FOCUS Focus Pharmaceuticals Ltd

PACKAGE LEAFLET: INFORMATION FOR THE USER

Citalopram 40mg/ml Oral Drops

Citalopram Hydrochloride

Nine important things you need to know about Citalopram Oral Drops.
You should read all of this leaflet carefully before taking your medicine. It includes a lot of additional important information.

- **Citalopram Oral Drops treat depression and panic attacks.** Like all medicines it can cause side effects. Before you start taking your medicine it is important that you and your doctor discuss the benefits of treatment against the possible side effects (See section 4, Possible side effects)
- **Citalopram Oral Drops should not be used by children and adolescents under 18 years of age** (See section 3, Children and adolescents under 18 years of age)
- **Some people who are depressed or anxious think of harming or killing themselves.** If you start to feel worse, or think of harming or killing yourself, see your doctor or go to a hospital straight away (See section 4, Possible side effects)
- **If you feel restless and feel like you can't sit or stand still, or you want to keep moving around, tell your doctor.** If your dose of Citalopram Oral Drops is increased it may make these feelings worse (See section 4, Possible side effects)
- **Citalopram Oral Drops do not work straight away.** Some people taking antidepressants feel worse before feeling better. Your doctor should ask to see you again a couple of weeks after you first start treatment. Tell your doctor if you haven't started feeling better (See section 3, How to take Citalopram Oral Drops)
- **Don't stop taking Citalopram Oral Drops without talking to your doctor.** If you stop taking your medicine suddenly or miss a dose, you may get withdrawal effects (See section 3, If you stop taking Citalopram Oral Drops)
- **Taking some other medicines with Citalopram can cause problems.** You may need to talk to your doctor (See section 2, What you need to know before you take Citalopram Oral Drops)
- If any of the side effects get serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, pharmacist or nurse
- If you are pregnant or planning to get pregnant, talk to your doctor (See section 2 Pregnancy, breast-feeding and fertility).

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 Oral Drops are and what they are used for
2. What you need to know before you take Citalopram Oral Drops
3. How to take Citalopram Oral Drops
4. Possible side effects
5. How to store Citalopram Oral Drops
6. Contents of the pack and other information

1. What Citalopram Oral Drops are and what they are used for

Your medicine is called Citalopram 40mg/ml Oral Drops (called Citalopram Oral Drops throughout the rest of this leaflet). Citalopram belongs to a group of medicines called antidepressants. They are also known as selective serotonin reuptake inhibitors (SSRIs). Everyone has a natural substance called serotonin in their brain. People who are depressed or anxious have lower levels of serotonin than others. It is not completely understood how SSRIs work but it is thought that they help by raising your levels of serotonin.

What this medicine does

Your doctor has prescribed Citalopram Oral Drops for one or more of the following reasons:

- to treat depression
- to treat panic attacks (strong and sudden feelings of fear and anxiety, the symptoms of which may include fast heart beat, trembling, fast shallow breathing, pins and needles in the arms and feeling faint).

2. What you need to know before you take Citalopram Oral Drops

Do not take Citalopram Oral Drops:

- if you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6)
- 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 Oral Drops" below
- if you are taking **pimozide** (for mental illness and paranoia)
- if you are breast-feeding
- if you are taking, or have recently taken, medicines called **Monoamine Oxidase Inhibitors (MAOIs)** including phenelzine, isocarboxazid, tranylcypromine, moclobemide, used to treat depression and selegiline, used to treat Parkinson's disease. The maximum dose of citalopram will be 8mg (4 drops)/(0.2ml) per day
  - **Wait 14 days** after stopping an irreversible MAOI before you take Citalopram Oral Drops
  - **Wait 7 days** after stopping Citalopram Oral Drops before starting a MAOI
  - for reversible MAOIs (RIMA) your doctor will tell you how many days to wait from stopping your RIMA to starting citalopram
  - if you are taking **linezolid** (an antibiotic) you can only take citalopram if kept under close observation by your doctor and your blood pressure is monitored.

