

## Package leaflet: Information for the user

### Citalopram 10 mg Film-coated Tablets

### Citalopram 20 mg Film-coated Tablets

Citalopram (as hydrobromide)

**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. 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

Citalopram is a Selective Serotonin Reuptake Inhibitor (SSRI) and belongs to a group of medicines known as antidepressants. These medicines help to normalise the levels of serotonin in the brain.

Disturbances in the serotonin system of the brain are key factors in the development of depression and related disorders.

Citalopram is used for the treatment of depression (including the prevention of the recurrence of symptoms) and panic disorders in adults.

*Depression* is characterised by low/depressed mood, lack of energy, melancholia, feelings of little or no worth, sleeping disorders, withdrawal and being unable to cope with daily tasks. Depression may also be accompanied by suicidal thoughts. Depressed patients may further suffer from symptoms of anxiety.

*Panic disorder* is characterised by patients developing unexpected attacks of intense panic or anxiety when faced with particular situations or due to the fear of experiencing new attacks. Precisely what triggers the attacks varies from patient to patient. The attacks recur when the patient faces the same situation again.

Following treatment initiation, an antidepressant effect should not be expected for at least two weeks. For the treatment of panic disorders the full therapeutic response may take up to 3 months to develop.

You must talk to a doctor if you do not feel better or if you feel worse.

#### 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)
- if you are taking monoamine oxidase inhibitors (also called MAOIs) or have taken them at any time within the last two weeks. MAOI's include medicines such as phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, selegiline (used in the treatment of Parkinson's disease), moclobemide (used in the treatment of depression) and linezolid (an antibiotic). Your doctor will tell you how to begin taking Citalopram, once you have stopped taking the MAOI. (see "Other medicines and Citalopram")
- 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 "Other medicines and Citalopram").

### **Warnings and precautions**

Talk to your doctor or pharmacist before taking Citalopram.

Please tell your doctor if you have any other condition or illness, as your doctor may need to take this into consideration. In particular, tell your doctor if you:

- are treated for panic attacks you may experience increased symptoms of anxiety when starting treatment. This reaction usually eases off within 2 weeks, during continued treatment. Your doctor will adapt your dosage (see section 3 "How to take Citalopram").
- suffer from epilepsy, seizures are a potential risk with antidepressant drugs.
- have a history of mania/hypomania, Citalopram should be used with caution and should be discontinued when you enter a manic phase.
- suffer from diabetes, treatment with Citalopram may alter glycaemic control. Insulin and/or oral hypoglycaemic dosage may need to be adjusted.
- have a bleeding disorder, or if you are pregnant (see "Pregnancy"). Citalopram may cause bleeding (e.g. skin and mucous bleeding).
- are using medicinal products that affect the coagulation of blood (see "Other medicines and Citalopram").
- have a stomach ulcer or have had any bleeding in the stomach or intestine in the past. Take special care if you are taking medicines that increase the risk of bleeding such as acetylsalicylic acid and NSAIDs (pain-relieving medicines).
- receive electro-convulsive therapy, because there is little experience, caution is advisable.
- are taking herbal remedies containing St. John's Wort (*Hypericum perforatum*). The concomitant use may result in an increased incidence of adverse reactions (see section "Other medicines and Citalopram").
- have severe kidney or liver problems.
- are psychotic with depressive episodes.
- are susceptible for QT-interval prolongation or have suspected congenital long QT-syndrome or suffer from hypokalaemia/hypomagnesaemia (low levels of potassium or magnesium in your blood).
- have a decreased level of sodium in the blood (hyponatraemia)
- suffer or have suffered from heart problems or have recently had a heart attack.
- 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).
- experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.
- suffer from mydriasis (dilation of the pupil of the eye), angle closure glaucoma or have had glaucoma (increased pressure in the eye).

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.

If treatment is stopped, since withdrawal reactions might occur (see "If you stop taking Citalopram"). 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.

### **Restlessness/Akathisia**

The use of citalopram has been linked to a distressing restlessness and need to move, often being unable to sit or stand still (akathisia). This is most likely to occur during the first few weeks of treatment. Increasing the dose may be harmful to patients who develop such symptoms.

