused while treated with Citalopram Viatris.
- if you suffer or have suffered from heart problems or have recently had a heart attack
- if you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets)
- if you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate

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

Children and adolescents

Citalopram Viatris 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 Viatris for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Citalopram Viatris 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 Viatris. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Citalopram Viatris 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.
- 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.

Symptoms such as restlessness, agitation or difficulty remaining still can also occur during the first few weeks of treatment. In some cases you may be unaware of the symptoms above and therefore it could be advisable to ask someone close to you to observe any signs of different behaviour.

Rare cases of 'serotonergic syndrome' have been reported in patients treated with this type of antidepressive medicine (SSRIs). If you experience high fever, twitching of the muscles, confusion and anxiety, you should contact your doctor, since these symptoms may indicate this condition.

Contact your doctor immediately or go to the nearest hospital if you experience distressing thoughts or experiences, or if any of the symptoms mentioned above occur during treatment.

Other medicines and Citalopram Viatris

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

Tell your doctor if you are taking or have taken any of the following medicines in the last 14 days (see section 'Do not take Citalopram Viatris'):

- monoamine oxidase inhibitors (MAOIs) used in the treatment of Parkinson's disease (e.g. selegiline), infections (e.g. linezolid) and depression (e.g. moclobemide)
- pimozide to treat psychotic condition.

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

- antidepressant medicines, for example desipramine, fluvoxamine
- medicine to treat mental illness such as lithium, risperidone, thioridazine and haloperidol
- medicines which increase the risk of bleeding (e.g. medicines to prevent blood clots (warfarin, ticlopidine, dipyridamol), salicylic acid derivatives (aspirin), NSAIDs (medicines used for pain and inflammation e.g. ibuprofen, diclofenac). Use of these medicines together with Citalopram Viatris can increase the risk of skin and mucous membrane bleeding.
- the herbal remedy St John's Wort (*Hypericum perforatum*)
- metoprolol (to treat heart failure or high blood pressure)
- cimetidine (to treat gastric ulcer)
- omeprazole, esomeprazole, lansoprazole (to treat gastric ulcer)
- fluconazole (used to treat fungal infections)
- medicines to treat certain heart conditions e.g. flecainide, propafenone
- any medicine that can reduce the amount of potassium or magnesium in the blood
- mefloquine (for malaria) and bupropion (to help stop smoking) as there is a risk of possible lowered seizure threshold
- sumatriptan or other triptans (to treat migraines), buprenorphine (for pain relief or to treat opioid addiction), tramadol (for pain relief) or tryptophan (to treat depression). These medicines may interact with Citalopram Viatris and may cause a life-threatening condition called serotonin syndrome (for symptoms see section 4 'Possible side effects').

Do not take Citalopram Viatris 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, anti-malarian treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.

Citalopram Viatris with alcohol

As with all antidepressants, it is sensible to avoid drinking alcohol whilst receiving treatment.

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.

Pregnancy

If you become pregnant during treatment with Citalopram Viatris, do not discontinue treatment without contacting your doctor.

Make sure your midwife and/or doctor know you are on Citalopram Viatris. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram Viatris 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.

The following other symptoms may occur in the baby immediately or soon after delivery if the mother has used this class of medicines during the later stages of pregnancy: seizures, temperature instability, feeding difficulty, vomiting, low blood sugar, increased muscle tension or floppy muscles, tremor, jitteriness, irritability, constant crying, drowsiness and difficulty sleeping. These symptoms are usually temporary. If your baby experiences any of these symptoms you should immediately contact your doctor or midwife.

If you take Citalopram Viatris 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 Viatris so they can advise you.

Breast-feeding

Citalopram passes into breast milk in small amounts. It is possible that a breast-feeding child may be affected. Do not use Citalopram Viatris when breast feeding unless the doctor has advised it.

Male 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 Viatris can cause side effects which may affect your ability to make judgements and to react to emergencies. Do not drive or use machines if you experience such side effects, e.g. if you feel drowsy or tired.