Serious side effects, known as Serotonin Syndrome, that can be life threatening, can occur if these instructions are not followed. Symptoms of these reactions include:

- high temperature (fever)
- stiffness
- muscle spasm
- rapid changes in body temperature
- rapid changes in heart and breathing rate and blood pressure
- confusion
- irritability and extreme agitation progressing to a coma.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Citalopram Oral Drops:

- If you have epilepsy (fits). Your doctor will monitor you carefully. **Tell your doctor immediately if you have a fit for the first time, or if you have fits more often than usual** (See section below, Other medicines and Citalopram Oral Drops)
- If you suffer from mania/hypomania (great excitement, difficulty concentrating, difficulty staying still), or hallucinations (strange visions or sounds). **If you start to have a manic period whilst taking this medicine tell your doctor immediately**
- If you are having electroconvulsive therapy (ECT; where a small electric current is passed through the brain). Your doctor will monitor you carefully
- If you have diabetes and are taking insulin and/or medicines to control it (See section below, Other medicines and Citalopram Oral Drops)
- If you take medicines known to affect the clotting of your blood (See section below, Other medicines and Citalopram Oral Drops). Citalopram Oral Drops can increase the risk of bleeding
- If you have a bleeding disorder where your blood doesn't clot properly. Citalopram Oral Drops can increase the risk of bleeding
- If you have, or have ever had, bleeding from ulcers in your stomach or intestines
- If you have problems with your liver or kidneys
- 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 using 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
- If you are under 18 years of age. Citalopram Oral Drops should not be used in children/adolescents under 18 years of age
- If you are elderly.

Medicines like Citalopram Oral Drops (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.
- 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 Oral Drops 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 Oral Drops for patients under 18 because he/she decides that this is in their best interests. If your doctor has prescribed Citalopram Oral Drops 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 Oral Drops. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Citalopram Oral Drops in this age group have not yet been demonstrated.

Other medicines and Citalopram Oral Drops

Talk to your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

This is especially important if you are taking or have recently taken any of the following:

- **Monoamine Oxidase Inhibitors (MAOIs)** such as phenelzine, isocarboxazid, tranylcypromine and moclobemide used to treat depression. Also selegiline, used to treat Parkinson's disease (See section above, "Do not take Citalopram Oral Drops")
- **Linezolid** (an antibiotic); see section "Do not take Citalopram Drops"
- **Pimozide** (for mental illness and paranoia); see section "Do not take Citalopram Drops"
- **Insulin or medicines for diabetes** such as chlorpropamide, glibenclamide, gliclazide, tolbutamide and metformin: if taken with citalopram your doctor may need to change your dose of diabetes medicine
- **Medicines that affect serotonin levels, causing Seratonin Syndrome**, such as tramadol (for severe pain), sumatriptan and buspirone (for anxiety) (for migraine if taken with citalopram you may have more severe side effects. Your doctor will need to monitor you carefully
- **Lithium** (for mania, manic-depression and recurring depression): if taken with citalopram you may have more severe side effects. Your doctor will monitor you carefully
- **Tryptophan** (for depression): if taken with citalopram you may have more severe side effects. Your doctor will monitor you carefully
- **St John's Wort** *(Hypericum perforatum)*, a herbal remedy for depression: if taken with citalopram you may have more side effects
- **Antidepressant medicines known as tricyclics** such as imipramine, amitriptyline, clomipramine and doxepin: if taken with citalopram, your doctor may need to change your dose of tricyclic antidepressant
- **Medicines known to affect the clotting of your blood:** if you take citalopram with one of the medicines below you may increase the risk of bleeding:
  - anticoagulants (blood thinning medicines), such as warfarin
  - aspirin (pain relief and blood thinning medicine)
  - pain relief medicines called non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and diclofenac
  - medicines for mental illness (antipsychotics) such as chlorpromazine, amisulpride, clozapine and risperidone
  - other medicines used to treat depression (tricyclic antidepressants) such as imipramine, amitriptyline, clomipramine and doxepin
- **Cimetidine** (for heartburn and stomach ulcers; it reduces stomach acid production): if taken with citalopram your doctor may need to change your dose of citalopram
- **Metoprolol** (for high blood pressure and heart disorders): if taken with citalopram your doctor may need to change your dose of metoprolol.

DO NOT TAKE Citalopram Oral Drops if you take drugs 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.

Taking Citalopram Oral Drops with food, drink and alcohol

- Citalopram Oral Drops may be taken with or without food
- Take Citalopram Oral Drops in a drink of water, orange juice or apple juice (see section 3, How to take Citalopram Oral Drops)
- Talk to your doctor about drinking alcohol while taking Citalopram Oral Drops.

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

Make sure your midwife and/or doctor knows you are on Citalopram Oral Drops. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram Oral Drops may increase the risk of a serious condition in babies, called persistent pulmonary hypertension of the new born (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

If you are breast-feeding speak to your doctor before taking Citalopram Drops. If you are already taking Citalopram Drops do not breast-feed as citalopram can pass to 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 generally affect people's ability to drive or use machines. However, your illness, medicine or both may affect your ability to drive or use machines.
Do not drive or use machines if you feel dizzy, sleepy or your co-ordination is affected.

