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, please ask your doctor, pharmacist or nurse.
- 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, pharmacist or nurse. 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 (SSRI’s).
Citalopram is used for the treatment of depressive illnesses (major depressive episodes).

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)
- if you are taking MAO (monoamine oxidase) inhibitors (medicines used for treatment of depression or Parkinson’s disease). The MAO-inhibitor called selegiline may be used in combination with citalopram, but only at doses of less than 10mg per day
- if you have recently taken MAO-inhibitors. Depending on the type of MAO-inhibitor you used to use, you may have to wait for up to 14 days after stopping the MAO-inhibitor before starting with Citalopram. If you stop taking Citalopram and want to start using MAO-inhibitors, you have to wait for at least 7 days. Please ask your doctor for advice.
- if you are taking linezolid unless you are under close medical supervision and monitored on blood pressure
- 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 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 medicines. Despite this, your doctor may prescribe Citalopram for patients under 18 because he/she decides 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**
If you are depressed 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 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, pharmacist or nurse before taking Citalopram tablets:

- if you have **diabetes** (as your doctor may need to adjust the dose of insulin your antidiabetic medicine)
- if you 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
- if you are receiving electro-convulsive treatment (ECT)
- if you have or have had **episodes of mania** (overactive behaviour or thoughts)
- if you have a history of **bleeding disorders** or are using medicines that affect **blood clotting** or increase the risk of bleeding
- if you suffer from **psychosis** with depressive episodes, because the psychotic symptoms may increase
- if you have **impaired kidney or liver function** (your doctor may need to reduce the dose of Citalopram and will also check your liver function)
- if you have or are prone to **heart rhythm disorders** (QT-interval prolongation or have suspected congenital QT-syndrome)
- 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
- if you suffer from **low blood levels of potassium or magnesium** (hypokalaemia/hypomagnesaemia)
- if you suffer from angle closure glaucoma or have had glaucoma
- if you suffer from **low blood sodium** (hyponatremia) 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 stabilize on stopping treatment.

Other warnings
- If whilst taking Citalopram you develop symptoms signs 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. He/she 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-affect 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, pins and needles, sleep disturbance, agitation, anxiety, nausea and/or vomiting, tremor, sweating, headache, diarrhoea, quick or irregular heartbeat, emotional instability, irritability and visual disturbances 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. 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.

The following medicinal products must not be used together with Citalopram tablets:
- MAO-inhibitors (medicinal products against depression or Parkinson’s disease). This applies both to irreversible MAO-inhibitors like phenelzine and to reversible MAO-inhibitors like moclobemide. The MAO-inhibitor called selegiline may be used in combination with citalopram, but only at doses of less than 10mg per day.
- If you have recently taken MAO-inhibitors. Depending on the type of MAO-inhibitor you used to use, you may have to wait for up to 14 days after stopping the MAO-inhibitor before starting with Citalopram. If you stop taking Citalopram and want to start using MAO-inhibitors, you have to wait for at least 7 days. Please ask your doctor for advice.
- Linezolid. Citalopram and linezolid may only 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, especially:
- sumatriptan or other triptans (to treat migraine), oxitryptan or tryptophan (substances that may influence the level of serotonin in the brain)
- other medicines for depression: tricyclic antidepressants, other serotonin re-uptake inhibitors or medicines containing lithium
- tramadol (to treat severe pain)
- St. John’s Wort (Hypericum perforatum) as the above medicines may lead to ‘serotonin syndrome’ (see ‘Other warnings’)
- desipramine (to treat depression) as the blood level of desipramin may be increased and a reduced dose may be needed
blood-thinning medicines (warfarin), other oral anticoagulants or medicines influencing blood clotting (e.g. non-steroidal antirheumatics, acetylsalicylic acid (aspirin), NSAID’s, dipyridamol and ticlopidine) as use with Citalopram may lead to increased/prolonged bleeding

- cimetidine (to reduce gastric acid)
- medicines to treat stomach ulcers (e.g. omeprazole, esomeprazole, lansoprazole)
- fluvoxamine (to treat depression)
- neuroleptics (to treat schizophrenia) as use with Citalopram can cause seizures.
- metoprolol (for high blood pressure or heart failure) as an increase in the blood level of metoprolol has been reported
- heart rhythm medicines or medicines which reduce blood levels of potassium or magnesium because citalopram also has this effect
- antipsychotic medicines (e. g. butyrophenones).

**Citalopram tablets with food, drink and alcohol**

You are advised NOT to drink alcohol with this medicine.
The film-coated 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.

**Pregnancy**

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.

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.

**Breast-feeding**

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.

**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.

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

**Adults**
The recommended dose is 20mg per day. This 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. 10-20mg per day. Elderly patients should not usually receive more than 20mg per day.

**Use in children and adolescents under the age of 18 years**
Citalopram should normally not be used (see ‘Use in 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 of 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 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 take more Citalopram tablets than you should**
If you have taken too much, contact a doctor immediately. Signs of possible overdose include nausea, vomiting, sweating, sleepiness, coma, seizures, faster pulse rate, disturbances of muscle tone, rapid breathing (hyperventilation), increased body temperature and rare changes in the activity of the heart muscle (ECG alterations).

**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. He or she 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, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

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

- thoughts of suicide and suicidal behaviour
- extrapyramidal disorder (e.g. involuntary movements, shaking, muscle rigidity and muscle contractions)
- restlessness and inability to stand or sit still (akathisia)
- a sudden, severe allergic reaction (anaphylactic reaction) characterised by a sharp drop in blood pressure, itchy skin rash, swelling of the lips, tongue or throat (angioedema), and breathing difficulties
- fast irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.
- reduced number of blood platelets (thrombocytopenia)

Very common (may affect more than 1 in 10 people):
- Feeling sick (nausea), dry mouth
- Headache
- Increased sweating
- Sleepiness, difficulty sleeping.

Common (may affect up to 1 in 10 people):
- Tremor, dizziness
- 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)
- Diarrhoea, vomiting, constipation, indigestion (dyspepsia), stomach pain, wind (flatulence), increased saliva
- Muscle pain (myalgia), joint pain (arthritis)
- Itching (pruritus)
- Tiredness, yawning
- Inability in women to achieve orgasm, menstrual pain, impotence, ejaculation failure
- Abnormal dreaming, 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 abnormalities
- Liver inflammation (hepatitis)
- Fever (pyrexia)
- Lower amount of blood sodium levels (hyponatraemia).

**Not known** (frequency cannot be estimated from the available data):
- 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
- Fits (convulsions)
- Serotonin syndrome (symptoms such as high fever, trembling, muscle twitches and anxiety)
- Movement disorder
- 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 medicines.
Withdrawal symptoms may occur when treatment is stopped (see “If you stop taking”). An increased risk of bone fractures has been observed in patients taking this type of medicines.

**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. 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 10/20/40mg 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 tablets are round, white film-coated tablets which come in three strengths. Citalopram 20mg tablets and Citalopram 40mg tablets can be divided into equal halves.

Pack size of 28.

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This leaflet was last revised in: March 2016
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