

CITALOPRAM 20MG FILM-COATED TABLETS CITALOPRAM 40MG FILM-COATED TABLETS

Read all of this leaflet carefully before you start taking medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Citalopram is and What it is used for
2. Before you take Citalopram
3. How to take Citalopram
4. Possible side effects
5. How to store Citalopram Tablets
6. Further information

1. WHAT CITALOPRAM IS AND WHAT IT IS USED FOR

Citalopram belong to the group of medicines known as antidepressants which work by relieving the symptoms of depressed mood.

Citalopram is to treat the symptoms of depression and, when you are feeling better, to help prevent these symptoms recurring. Citalopram is also beneficial in relieving symptoms in patients prone to panic attacks.

Treatment for depression is usually continued for at least six months, and for panic disorder for at least three months.

2. BEFORE YOU TAKE CITALOPRAM

Do not take Citalopram

- If you are allergic (hypersensitive) to Citalopram or any of the other ingredients of Citalopram Tablets.
- If you are taking antidepressant medicines of the type called monoamine oxidase inhibitors (MAOIs), MAOIs typically prescribed are phenelzine, isocarboxazid, tranylcypromine, selegiline, linezolid or moclobemide. Even if you have finished taking the MAOI medicine you will need to wait 2 weeks before starting your Citalopram. You must wait at least one day between stopping the reversible monoamine oxidase inhibitor (RIMA) moclobemide and starting Citalopram. If your doctor asks you to take an MAOI you will be asked to stop taking your Citalopram at least seven days before starting MAOI.
- If you are simultaneously taking the antipsychotic medicine pimozide (see "Taking other medicine")
- If you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how to the heart is functioning)
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm. Also refer to the section "Taking other medicines" below.

Take special care with Citalopram

- If you have episodes of mania or panic disorder
- If you have a decreased level of sodium in the blood
- If you have diabetes (you may need an adjustment of your antidiabetic therapy)
- If you have epilepsy or a history of seizures or fits
- If you are receiving electroconvulsive treatment
- If you have a bleeding disorder; also let your doctor know if you have a stomach ulcer or have had any bleeding in the stomach or intestine in the past.
- If you have experience restlessness and/or a need to move often (akathisia)
- 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 diarrhea 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 function of the heart rate

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 behavior 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 behavior.

Use in children and adolescents under 18 years of age

Citalopram should normally not be used for children and

the symptoms listed above develop or worsen when patients under 18 are taking Citalopram. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioral development of Citalopram in this age group have not yet been demonstrated.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any Other medicines, including medicines obtained without a prescription.

Tell your doctor if you are taking

- Drugs to control fits (anti convulsants) or if your fits have increased whilst taking Lithium or tryptophan medication (prescribed for people with depression or for people prone to attacks of mania)
- Medicines to thin your blood (anti coagulants) and aspirin
- Pain relief medicines called Non-steroidal anti-inflammatory drugs (NSADs) such as Ibuprofen
- Serotonergic drugs, such as a medicine used to relieve pain, called tramadol and a migraine medicine called Sumatriptan can be taken with Citalopram. However, if you feel unwell after taking tramadol or sumatriptan do not take these again. Continue to take your Citalopram and tell your doctor.
- Cimetidine, when used in high doses (used to treat stomach ulcers); blood levels of citalopram may be increased.
- Metoprolol (used for high blood pressure and/or heart disease); the blood levels of metoprolol are increased.

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

Taking Citalopram with food and drink

Do not consume alcohol during treatment with Citalopram. Citalopram can be taken with or without food.

Pregnancy, breast-feeding and fertility

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

Do not take Citalopram if you are pregnant or breast-feeding unless you and your doctor have discussed the risk and benefits involved. If you take this group of medicines (antidepressants) 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 doctor.

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.

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

Do not drive or work any tools or machinery, if you feel dizzy or sleepy when you start to take this medicine until these effects wear off.

Important Information about some of the ingredients of Citalopram

Citalopram Tablets contain lactose. If you have been told by your doctor that you have an intolerance to lactose or some types of sugar, contact your doctor before taking this medicinal product

3. HOW TO TAKE CITALOPRAM

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

Swallow the tablets with a drink of water. Do not chew them.

Usually doctor will prescribe between 20 and 40 mg per day, taken as a single dose either in the morning or in the evening.

How much to take

Adults

Depression

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

Panic 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. 20mg per day.

Citalopram should not be used in the treatment of children and adolescents under the age of 18 years (see "Take special care with Citalopram")

symptoms recurring. Citalopram is also beneficial in relieving symptoms in patients prone to panic attacks. Treatment for depression is usually continued for at least six months, and for panic disorder for at least three months.