Citalopram Viatris contains 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 Viatris

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

How much to take

Adults

- **Depression**

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

- **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.

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.

Method of administration

- Take the tablets either in the morning or evening, with or without food.
- Swallow the tablets with a drink of water.
- Citalopram Viatriis 20 mg and 40 mg tablets can be divided into equal doses.
- Citalopram Viatriis 30 mg scoreline is only there to help you break the tablet if you have difficulty swallowing it whole.

Treatment time

As with other medicines used to treat depression, improvement does not occur immediately.

Following the start of treatment, it can take up to 2-3 weeks until the medicine has any effect. When treating anxiety disorders, it can take several weeks before any improvement occurs and some patients can experience a temporary period of heightened anxiety after starting treatment, which generally resolves during continued treatment. Therefore, it is very important to follow the doctor's instructions very carefully and not to discontinue treatment or change the dose without the advice of your doctor. For depression, the treatment usually continues for six months following improvement. The treatment of anxiety disorders is long term. When improvement has occurred, the treatment should continue according to your doctor's instruction.

If you take more Citalopram Viatriis than you should

If you take more Citalopram Viatriis than you should contact your doctor or local accident and emergency department immediately.

If you forget to take Citalopram Viatriis

If you forget to take Citalopram Viatriis, do not take a double dose to make up for a forgotten tablet, just carry on as before.

If you stop taking Citalopram Viatriis

Do not suddenly stop taking your medicine without consulting your doctor. If you need to stop taking your medicine, the doctor will usually advise you to reduce the dose slowly over a few weeks. When stopping treatment abruptly you may suffer so called withdrawal symptoms (see section 4 'Withdrawal symptoms seen on discontinuation').

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. Side effects are most common at the beginning of treatment, but usually improves during the first few weeks. If you get any of the following symptoms you should stop taking Citalopram Viatriis and see your doctor immediately:

- fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes (frequency: not known)
- serious allergic reaction which causes swelling of the face, tongue or the throat, difficulties swallowing or breathing, and hives (frequency: not known)
- serotonin syndrome (you may experience symptoms such as involuntary, rhythmic contractions of muscles, including the muscles that control movement of the eye, agitation,

hallucinations, confusion, anxiety, coma, excessive sweating, tremor, exaggeration of reflexes, increased muscle tension, body temperature above 38°C) (frequency: not known)

- nausea, vomiting, loss of appetite, feeling generally unwell, fever, itching, yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine (hepatitis) (frequency: rare)
- seizure (fits), or if you are epileptic, and you notice an increase in the number of seizures you are having (frequency: rare)

Occasionally, thoughts of suicide or self-harm may occur or may increase in the first few weeks of treatment for depression, until the antidepressant effect becomes apparent. Tell your doctor immediately if you have any distressing thoughts or experiences. Patients who are prone to panic attacks may actually experience a temporary period of heightened anxiety after starting treatment. This generally resolves during the first 1-2 weeks.

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

- difficulty sleeping, drowsiness
- dry mouth, feeling sick
- increased sweating
- headache

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

- changes in heart rhythm
- feeling agitated or nervous, anxiety
- loss of concentration, attention difficulties, confusion, strange dreams, numbed emotions
- dizziness
- trembling, tingling (pins and needles)
- blurred vision, ringing in the ears, runny nose
- being sick, constipation, diarrhoea, stomach ache, indigestion, increased saliva, wind
- loss of appetite, weight loss, anorexia
- itchiness
- muscle pain, joint pain
- problems with ejaculation, impotence, decreased libido, abnormal orgasm in females
- irregular menstruation, changes in passing urine
- a feeling of weakness, tiredness, yawning, general feeling of illness

Uncommon side effects (may affect up to 1 in 100 people)