### **Thoughts of suicide and worsening of your depression or anxiety disorder**

If you are depressed and/or have anxiety disorders you can sometimes have thoughts of harming or killing yourself. These may be increased when first starting antidepressants, since these medicines all take time to work, usually about two weeks but sometimes longer.

You may be more likely to think like this if you:

- have previously had thoughts about killing or harming yourself
- are a **young adult**. Information from clinical trials has shown an increased risk of suicidal behaviour in adults aged less than 25 years with psychiatric conditions who were treated with an antidepressant.

If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to a hospital straight away. You may find it helpful to tell a relative or a close friend** that you are depressed or have anxiety disorders, 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.

### **Serotonin syndrome**

In some patients, Citalopram therapy can lead to the development of a so-called serotonin syndrome. Immediately contact your doctor if you experience a combination of symptoms including high fever, muscle rigidity, shivering, agitation, confusion or anxiety, since they may indicate the development of this syndrome.

### **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**

Tell your doctor or pharmacist if you are taking, or have recently taken or might take any other medicines, including medicines obtained without prescription.

Do not take Citalopram if you are taking any of the following medicines:

- medicines for heart rhythm problems, such as quinidine, procainamide, disopyramide, amiodarone and sotalol (Class IA and III antiarrhythmics),
- antipsychotics such as pimozide and haloperidol,
- medicines to treat depression such as tricyclic antidepressants,
- medicines to treat infections such as sparfloxacin, moxifloxacin, erythromycin IV, pentamidine,
- anti-malarial treatment particularly halofantrine,
- certain antihistamines to treat allergies such as astemizole, mizolastine.

You should also tell your doctor if you are taking any of the following:

- monoamine oxidase inhibitors (MAOI's), such as moclobemide (to treat depression), selegiline (to treat Parkinson's disease) and the antibiotic linezolid. Do not take Citalopram for fourteen days after discontinuation of treatment with a so called *irreversible* MAOI. Do not take Citalopram for the time specified after discontinuation of treatment with a *reversible* MAOI (e.g. moclobemide), as directed by your doctor. Do not take MAOIs for seven days after discontinuation of treatment with Citalopram. Do not use Citalopram if you are taking more than 10 mg/day of the MAOI selegiline.
- medicines for depression, such as fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine, bupropion, tricyclic antidepressants like nortriptyline, desipramine, clomipramine and the herbal remedy St. John's Wort (*Hypericum perforatum*)
- Buprenorphine (a type of opioid medicine). Concomitant use increases the risk of serotonin syndrome, a potentially life-threatening condition.

medicines for migraine, such as sumatriptan and other triptans

medicines for pain, such as tramadol

medicines for pain and inflammation, called non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, ketoprofen and diclofenac

medicines to prevent blood clotting, such as acetylsalicylic acid, dipyridamol, ticlopidine

medicines that can cause a reduction of your blood levels of potassium (hypokalaemia) or magnesium

(hypomagnesaemia)

- medicines for irregular heartbeat, such as propafenone, flecainide
- medicines for heart failure, such as metoprolol
- medicines for stomach ulcer, such as omeprazole, lansoprazole, cimetidine
- medicines used to treat fungal infections, such as fluconazole
- medicines for psychiatric illness, such as lithium, risperidone, chlorpromazine, thioridazine, chlorprothixen, haloperidol
- medicines for malaria, such as mefloquin
- other medicinal products with serotonergic effects such as oxitriptan or tryptophan

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

Citalopram has been shown not to increase the effects of alcohol. Nevertheless, you are advised not to drink alcohol during treatment with Citalopram. Citalopram can 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*

Citalopram should not be used during pregnancy unless advised by a doctor taking into account all the risks. You should not discontinue 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.

If you are taking Citalopram in the last 3 months of pregnancy, let your doctor know as your baby might have some symptoms when it is born. These symptoms usually begin during the first 24 hours after the baby is born. They include not being able to sleep or feed properly.

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.

#### *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.

### **Driving and using machines**

Citalopram may affect your ability to drive a car or use machines. Do not drive or use machines until you know how Citalopram affects you.

## **3. How to take Citalopram**

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

The recommended dose is:

#### Adults

#### *Treatment of depression*

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

### *Treatment of panic disorders*

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.