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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 attempt, suicidal thoughts and hostility (predominantly aggression, oppositional behavior and anger) when they take this class of medicines. Despite this, your doctor may prescribe citalopram for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Citalopram for a patient under 18 and you want to discuss this, please go back to your doctor. You should inform your doctor if any of

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Taking Citalopram with food and drink

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Pregnancy, breast-feeding and fertility

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Usually doctor will prescribe between 20 and 40 mg per day, taken as a single dose either in the morning or in the evening.

How much to take

Adults

Depression

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

Panic disorder

The starting dose is 10 mg per day for the first week before increasing the dose to 20 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. 20mg per day.

Citalopram should not be used in the treatment of children and adolescents under the age of 18 years (see "Taken special care with Citalopram")

Patients with special risks

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

It may take several days before you feel any benefit from these tablets. This is normal for this type of medicine. Continue to take your tablets for as long as your doctor recommends. Do not stop taking them even if you begin to feel better, unless you are told to do so by your doctor. Never change the dose of your medicine without talking to your doctor first.

If you take more Citalopram than You should

Too many at once can be dangerous. If you have accidentally taken too many tablets, contact your doctor. If you are unable to contact your doctor, go to your local hospital casualty department at once.

If you forget to take Citalopram

If you forget to take your medicine, do not worry and take the next dose at the right time. Do not take a double dose to make up for a forgotten tablet.

If you stop taking Citalopram

Do not stop taking Citalopram on your own. Your doctor will advise when to discontinue the treatment.

When you stop taking Citalopram, especially if it is abruptly, you may feel discontinuation or withdrawal symptoms. These are common when treatment with Citalopram is stopped. The risk is higher, when Citalopram has been used for a long time or in high doses or when the dose is reduced too quickly. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Citalopram, please contact your doctor. He or she may ask you to start taking your tablets again and come off them more slowly.

Discontinuation symptoms such as dizziness (unsteady or off-balance), feeling like pins and needles, burning sensation and (less commonly) electric shock sensations (including in the head), sleep disturbances (vivid dreams, nightmares, inability to sleep), tingling, headache, feeling anxious, feeling sick (nausea), sweating (including night sweats), feeling restless or agitated, tremor (shakiness), feeling confused or disoriented, feeling emotional or irritable, diarrhea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations).

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

After taking your medicine - Special Information relating to your disease

As with other medicines used to treat depression or related diseases, improvement may not be 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 should disappear with 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.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Citalopram can cause side effects, although not everybody gets them. If any of the following happens, stop taking Citalopram and tell your doctor immediately or go to the casualty department at your nearest hospital:

Serotonin syndrome has been reported in patients treated with these types of antidepressants (SSRIs). Tell your doctor if you experience high fever, trembling, muscle twitches and anxiety, because these symptoms may indicate the development of this condition. Treatment with citalopram should be discontinued immediately.

You should see your doctor immediately if you experience allergic symptoms such as a swollen face, tongue and/or pharynx and/or difficulty to swallow or a sudden rash (like 'hives') together with difficulties in breathing.

These may be very serious side effects. If you have them, you may have had a serious allergic reaction to citalopram. You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare. The following side effects have been reported at the approximate frequencies shown: very common (affecting more than one person in 10):

Common (affecting fewer than one person in ten but more than one person in 100):

Uncommon (affecting fewer than one person in 100 but more than one person in 1,000):

Rare (affecting fewer than one person in 1,000 but more than one person in 10,000): Very Rare (affecting fewer than one person in 10,000 but more than one person in 100,000):

Very common (affecting more than one person in 10)

- Sleepiness
- Difficulty sleeping
- Feeling sick
- Dry mouth
- Increased sweating

Common (affecting fewer than one person in ten but more than one person in 100)

- Reduction in weight
- Problems with concentration
- Abnormal dreaming
- Emotional disturbances
- Impairment or voluntary movement i.e. Tremors
- Lightheadedness (dizziness)
- Ringing in ears
- Anxiety
- Decreased sex drive
- Loss of appetite
- Confusion
- Pins and needles
- Vomiting
- Frequent and watery bowel movements (diarrhea)
- Irregular and infrequent or difficult evacuation of the

- Increased appetite
- Weight gain
- Aggressiveness
- Depersonalization
- Hallucination
- Mania
- Slowing of the heart beat
- Light sensitivity of the skin
- Fainting
- Enlarged pupils
- Fast heart beat
- Nettle rash
- Loss of hair
- Rash
- Skin and mucous bleeding
- Difficulties urinating
- Abnormally heavy or prolonged menstruation
- Swelling of the arms or legs

Rare (affecting fewer than one person in 1,000 but more than one person in 10,000)