Citalopram Oral Drops contain Methyl parahydroxybenzoate, propyl parahydroxybenzoate and ethanol

- Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) - these may cause allergic reactions (possibly delayed)
- Small amounts of ethanol (alcohol), less than 100mg alcohol in the maximum daily dose of 24 drops. This should not affect you.

3. How to take Citalopram Oral Drops

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

- take your drops as a single dose once a day either in the morning or evening unless your doctor has instructed otherwise
- take your drops in a drink of water, orange juice or apple juice
- to take your drops, unscrew the bottle cap then carefully tip the bottle up until the drops start to come out
- count the required number of drops into your drink, stir it and then drink all of it **immediately**
- do not leave your drink where someone else may drink it as your medicine could harm them.

If you have been taking Citalopram Tablets and are now taking Citalopram Oral Drops the total dose of citalopram per day may be less as the drops work better than the tablets. For example, if you were taking one 20mg citalopram tablet a day your doctor will tell you to take 8 drops (16mg) of Citalopram Oral Drops per day.

Adults - depression

- The recommended dose is 16mg (8 drops)/(0.4ml) per day
- This may be increased by your doctor to a maximum of 32mg (16drops)/(0.8ml) per day.

Adults - panic attacks

- The recommended starting dose is 8mg (4 drops)/(0.2ml) per day for the first week before increasing the dose to 16-24mg (8-12 drops)/(0.4 -0.6 ml) per day
- The dose may be increased by your doctor to a maximum of 32mg (16 drops)/ (0.8ml) per day.

Elderly patients (above 65 years of age)

- The recommended starting dose should be decreased to half the recommended dose, e.g. 8-16mg per day
- Elderly patients should not usually receive more than 16mg (8 drops)/(0.4ml) per day.

Patients with liver problems

- Patients with liver complaints should not receive more than 16mg (8 drops)/(0.4ml) per day.

Patients with kidney problems

- If you have mild or moderate kidney problems you can take the normal adult dose
- If you have severe kidney problems your doctor will tell you how many drops to take.

Children and adolescents under 18 years of age

- Citalopram Oral Drops should not be used for children and adolescents under 18 years of age.

It may take 1 to 2 weeks of treatment before you begin to feel better. This is normal for this type of medicine. Your doctor should ask to see you 3 to 4 weeks after you start taking your medicine. If you do not feel any better, tell your doctor.

If you take more Citalopram Oral Drops than you should

- If you take more drops than your doctor has told you to contact a doctor or your nearest hospital casualty department immediately and take your Citalopram Oral Drops with you.

If you forget to take Citalopram Oral Drops

- If you forget to take a dose, do not worry. Take the next dose when it is due
- Do not take a double dose to make up for a forgotten dose.

If you stop taking Citalopram Oral Drops

You must continue to take your drops for as long as your doctor tells you to even if you feel better; this may be for six months or more. Speak to your doctor before you stop taking Citalopram Oral Drops.

- Do not stop taking your medicine suddenly. Your doctor will tell you how to reduce your dose slowly over a number of weeks or months to help lower the chance of you getting withdrawal symptoms
- Stopping Citalopram Oral Drops (particularly if they are stopped suddenly) can lead to **withdrawal symptoms.** The most common are:
  - dizziness
  - change in sensitivity to touch (increase or decrease), tingling, pins and needles, very sensitive skin and electric shock sensations
  - problems sleeping (vivid dreams, nightmares, not able to sleep)
  - feeling agitated or anxious
  - feeling or being sick
  - shaking (tremor)
  - feeling confused
  - sweating
  - headache
  - diarrhoea
  - a feeling of irregular and/or pounding of the heart (palpitations)
  - feeling emotional or irritable
  - visual disturbances
- These symptoms usually appear within the first few days of stopping your medicine. In most people the symptoms are mild and go away on their own within two weeks. For some people they may be more severe and last longer
- If you get severe withdrawal symptoms tell your doctor. He/she may ask you to start taking your medicine again and then to start coming off it again 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.

