Pharmacode position may change as per Supplier's m/c requirement & additional small pharma code may appear on the front / back panel

Package leaflet: Information for the user

Citalopram 10 mg film-coated tablets
Citalopram 20 mg film-coated tablets
Citalopram 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 symptoms 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. Possible side effects
5. How to store Citalopram
6. Contents of the pack and other information

1. What Citalopram is and what it is used for

How does Citalopram work?
Citalopram is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to correct certain chemical imbalances in the brain that are causing the symptoms of your illness.

What is Citalopram used for?
Citalopram film-coated tablets contains citalopram and 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

Do not take Citalopram
- If you are allergic to Citalopram or any of the other ingredients of this medicine (listed in section 6). Consult your doctor if you think you might be.
- at the same time as taking medication known as monoamine oxidase inhibitors (MAOIs). MAOIs include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, and moclobemide (used for the treatment of depression), selegiline (used in the treatment of Parkinson's disease) and linezolid (an antibiotic). Even if you have finished taking one of the following MAOIs: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine you will need to wait 2 weeks before you start taking your citalopram tablets. One day must elapse after you have finished taking moclobemide. After stopping citalopram you must allow 1 week before taking any MAOI.
- If you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning)
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm. *Also refer to the section "Other medicines and Citalopram" below*.
- If you are taking buprenorphine-containing medicinal products. The use of these medicines together with Citalopram can lead to serotonin syndrome, a potentially life-threatening condition (see "Other medicines and citalopram").

Warnings and precautions
Talk to your doctor or pharmacist before taking Citalopram if you have any medical problems, especially if you have
- History of bleeding disorders or have ever suffered from bleeding in the stomach or intestine, or if you are pregnant (see 'Pregnancy, breast-feeding and fertility').
- Liver disease
- Kidney disease
- Diabetes (you may need an adjustment of your antidiabetic therapy)
- Epilepsy or a history of seizures or fits
- Mania or panic disorder
- Low blood levels of sodium
- ECT (electroconvulsive therapy)
- Suffered or suffer from heart problems or have recently had a heart attack
- 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)
- Experienced a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate
- If you have or have previously had eye problems, such as certain kinds of glaucoma (increased pressure in the eye).

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

Please note:
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. 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.

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.

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 behaviour 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 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 behavioural development of Citalopram in this age group have not yet been demonstrated.

Other medicines and Citalopram
Medicines may affect the action of other medicines and this can sometimes cause serious adverse reactions. Please tell your doctor or pharmacist if you are taking, have taken or might take any other medicines
This includes other medicines for depression (see Do not take citalopram).
- The herbal remedy St John's wort (*Hypericum perforatum*). This should not be taken at the same time as citalopram.
- Monoamine oxidase inhibitors (MAOIs). These should not be taken at the same time as citalopram (see Do not take citalopram).

Tell your doctor if you are taking any of the following medicines:
- Linezolid (an antibiotic)
- Sumatriptan (used to treat migraine) or tramadol and buprenorphine and similar medicines (strong pain killers). Taking these medicines together with Citalopram can lead to serotonin syndrome, a potentially life-threatening condition. The syndrome may be associated with 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.
- 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
- Imipramine and desipramine (used to treat depression)
- Medicines containing selegiline (used to treat Parkinson's disease)
- Cimetidine, lansoprazole and omeprazole (used to treat stomach ulcers), fluconazole (used to treat fungal infections), fluvoxamine (antidepressant) and ticlopidine (used to reduce the risk of stroke). These may cause increased blood levels of citalopram.
- Mefloquine (used to treat malaria)
- 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)

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.

Taking Citalopram with food, drink and alcohol
Citalopram can be taken with or without food (see section 3 "How to take citalopram").

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
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.
Ask your doctor or pharmacist for advice before taking any medicine. If you are pregnant, think you might be pregnant, or are trying to become pregnant, tell your doctor. 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/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 of birth you should be aware that the following effects may be seen in your newborn: fits, being too hot or cold, feeding difficulties, vomiting, low blood sugar, stiff or floppy muscles, overactive reflexes, tremor, jitteriness, irritability, lethargy, constant crying, sleepiness or sleeping difficulties. If your newborn baby gets any of these symptoms please contact your midwife and/or doctor immediately.

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

Fertility
Citalopram has been shown to reduce the quality of sperm in animal studies. Theoretically, this could affect fertility, but impact on human fertility has not been observed as yet.

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

Citalopram contains Lactose monohydrate.
Citalopram tablets contain lactose monohydrate. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Citalopram contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Citalopram

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

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. 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. For further information, please see section 2, **what you need to know before you take citalopram.**

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

How and when to take citalopram
Citalopram is taken every day as a single daily dose. Citalopram can be taken any time of the day with or without food. Swallow the tablets with a drink of water. Do not chew them (they have a bitter taste).

Duration of treatment
Like other medicines for depression and panic disorder these tablets may take a few weeks before you feel any improvement. Continue to take citalopram even if it takes some time before you feel any improvement in your condition. The duration of treatment is individual, usually at least 6 months. Continue to take the 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. The underlying illness may persist for a long time and if you stop your treatment too soon your symptoms may return.

