

## **Important things you need to know about Citalopram**

**Please read all of this leaflet before you start to take your medicine as it contains important information about Citalopram**

- **Citalopram is used to treat depression and panic disorders with or without agoraphobia (fear of leaving the house, entering shops or fear of public places)**
- **Citalopram is not for use in children and adolescents under 18 years of age**

**If you have any concerns about how you feel, or about this medication, it is important that you talk to your doctor - even if you feel anxious or worried about doing so.**

You may find it helpful to tell a friend or relative that you are depressed, and that you have been prescribed this medication; it might be useful to show them this leaflet.

- **Citalopram may not start to work immediately.** Some people taking antidepressants may feel worse before feeling better. Your doctor may ask to see you again a couple of weeks after you start treatment and then regularly until you start to feel well again. Tell your doctor if you do not start to feel better
- **Some people who are depressed may think of harming or killing themselves. If this happens you should see your doctor or go to a hospital straight away** – see in section 2 ‘Thoughts of suicide and worsening of your depression or anxiety disorder’
- **If you take too many tablets it is important to seek immediate medical attention, even if you feel well, because of the risk of serious side effects**
- **Do not stop taking Citalopram or change your dose without the advice of your doctor even if you feel better.** If you stop taking Citalopram abruptly you may get withdrawal reactions – see in section 3 ‘How to take Citalopram Tablets’
- **Taking certain other medicines with Citalopram may cause problems. You should tell your doctor if you are taking any other medicines** – see in section 2 ‘What you need to know before you take Citalopram Tablets - Other medicines and Citalopram’

**Keep this leaflet. You may need to read it again.**

**If you have more questions, ask your doctor or pharmacist.**

**Leaflet date December 2023.**

## **Package leaflet: Information for the patient**

**Citalopram 10 mg Film-coated Tablets**  
**Citalopram 20 mg Film-coated Tablets**  
**Citalopram 40 mg Film-coated Tablets**  
citalopram 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, 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 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 are they 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 are they 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 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 with or without agoraphobia (e.g. fear of leaving the house, entering shops, or fear of public places).

### **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). An allergic reaction may include rash, itching, swelling of face, lips or hands/feet, or breathing difficulties.
- If you are taking medicines called monoamine oxidase inhibitors (MAOIs), or have stopped taking them within the past two weeks. Treatment must not begin any sooner than two weeks after you stop taking an irreversible MAO inhibitor, or the time specified by your doctor after you stop taking a reversible MAO inhibitor (e. g. moclobemide). Your doctor will tell you

how to begin taking Citalopram Tablets once you have stopped taking the MAOI. At least one week should pass after you stop taking Citalopram Tablets before beginning treatment with a MAO inhibitor.

- If you are taking medicines such as linezolid (an antibiotic) and/or pimozide (used to treat mental disorders).
  - 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.

### **Warnings and precautions**

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.

### **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.
- 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.

Talk to your doctor, pharmacist or nurse before taking Citalopram Tablets, if you have, or ever had

- Epilepsy (seizure or fits).
- Problems with your kidneys and/or liver. Your doctor may reduce the dose of the tablets if your kidneys and/or liver are not working properly.
- Low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma. This effect is more likely to occur if you are a female older patient. However, your blood sodium level becomes normal once you stop taking this medicine.
- You are being treated with electroconvulsive therapy.
- Mania (feeling elated or emotionally “high”).
- Severe mental condition in which the person loses contact with reality and is unable to think and judge clearly.
- Diabetes (dose of insulin and/or oral anti-diabetic medicines may need to be adjusted).
- Angle-closure glaucoma or history of glaucoma.
- History of bleeding or have ever suffered from bleeding in the stomach or intestine, or if you are pregnant (see “Pregnancy, breast-feeding and fertility”) and/or if you are taking medicines known to affect blood clotting or increase risk of bleeding such as:
  - NSAIDs (e.g. Aspirin, Ibuprofen and Diclofenac)
  - Ticlopidine, dipyridamol (medicine known to affect blood platelets)

- Atypical antipsychotics (e.g. clozapine), Phenothiazines (e.g. Chlorpromazine, Thioridazine), tricyclic antidepressants (e.g. Imipramine, Desipramine) (see section “Other medicines and Citalopram Tablets” below).
- 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.

Symptoms such as restlessness, for example, you cannot sit or stand still, can occur during the first weeks of treatment. Tell your doctor immediately if you experience these symptoms. Then a dosage adjustment may be helpful.

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.

In some rare instances, during treatment with Citalopram Tablets, certain concurrent serotonergic effects serotonin syndrome or a condition resembling malignant neuroleptic syndrome may develop, in particular when taken along with other serotonergic and/or neuroleptic substances. As these syndromes may possibly lead to life-threatening conditions, treatment with Citalopram Tablets should be stopped whenever they occur, and a supportive symptomatic treatment should be initiated. These syndromes are characterised by a number of symptoms occurring simultaneously, such as motor restlessness, confusion, sweating, hallucinations, increased reflexes, stiffness in muscle, shaking chills, increased heart rate, and trembling (see also “Possible side effects”). Rhabdomyolysis (temporary paralysis or weakness of muscles) can occur rarely.