If you have any of the following side effects while taking your medicine tell your doctor immediately or go to hospital straight away:

- **thoughts of suicide and worsening of your depression or anxiety disorder.** If you have thoughts of harming or killing yourself at any time, **contact your doctor or go to 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
- epilepsy and have more fits than normal or if you have a fit for the first time
- severe allergic reaction which may include a red and lumpy skin rash, difficulty breathing, swelling of face, mouth, lips or eyelids, unexplained high temperature (fever) and feeling faint. **If the swelling affects your throat and makes breathing and swallowing difficult, go to hospital straight away**
- feel restless and feel like you can't sit or stand still (akathisia). Feel tired, weak or confused with achy stiff or uncoordinated muscles
- unusual bruising or bleeding, vomiting blood or if you have blood in your stools
- serotonin syndrome, a serious condition which may include agitation, confusion, restlessness, sweating, shaking, shivering, hallucinations (strange visions or sounds), sudden jerks of the muscles, a fast heart beat, high temperature (fever). It can also lead to fits and coma
- fast, irregular heart beat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

Other possible side effects during treatment

The side effects are generally mild and most noticeable during the first one to two weeks of treatment, disappearing as you begin to feel better.

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

- increased sweating
- headache
- feeling sleepy
- difficulty falling or staying asleep (insomnia)
- feeling sick
- dry mouth
- a feeling of no energy.

Common (may affect up to 1 in 10 people)

- rash, itching skin
- change in sensitivity to touch (increase or decrease), tingling, pins and needles feeling and very sensitive skin
- migraine
- constipation
- diarrhoea
- a feeling of irregular and/or forceful beating of the heart (palpitations)
- altered taste, decreased appetite, weight loss
- disturbed sleep
- decreased sex drive, unable to get or keep an erection (impotence), failure to ejaculate, lack of orgasm in females
- difficulty concentrating
- strange dreams
- confusion
- anxiety, agitation or nervousness
- yawning
- indigestion or upset stomach, pain in your abdomen
- being sick
- wind (flatulence)
- more saliva than normal
- runny nose
- excessive tiredness
- dizziness
- ringing in the ears (tinnitus)
- aching muscles and joints.

Uncommon (may affect up to 1 in 100 people)

- muscle pain
- lack of movement, stiffness, shaking or abnormal movement of the mouth and tongue
- ringing in the ears (tinnitus)
- a feeling of elation or wellbeing
- increased sex drive
- coughing
- feeling of being uncomfortable, general aches and pains
- hallucinations (strange visions or sounds), mania (great excitement, difficulty concentrating, difficulty staying still)
- feeling unreal or detached from your surroundings
- develop rashes when exposed to the sun
- increase in appetite or increase in weight
- become aggressive
- fainting spells
- enlarged pupils
- unusually fast or slow heart rate
- nettle-like rash
- hair loss
- vaginal bleeding
- swelling of arms and legs
- difficulty urinating.

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

- fits
- fever
- hepatitis where your skin and whites of your eyes appear yellow
- problems controlling movement
- increased sex drive
- coughing
- feeling of being uncomfortable, general aches and pains.

Not known (frequency cannot be estimated from available data)

- abnormal results in a blood test to check your liver function
- concentrated urine (dark in colour), feel or are sick, have muscle cramps, confusion and fits which may be due to inappropriate ADH (anti-diuretic hormone) secretion. If you have these symptoms contact your doctor as soon as possible
- an increased risk of bone fractures particularly if you are older than 50 years of age
- problems with blood clotting
- low potassium levels leading to muscle weakening
- panic attacks
- grinding teeth
- restlessness or restless leg
- nose bleed or abnormal bruising
- abnormal production of breast milk
- painful erections.

See section 2 of this leaflet for side effects that may be caused by some of the other ingredients in your medicine (Citalopram Oral Drops contain Methyl parahydroxybenzoate, propyl parahydroxybenzoate and ethanol).

If you have any other symptoms that you do not understand, tell your doctor or pharmacist.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any 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 Oral Drops

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 bottle label after EXP. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Once opened do not keep your drops for more than 16 weeks.

Once diluted drink your medicine immediately.

Do not use if you notice any damage to the bottle dropper or any visible signs of deterioration in your medicine. Return it to your pharmacist.

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 Oral Drops contain

- The active substance is citalopram. Each 1ml of Citalopram Oral Drops contains 40mg of citalopram (as hydrochloride).
- The other ingredients are methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216), ethanol (96 per cent), hydroxyethylcellulose and water (see section 2, What you need to know before you take Citalopram Oral Drops).

What Citalopram Oral Drops look like and contents of the pack

Citalopram Oral Drops are a colourless to yellowish clear solution in an amber glass bottle fitted with a dropper device and screw cap.

Each bottle of Citalopram Oral Drops contains 15ml of solution. There are 20 drops in each ml.

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