The therapeutic effects usually appear after 2 – 4 weeks; further improvement is to be expected if taken for a longer period.

### Use in children and adolescents (under 18 years of age):

Citalopram should not be used in the treatment of children and adolescents under the age of 18 years (see “Warnings and precautions”).

### Elderly patients (>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.

### Reduced liver function

Patients with a mildly to moderately reduced liver function should receive a starting dose of 10 mg per day.

Patients with liver complaints should not receive more than 20 mg per day. Caution and extra careful dosing is advised in patients with a severely reduced liver function. Patients with a reduced liver function should be clinically monitored.

### Reduced kidney function

The doctor may decide to prescribe a dose lower than that described above.

Citalopram should be taken as a single dose, either in the morning or the evening. The tablets can be taken with or without food. The tablets should be swallowed whole with a drink of water or other fluid.

### **Duration of treatment:**

Citalopram does not work immediately. It may take 2-4 weeks before you feel any benefit from these tablets. This is normal for this type of medicine. For the treatment of panic disorders the full therapeutic response may take up to 3 months to develop. It may be necessary to continue treatment for several months. Continue to take the tablets 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**

If you have taken more Citalopram than you should, talk to a doctor or pharmacist immediately or go to your nearest hospital emergency department. Do this even if there are no signs of discomfort or poisoning. Take the Citalopram tablets box/container with you if you go to a doctor, pharmacist or hospital.

Symptoms in case of an overdose: Sleepiness, a condition of near unconsciousness, with apparent mental inactivity and reduced ability to respond to stimulation (coma stupor), seizures, changes in cardiac rhythm (e.g. prolonged QT-interval), cardiac arrhythmia, nausea, vomiting, transpiration, bluish discoloration of the skin due to an inadequate amount of oxygen in the blood (cyanosis), hyperventilation. Features of serotonin syndrome may occur (see “Possible side effects”), particularly when other substances are co-ingested.

### **If you forget to take Citalopram**

If you miss a dose, take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

### **If you stop taking Citalopram**

Do not stop taking Citalopram unless you are told to do so by your doctor. Since withdrawal reactions may occur when the treatment is stopped, it is advised to reduce the dose gradually at intervals of 1-2 weeks. If you stop taking Citalopram tablets too quickly, you may experience discontinuation symptoms. Most people find that the symptoms are mild and go away on their own within two weeks. However, in some patients they may be more severe in intensity or they may be prolonged (2-3 months or more). If you get severe discontinuation symptoms when you stop taking Citalopram tablets, please contact your doctor.

Withdrawal reactions include: dizziness, pins and needles or numbness, headache, nausea, vomiting, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxious, sweating, feeling restless or agitated, tremor, feeling confused or disorientated, feeling emotional or irritable, diarrhoea (loose stools), visual disturbances, fluttering or pounding heartbeat (palpitations). 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.

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.

**If you experience any of the following symptoms, stop taking Citalopram and see your doctor immediately or go to the casualty department at your nearest hospital:**

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

- Hyponatraemia: abnormally low blood levels of sodium which can cause tiredness, confusion, and muscle twitching

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

- High fever, agitation, confusion, trembling and abrupt contractions of muscles; these may be signs of a rare condition called serotonin syndrome which has been reported with the combined use of antidepressants.
- Swelling of skin, tongue, lips, or face, feeling dizzy or having difficulties breathing or swallowing (serious allergic reaction)
- Unusual bleeds, including gastrointestinal bleeds
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes

The majority of the side effects listed below are mild. Please be aware that many of the effects may also be symptoms of your illness and therefore will improve when you start to get better.