#### 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.

#### **Children and adolescents**

Citalopram Tablets 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 Tablets for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Citalopram Tablets 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 Tablets.

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.

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

Citalopram Tablets are to be taken as a single daily dose. Citalopram Tablets can be taken any time of the day with or without food.

Do not drink alcohol while you are taking Citalopram Tablets.

## **Other medicines and Citalopram Tablets**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Some medicines can cause problems if you take them with this medicine.

Care is needed if you are taking the following medicines:

- Non-selective monoamine oxidase inhibitors (MAOIs)", containing phenelzine, iproniazid, isocarboxazid, nialamide, and tranylcypromine as active ingredients.
- Reversible, selective monoamine oxidase inhibitors", containing moclobemide (used to treat depression).
- "Irreversible monoamine oxidase inhibitors", containing selegiline (used to treat Parkinson's disease). These increase the risk of side effects.
- Lithium (used in the treatment of manic-depressive disorder) and tryptophan.
- Imipramine and desipramine (both used to treat depression).
- Sumatriptan and similar medicines (used to treat migraine), dextromethorphan (used to relieve cough), pethidine (pain killer) and tramadol (used against severe pain). These increase the risk of side effects.
- St. John's Wort (*Hypericum perforatum*) - a herbal remedy used for depression.
- Aspirin and non-steroidal anti-inflammatory drugs (medicines used for pain relief or to thin the blood, so called anticoagulants).
- Ticlopidine, dipyridamol (medicine known to affect blood platelets)
- For mental illnesses, such as atypical antipsychotics (e.g., clozapine, risperidone, olanzapine, quetiapine) or phenothiazines (e.g., chlorpromazine, trifluperazine), or antidepressants (e.g., imipramine, clomipramine, desipramine). Taking Citalopram along with these medicines can increase your chances of bleeding.
- Medicines that lower blood potassium and magnesium level.
- 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).
- Carbamazepine (used to treat fits)
- 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).

**DO NOT TAKE Citalopram Tablets** 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.

## **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. Your doctor will have to decide whether treatment with Citalopram Tablets is clearly necessary or whether an alternative treatment is possible for you.

You should not stop treatment with Citalopram Tablets abruptly due to pregnancy or other reasons.

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, breathing difficulties, blue or purple coloration of the skin or mucous membranes, 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.

Citalopram is known to be found in breast milk. Its effects on children taking breast milk have not been established. If treatment with citalopram is considered necessary, discontinuation of breast feeding should be considered.

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.

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.

#### **Driving and using machines**

This medicine may cause side-effects (such as feeling dizzy, sleepy, confused and having problems with eyesight) that affect how well you concentrate and how quickly you can react. If you get these side-effects, do not drive or use machines or anything else where you need to be alert and concentrate.

#### **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.

### **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.

#### **How much to take**

It is important to take your tablets as instructed by your doctor.

The label will tell you how many to take and how often. If it does not, or you are not sure, ask your doctor or pharmacist.

#### **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.

**Older 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. Older patients should not usually receive more than 20 mg per day.

**Children and adolescents (< 18 years)**

Citalopram should not be given to children and 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).

The score line is not intended for breaking the tablet.

**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.

If you have the impression that the effect of Citalopram Tablets is too strong or too weak, talk to your doctor or pharmacist.

**If you take more Citalopram Tablets than you should**

Never take more tablets than your doctor recommends. If you have taken too many tablets, or if someone accidentally swallows some, contact your doctor or the nearest hospital for advice. Show them the pack of tablets. The most likely signs of taking too many tablets (overdose) are: feeling dizzy or drowsy, sweating, very high fever, bluish or purplish tinge to the skin and mucous membranes, serotonin syndrome, feeling or being sick (nausea or vomiting), dilated pupils, rapid or deep breathing, having abnormal heartbeats, abnormal heart rhythm, high or low blood pressure, heart attack, uncontrollable muscle spasms affecting the eyes, head, neck and body, shaking or tremors, fits, feeling agitated or anxious and coma.

**If you forget to take Citalopram Tablets**

If you forget to take your dose of this medicine, simply carry on with the next dose as usual. Do not take a double dose to make up for a forgotten dose.

**If you stop taking Citalopram Tablets**

Do not stop taking this medicine until your doctor tells you to, even if you feel better.

If you stop suddenly after taking this medicine for a long time you can experience withdrawal effects, symptoms such as dizziness, diarrhoea, numbness and tingling, sweating, headache, fast or irregular heartbeats, emotional instability, irritability, agitation or anxiety, sleep disturbances

including inability to sleep and/or intense dream, shaking or tremor, confusion, visual disturbances, nausea and vomiting may occur. These symptoms are generally non-serious and disappear within a few days. Citalopram should always be stopped gradually over 1-2 weeks period.

If you get withdrawal effects when you are coming off your tablets your doctor may decide that you should come off them more slowly.

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.

They are most prominent during the first one or two weeks of treatment and usually decrease as your depression improves.