- Increased body temperature
- Bleeding
- Lower amounts of blood sodium
- Fits
- Slowness of movement
- Taste abnormalities
- Liver disease (Hepatitis)

Frequency not known (cannot be estimated from the available data):

- blood disease characterized by an abnormally small number of platelets in the blood
- hypersensitivity (rash)
- serious allergic reaction which causes difficulty in breathing or dizziness
- abnormally low level of potassium in the circulating blood leading to weakness and heart abnormalities
- sudden attack of fear
- clenching or grinding the teeth
- restlessness
- thoughts of harming themselves or thoughts of killing themselves
- fits
- disturbances of muscular movement
- marked or uncontrollable restlessness and fidgeting (akathisia)
- blurred vision
- hear rhythm problems
- lowering of blood pressure when suddenly standing up
- bleeding from the nose
- bleeding of stomach and intestine
- abnormal liver function test
- bruising
- serious allergic reaction which causes swelling of the face or throat
- vaginal bleeding at regular intervals
- painful erection in males
- milky secretion from the male breasts

If you get any of the following symptoms you should stop taking Citalopram and see doctor immediately;

- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

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

Since withdrawal reactions may occur when the treatment is stopped, it is advised to reduce the dose gradually at intervals of 1-2 weeks. Withdrawal reactions include: dizziness, pins and needles or numbness, headache, nausea and anxiety. Most of the withdrawal reactions are mild and self-limiting in nature. If treatment is being stopped, it is advised that the dose is gradually reduced over 1-2 week periods.

Some side effects may disappear after a few days. If they are troublesome or persistent, or if you develop any other unusual side-effects while taking Citalopram, please tell your doctor. If any of the side effects gets serious or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CITALOPRAM TABLETS

Keep out of the reach and sight of children. Store in a cool dry place protected from light below 30°C.

This medicinal product does not require any special storage conditions.

Do not use Citalopram Tablets after the expiry date which is stated on the carton after

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

Do not use Citalopram if you notice the visible signs of deterioration.

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. FUTURE INFORMATION

What Citalopram contains:

The active substance is Citalopram.

Each film-coated tablet contains 20 mg citalopram (as citalopram hydro bromide). Each film-coated tablet contains 40 mg citalopram (as citalopram hydro bromide).

The other ingredients are:

Lactose monohydrate, Maize starch, Povidone, Cross carmellose sodium, Cellulose microcrystalline, Magnesium stearate

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

After taking your medicine - Special Information relating to your disease

As with other medicines used to treat depression or related diseases, improvement may not be 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 should disappear with 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.

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.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Citalopram can cause side effects, although not everybody gets them. If any of the following happens, stop taking Citalopram and tell your doctor immediately or go to the casualty department at your nearest hospital:

Serotonin syndrome has been reported in patients treated with these types of antidepressants (SSRIs). Tell your doctor if you experience high fever, trembling, muscle twitches and anxiety, because these symptoms may indicate the development of this condition. Treatment with citalopram should be discontinued immediately.

You should see your doctor immediately if you experience allergic symptoms such as a swollen face, tongue and/or pharynx and/or difficulty to swallow or a sudden rash (like 'hives') together with difficulties in breathing.

These may be very serious side effects. If you have them, you may have had a serious allergic reaction to citalopram. You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

The following side effects have been reported at the approximate frequencies shown: very common (affecting more than one person in 10):

Common (affecting fewer than one person in ten but more than one person in 100):

Uncommon (affecting fewer than one person in 100 but more than one person in 1,000):

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- Lightheadedness (dizziness)
- Ringing in ears
- Anxiety
- Decreased sex drive
- Loss of appetite
- Confusion
- Pins and needles
- Vomiting
- Frequent and watery bowel movements (diarrhea)
- Irregular and infrequent or difficult evacuation of the bowels (constipation)
- Muscle and joint pain
- Tiredness
- Inability of women to achieve orgasm impotence
- Ejaculation failure
- Rash and itching
- Yawning

Uncommon (affecting fewer than one person in 100 but more than one in 1,000)

- blood disease characterized by an abnormally small number of platelets in the blood
- hypersensitivity (rash)
- serious allergic reaction which causes difficulty in breathing or dizziness
- abnormally low level of potassium in the circulating blood leading to weakness and heart abnormalities
- sudden attack of fear
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Presentation: 10 x 10, 10 x 3 x 10 or Jar 1000

Shelf Life: 4 years

Date of Publication of Leaflet: August 2017

KEEP OUT OF REACH OF CHILDREN

Made in Ghana by:

KINAPharma LIMITED

B920/10 Mausoleum Lane,

North Industrial Area, Accra, Ghana