The following side effects have been reported at the approximate frequencies shown:

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

- Headache
- Sleepiness, difficulty sleeping
- Feeling sick (nausea), dry mouth
- Increased sweating

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

- Decreased appetite, decreased weight, weight loss (anorexia)
- Agitation, anxiety, nervousness, confusion
- Abnormal dreaming
- Decreased sex drive (libido)
- Tremor, dizziness
- Sensation of tingling or numbness in the skin (paraesthesia)
- Problems with concentration
- Ringing in ears (tinnitus)
- Tiredness (fatigue), yawning
- Diarrhoea, vomiting, constipation
- Itching (pruritus), prickling of the skin
- Muscle pain (myalgia), joint pain (arthralgia)
- Inability in women to achieve orgasm, impotence, ejaculation failure
- Fever

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

- Increased appetite, increased weight
- Aggression, feeling detached from yourself (depersonalisation), hallucinations, mania (feeling highly excited, being over-active and easily irritated or distracted)
- Fainting (syncope)
- Dilated pupils (mydriasis)
- Slow heartbeat
- Fast heartbeat
- Hives (urticaria), rash
- Hair loss (alopecia)
- Redness or red/purple spots on the skin (purpura)
- Photosensitivity (skin rash caused by exposure to sunlight)
- Problems passing urine (urinary retention)
- Heavy menstrual period (menorrhagia)
- Generalized swelling (oedema)

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

- Low levels of sodium in the blood (hyponatraemia)
- A major fit ('grand mal convulsion'), involuntary movements (dyskinesia)
- Taste abnormalities
- Bleeding (e.g. vaginal, gastrointestinal, skin and soft tissue bleeding)
- Liver inflammation (hepatitis)

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

- Reduced number of blood platelets (thrombocytopenia)
- A sudden, severe allergic reaction (anaphylactic reaction) characterized by a sharp drop in blood pressure, itchy skin rash, swelling of the lips, tongue or throat, and breathing difficulties
- Allergy (hypersensitivity)
- Condition known as SIADH (Syndrome of Inappropriate Secretion of Antidiuretic Hormone) predominantly in the elderly
- Low levels of potassium in the blood (hypokalaemia)
- Panic attacks, teeth grinding (bruxism), restlessness
- Thoughts of suicidal behaviour
- Fits (convulsions)
- Serotonin syndrome (symptoms such as high fever, trembling, muscle twitches and anxiety)
- Extrapyrimal disorders (e.g. involuntary movements, shaking, muscle rigidity and muscle contractions)
- Feeling of restlessness and not being able to keep still (akathisia)
- Movement disorders
- Vision disturbance
- Heart condition called QT-prolongation (irregular heartbeat recognisable on ECG)
- Abnormality of the rhythm or rate of the heart beat (arrhythmia)
- Dizziness when standing up fast, caused by low blood pressure (orthostatic hypotension)
- Nosebleed (epistaxis)
- Blood in the stools (gastrointestinal or rectal haemorrhage)
- Abnormal liver function tests
- Bruising (ecchymosis)
- Swelling (angio-oedema) of the skin or of the tissue lining internal cavities of the body (mucous membrane)
- Abnormal milk secretion from the breast in men (galactorrhoea)
- Painful prolonged erection (priapism)
- Irregular menstrual bleeding (metrorrhagia)
- An increased risk of bone fractures has been observed in patients taking this type of medicine.
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see "Pregnancy" in section 2 for more information

Withdrawal symptoms may occur when treatment is stopped (see 'If you stop taking Citalopram').

## **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 HPRA Pharmacovigilance, Website:

[www.hpra.ie](http://www.hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Citalopram**

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

Do not store above 25 °C.

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.

Contents of the pack and other information

### **What Citalopram contains**

- The active substance is citalopram. Each tablet contains 10 mg or 20 mg citalopram as citalopram hydrobromide.
- The other ingredients are:  
*Core:* mannitol, microcrystalline cellulose, silica colloidal anhydrous, magnesium stearate  
*Film-coat:* hypromellose, titanium dioxide (E171), macrogol 6000

### **What Citalopram looks like and contents of the pack**

Citalopram 10 mg: white, circular, coated, biconvex tablets.

Citalopram 20 mg: white, circular, coated, biconvex tablets, scored on both sides with side scores. The 20 mg tablet can be divided into equal halves.

Citalopram tablets are packed in PVC/PVDC/Al blister packs or HDPE tablet containers with LDPE cap.

Pack sizes: 7, 14, 21, 28, 30, 50, 56, 60, 84, 98, 100 or 500 tablets.

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder**

Accord Healthcare Ireland Ltd, Euro House, Euro Business Park, Little Island, Cork T45 K857, Ireland

### **Manufacturers**

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