**If you get any of the following symptoms you should stop taking Citalopram Tablets and see your doctor immediately:**

- Allergic reactions
- Angioedema, such as
  - swollen face, tongue or pharynx
  - difficulty in swallowing
  - hives and difficulties to breath
- Serotonin syndrome (symptoms: motor restlessness, confusion, sweating, hallucinations, increased reflexes, stiffness in muscles, shaking chills, increased heart rate and trembling)
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

#### **Very common: (more than 1 in 10 patients treated)**

- Not sleeping well or feeling sleepy
- Headaches, dizziness
- Fluttering or pounding heartbeat
- Feeling sick (nausea), dry mouth
- Increased sweating
- Visual disturbances
- Feeling of weakness

#### **Common: (less than 1 in 10 but more than 1 in 100 patients treated)**

- Feeling agitated, nervousness
- Sleep disorders (excessive sleepiness, abnormal dreaming), impaired concentration, abnormal dreaming, loss of memory, anxiety, decreased sex drive, abnormal orgasm (female), decreased appetite, feeling of complete dissatisfaction and confusion.
- Migraine and paraesthesia (sensation of pricking, tingling, or creeping on the skin)
- Feeling shaky (tremors)
- Change in blood pressure (can increase or drop)
- Indigestion, vomiting, constipation, diarrhea (loose stools), stomach pains, increased wind and saliva
- Difficulty in urine passing, excessive secretion of urine
- Muscle pain, joint pain
- Decrease in weight

- Inflammation of the nasal passages and sinuses
- Failure of ejaculation in males, impotence, painful menstruation has been reported in some female patients.
- Pruritus (localized or generalized itching of skin)
- Problems with eyesight
- Ringing of ear
- Fatigue, yawning

**Uncommon: (less than 1 in 100 but more than 1 in 1000 patients treated)**

- Aggression; seeing, feeling or hearing things that are not there (hallucination); mood of excitement, over-activity and uninhibited behaviour (mania); depersonalisation; feeling of extreme happiness and increased sexual drive
- Increased appetite, increase in weight
- Abnormal heart rate
- Fainting
- Dilated pupils
- Rash, hives, hair loss, unusual bleeding or bruising under the skin,
- Unable to pass urine
- Heavy menstrual periods
- Coughing
- Swelling of hands, ankles or feet
- Increase sensitivity of skin to sunlight
- Allergic reactions, malaise (general feeling of being unwell)

**Rare: (less than 1 in 1000 but more than 1 in 10000 patients treated)**

- Abnormal bleeding, mostly of the skin and mucous membranes, gastrointestinal bleeding, vaginal bleeding
- Tiredness, confusion and twitching of your muscles. These may be signs of a low blood level of sodium.
- Taste abnormalities
- Fits, uncontrollable twitching, jerking or writhing movements
- Liver disease, characterised by yellowing of the skin and eyes, light coloured bowel motions, dark coloured urine etc
- Fever or high temperature.

**Very rare: (less than 1 in 10000 patients treated, including isolated reports)**

- Rapid rhythm of heart
- Increased prolactin levels

**Not known**

- Bleeding or bruising more easily than normal
- Heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “Pregnancy, breast-feeding and fertility” in section 2 for more information
- Overproduction of a hormone causing fluid retention, resulting in weakness, tiredness or confusion
- Low potassium levels in the blood
- Panic attack, grinding of the teeth, restlessness, suicidal ideation, suicidal behaviour
- Abnormal involuntary movements (extrapyramidal disorders)
- Restlessness or difficulty sitting still, movement disorder
- Feeling faint or light headed on standing up due to decrease in blood pressure
- Nose bleed
- Abnormal liver function test

- Persistent painful erection of the penis which occurs without sexual arousal
- Abnormal production of breast milk in men and women

Bone fractures have been reported in patients aged 50 years and older.

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. 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](http://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.

Do not use this medicine after the expiry date which is stated on the carton and blister strip. The expiry date refers to the last day of that month.

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 hydrobromide.

Each 10 mg film-coated tablet contains 12.5 mg citalopram hydrobromide equivalent to 10 mg citalopram.

Each 20 mg film-coated tablet contains 25 mg citalopram hydrobromide equivalent to 20 mg citalopram.

Each 40 mg film-coated tablet contains 50 mg citalopram hydrobromide equivalent to 40 mg citalopram.

The other ingredients are lactose monohydrate, microcrystalline cellulose, maize starch, copovidone, croscarmellose sodium and magnesium stearate. The ingredients of the film-coating material, Opadry White 20H 58983 comprise of hypromellose, titanium dioxide (E171), propylene glycol, hydroxypropyl cellulose and talc.

### **What Citalopram Tablets look like and content of the pack**

Citalopram Tablets are white to off-white, circular biconvex film-coated tablets.

- 10 mg tablets are marked with “10” on one side and plain on the other side.
- 20 mg tablets are marked with “20” on one side and a score line on the other side.
- 40 mg tablets are marked with “40” on one side and a score line on the other side.

Citalopram Tablets are available as blister strips in pack sizes of 1, 14, 20, 28, 30, 50, 56, 98, 100 or 250 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

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