- increased appetite, weight gain
- slowing of the heartbeat, fast heartbeat, fainting
- aggressiveness, feeling high, depersonalisation, hallucinations, feeling over-excited which causes unusual behaviour
- dilated pupils
- coughing, breathlessness or difficulty breathing
- sensitivity of the skin to light, rash, hives (nettle rash), reddish spots on skin, hair loss
- failure to orgasm in women
- difficulty passing urine
- heavy periods
- swelling due to excessive fluid in the body

Rare side effects (may affect up to 1 in 1,000 people)

- low blood levels of sodium which can cause tiredness and confusion
- muscle twitching, uncontrollable twitching, jerking or writhing body movements and other movement disorders
- changes in taste
- bleeding
- fever

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

- feeling faint or light-headed on standing up
- reduction in blood platelets which increases risk of bleeding or bruising, bruising, nose bleed, gastrointestinal and rectal bleeding, vaginal bleeding
- allergic reactions
- overproduction of a hormone causing fluid retention, resulting in weakness, tiredness or confusion
- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- panic attack, feeling restless or difficulty sitting still
- teeth grinding (when asleep)
- movement disorders
- problems with eyesight
- unusual or very fast heart rate or chest pain
- persistent painful erection
- increased blood levels of the hormone prolactin
- abnormal milky discharge from the breast in men
- abnormal results in liver function tests
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see Pregnancy, breast-feeding, fertility in section 2 for more information

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

Withdrawal symptoms seen on discontinuation:

Discontinuation of Citalopram Viatris (particularly when abrupt) commonly leads to so called withdrawal symptoms. When discontinuing treatment with Citalopram Viatris your doctor may advise you to lower the dose gradually. The risk of withdrawal symptoms increases if the dose is not lowered gradually. If you experience withdrawal symptoms, this does not mean that you are addicted or will not be able to stop taking Citalopram Viatris. Withdrawal symptoms that have been reported are: dizziness, sensory disturbances such as pins and needles and electric shock sensations, sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, confusion, sweating, headache, diarrhoea, irregular heartbeats, emotional instability, irritability, and visual disturbances. Generally these events are mild to moderate and are self-limiting, however, in some patients they may be severe and/or prolonged. Contact your doctor if you experience severe withdrawal symptoms after discontinuing treatment. The doctor may ask you to start taking Citalopram Viatris again in order to discontinue treatment at a slower pace.

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

5. How to store Citalopram Viatris

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 after EXP. The expiry date refers to the last day of that month.

This medicine 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 to protect the environment.

6. Contents of the pack and other information

What Citalopram Viatris contains

- The active substance is citalopram. Each tablet contains citalopram hydrobromide equivalent to 10 mg, 20 mg, 30 mg or 40 mg of citalopram.
- The other ingredients are maize starch, lactose monohydrate (see section 2 'Citalopram Viatris contains lactose'), cellulose microcrystalline, povidone, crospovidone, magnesium stearate, hypromellose (E464), macrogol 4000 and titanium dioxide (E171).

What Citalopram Viatris looks like and contents of the pack

Citalopram Viatris 10 mg tablets are white round film-coated tablets with "CM" over "10" on one side and "G" on the other side.

Citalopram Viatris 20 mg tablets are white oval film-coated tablets with "CM" scoreline 20" on one side and "G" on the other side. The tablet can be divided into equal doses.

Citalopram Viatris 30 mg tablets are white oval film-coated tablets with "CM" scoreline 30" on one side and "G" on the other. The scoreline is only there to help you break the tablet if you have difficulty swallowing it whole.

Citalopram Viatris 40 mg tablets are white oval film-coated tablets with "CM" scoreline 40" on one side and "G" on the other side. The tablet can be divided into equal doses.

Citalopram Viatris is available in blister packs of 12, 14, 20, 28, 30, 50, 56, 98, 100, 250 (20 mg/30 mg/40 mg only), 500 tablets or calendar blister packs of 28 tablets or single dose blister packs of 14, 28, 49 (10 mg only), 50, 56, 100, 250 and 500 tablets.

Citalopram Viatris is available in bottles of 100, 250, 500 and 1000 tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder

[to be completed nationally]

Manufacturer:

[to be completed nationally]

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