Patients who have recurrent depression benefit from continued treatment, sometimes for several years, to prevent the occurrence of new depressive episodes.

Never change the dose of the medicine without talking to your doctor first.

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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 nearest hospital emergency department immediately. Do this even if there are no signs of discomfort or poisoning. Take the citalopram box/container with you if you go to a doctor or hospital. Some of the signs of an overdosage could be life-threatening.

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

If you forget to take Citalopram
If you forget to take a dose, take the next dose at the usual time. Do not take a double dose.

Effects when treatment with Citalopram is stopped
Stopping this medicine quickly may cause symptoms such as dizziness, nausea and numbness or tingling in hands or feet, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, headaches, feeling or being sick, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations). These are usually non-serious and disappear within a few days. When you have completed your course of treatment, the dose of citalopram is usually reduced gradually over a couple of weeks.

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.

Serious side effects
Stop taking citalopram and seek medical advice immediately if you have any of the following symptoms:
- Difficulty in 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.**

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

Common: may affect up to 1 in 10 people
- Lack of appetite
- Agitation
- Anxiety
- Decreased sex drive
- Nervousness
- Confusion
- Abnormal dreams
- Reduced emotions, indifference (apathy)
- Tremor
- Tingling or numbness in the hands or feet
- Dizziness
- Problems concentrating
- Migraine
- Loss of memory (amnesia)
- Ringing in the ears (tinnitus)
- Palpitations
- Yawning
- Blocked or runny nose (rhinitis)
- Diarrhoea
- Vomiting
- Constipation
- Stomach pain
- Flatulence (wind)
- Increase in saliva (drooling)
- Itching
- Pain in muscles and joints
- For men, problems with ejaculation and erection
- For women, failing to reach an orgasm
- Tiredness
- Prickling of the skin
- Loss of weight

Uncommon: may affect up to 1 in 100 people
- Bruising easily
- Increased appetite
- Aggression
- Hallucinations
- Mania
- Fainting
- Large pupils (the dark centre of the eye)
- Fast heart beat
- Slow heart beat
- Nettle rash
- Loss of hair
- Rash
- Sensitivity to sunlight
- Difficulties urinating
- Urinary hesitation, decreased urination
- Excessive menstrual bleeding
- Swelling of the arms or legs
- Increased weight

Rare: may affect up to 1 in 1,000 people
- Increased sex drive
- Convulsions
- Involuntary movements
- Taste disturbances
- Bleeding
- Coughing
- Hepatitis
- Feeling unwell (malaise)

Some patient have reported (frequency not known)
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see 'Pregnancy, breast-feeding and fertility' in section 2 for more information.
- Thoughts of harming or killing themselves, see also section 2 **"What you need to know before you take citalopram"**
- An increase in bleeding or bruising caused by a decrease in blood platelets (thrombocytopenia)
- Rash (hypersensitivity)
- Low potassium levels in the blood (hypokalaemia), which can cause muscle weakness, twitching or abnormal heart rhythms
- Panic attack
- Grinding teeth
- Restlessness
- Unusual muscle movements or stiffness
- Involuntary movements of the muscles (akathisia)
- Low blood pressure
- Nosebleed
- Bleeding disorders including skin and mucosal bleeding (ecchymosis)
- Sudden swelling of skin or mucosa
- In men, painful erections
- Flow of breast milk in men or in women who are not breast-feeding (galactorrhoea)
- Irregular menstrual periods
- Abnormal liver function tests
- An increased risk of bone fractures has been observed in patients taking this type of medicines
- 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 citalopram, 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 national reporting system listed in Yellow Card Scheme, Website: 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.

This medicine does not require any special storage conditions.

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.

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

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 contains
- The active substance is Citalopram.
  Each film-coated tablet contains 10 mg citalopram (as citalopram hydrobromide).
  Each film-coated tablet contains 20 mg citalopram (as citalopram hydrobromide).
  Each film-coated tablet contains 40 mg citalopram (as citalopram hydrobromide).
- The other ingredients are:
  Core tablets:
  Lactose monohydrate, Maize starch, Copovidone, Croscarmellose sodium, Cellulose microcrystalline, Magnesium stearate
  Film-coating:
  Hypromellose, Macrogol 400, Titanium dioxide (E 171)

What Citalopram looks like and contents of the pack
Film-coated tablet.

Citalopram 10 mg film-coated tablets are white coloured, biconvex, round shaped film-coated tablets debossed with 'A' on one side and '05' on the other side.

Citalopram 20 mg film-coated tablets are white coloured, biconvex, capsule shaped film-coated tablets marked with 'A' on one side and with a score line in between '0' and '6' on the other side. The tablet can be divided into equal doses.

Citalopram 40 mg film-coated tablets are white coloured, biconvex, capsule shaped film-coated tablets marked with 'A' on one side and with a score line in between '0' and '7' on the other side. The tablet can be divided into equal doses.

A pack of Citalopram contains 10, 14, 20, 28, 30, 50, 56, 84, 98 and 100 film-coated tablets.

Not all pack sizes may be marketed.

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