

PACKAGE LEAFLET: INFORMATION FOR THE USER

Citalopram 20mg film-coated tablets

Citalopram 40mg film-coated tablets

Citalopram

Read all of this leaflet carefully before you start taking this medicine.

- 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. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What *Citalopram* is and what it is used for
2. Before you take *Citalopram*
3. How to take *Citalopram*
4. Possible side effects
5. How to store *Citalopram*
6. Further information

1. WHAT *Citalopram* IS AND WHAT IT IS USED FOR

Citalopram belongs to a group of antidepressants called selective serotonin re-uptake inhibitors (SSRIs). Everyone has a substance called serotonin in their brain. Low levels of serotonin are thought to be a cause of depression. It is not fully understood how citalopram works, but it may help by increasing the amount of serotonin in the brain.

***Citalopram* is used to treat**

- depression (major depressive episodes)

2. BEFORE YOU TAKE *Citalopram*



Do NOT take *Citalopram*

- if you are **allergic (hypersensitive)** to citalopram or any of the other ingredients of *Citalopram*
 - if you are taking or have recently taken medicines called **monoamine oxidase inhibitors** (MAOIs; amongst others used to treat depression). You may have to wait for up to 14 days after quitting the use of a MAOI. The MAOI selegiline (used to treat Parkinson's disease) may be used, but not in doses exceeding 10 mg per day. When changing from *Citalopram* to MAOIs, you have to wait for at least seven days before you start taking MAOIs.
 - if you are taking **linezolid** (used to treat bacterial infections), unless you are closely observed by your doctor and your blood pressure is monitored.
 - if you are taking **pimozide** (medicine used to treat certain psychiatric conditions)
- If any of this applies to you please inform your doctor **before** taking *Citalopram*.

Take special care with *Citalopram*

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.

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.
- 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, 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.

SENSE OF RESTLESSNESS/PYCHOMOTOR AGITATION

Take special care if you develop symptoms such as inner sense of restlessness and psychomotor agitation such as an inability to sit or stand still usually associated with subjective distress (akathisia). This is most likely to occur within the first few weeks of treatment (see section 4. "Possible side effects").

SEROTONIN SYNDROME

See section 4. "Possible side effects", under "rare".

REDUCED LEVELS OF SODIUM IN THE BLOOD

Citalopram can in rare cases, predominantly in elderly patients, cause reduced levels of sodium in the blood and an inappropriate secretion of a hormone of the brain regulating the water balance of the body (syndrome of inappropriate anti-diuretic hormone secretion [SIADH]). **Inform your doctor** if you start feeling sick and unwell with **weak muscles** or **confused** while being treated with *Citalopram*.

WITHDRAWAL SYMPTOMS SEEN ON DISCONTINUATION

Please see "If you stop taking *Citalopram*".

PLEASE INFORM YOUR DOCTOR:

- if you are **taking any other medicines** (see "Taking other medicines")
- if you have **diabetes**.
- if you have **epilepsy** or a history of fits or start suffering from seizures during treatment with *Citalopram*
- if you are having **electro-convulsive therapy** (ECT)
- if you suffer from episodes of mania/hypomania (**overactive behaviour or thoughts**)
- if you have a history of **bleeding disorders** or bleed easily or or if you use medicines which possibly increase tendency to bleed (see section "Taking other medicines").

- if you have **heart disorders**
- if you have **low blood levels** of **potassium** or **magnesium**
- if you have other *psychiatric conditions* (psychosis)
- if you suffer from **liver or kidney problems**.

Taking other medicines

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

If you are taking or have recently taken any of the medicines in the list below, and you have not already discussed these with your doctor, go back to your doctor and ask what to do.

- **monoamine oxidase inhibitors**, **linezolid** and **pimozide** (see “Do not take *Citalopram*“)
- medicines called triptans such as sumatriptan (used to treat **migraine**)
- tramadol (medicine used to treat **severe pain**)
- **anticoagulants**, dipyridamol and ticlopidine (medicines to **thin the blood**)
- acetylsalicylic acid, non-steroidal anti-inflammatory drugs (NSAID’s) such as ibuprofen (medicines used to treat **inflammation and pain**)
- neuroleptics (phenothiazines [e.g. thioridazine], thioxanthenes, butyrophenones [e.g. haloperidol]), atypical antipsychotics, e.g. risperidone (medicines used to treat **certain psychiatric conditions**)
- tricyclic antidepressants (medicines used to treat **depression**)
- **herbal remedies** containing **St. John's Wort** (*Hypericum perforatum*)
- cimetidine, omeprazole, esomeprazole, lansoprazole (medicines used to **lower the production of stomach acid**)
- tryptophan, oxitriptan (**serotonin-precursors**)
- lithium (medicine used to treat **mania**)
- imipramine, desipramine, clomipramine, nortriptyline (medicines used to treat **depression**)
- fluvoxamine (medicine used to treat **depression** and **obsessive compulsive disorder**)
- mefloquin (medicine used to treat **malaria**)
- bupropion (medicine used to treat **depression** and to **support to give up smoking**)
- flecainide, propafenone (medicines used to treat **irregular heartbeat**)
- metoprolol (medicine used to treat **cardiac failure**)
- medicinal products which may **change the ECG** or may **cause low blood levels of potassium or magnesium**. Please ask your doctor or pharmacist if the medicinal product(s) you are taking/using concomitantly with *Citalopram* belong(s) to this group.

Taking *Citalopram* with food and drink

It is recommended not to drink alcohol during treatment with *Citalopram*.
Citalopram can be taken with or without food.

Pregnancy and breast-feeding

Do not take *Citalopram* if you are pregnant or planning to become pregnant, unless your doctor considers it absolutely necessary.

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.

You should not discontinue treatment with *Citalopram* abruptly. 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, trouble with breathing, a blue-ish skin or being too hot or cold,

being sick, crying a lot, stiff or floppy muscles, lethargy, tremors, jitters or fits. If your baby has any of these symptoms when it is born, contact your doctor immediately who will be able to advise you.

Citalopram passes into breast milk in small amounts. There is a risk of an effect on the baby. Talk to your doctor before you start breast-feeding.

Driving and using machines

Citalopram has minor or moderate influence on the ability to drive and use machines.

Do not drive or use machines until you know how *Citalopram* affects you. Please ask your doctor or pharmacist if you are unsure about anything.

3. HOW TO TAKE *Citalopram*

Always take *Citalopram* exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

20 mg

ADULTS

The starting dose is 1 film-coated tablet (20 mg citalopram) per day. This may be increased by your doctor to a maximum of 3 film-coated tablets (60 mg citalopram) per day.

ELDERLY PATIENTS (>65 YEARS OF AGE)

The starting dose is ½-1 film-coated tablet (10-20 mg citalopram) per day. This may be increased by your doctor to a maximum of 2 film-coated tablets (40 mg citalopram) per day.

REDUCED HEPATIC FUNCTION

The starting dose is ½ film-coated tablet (10 mg citalopram) per day for the first two weeks. This may be increased by your doctor to a maximum of 1½ film-coated tablets (30 mg citalopram) per day.

40 mg

Citalopram 40 mg is not suitable for all dosages described below. For these dosages, other products containing citalopram are available on the market.

ADULTS

The starting dose is ½ film-coated tablet (20 mg citalopram) per day. This may be increased by your doctor to a maximum of 1½ film-coated tablets (60 mg citalopram) per day.

ELDERLY PATIENTS (>65 YEARS OF AGE)

The starting dose is 10-20 mg citalopram per day. This may be increased by your doctor to a maximum of 1 film-coated tablet (40 mg citalopram) per day.

REDUCED HEPATIC FUNCTION

The starting dose is 10 mg citalopram per day for the first two weeks. This may be increased by your doctor to a maximum of 30 mg citalopram per day.

TIME AND METHOD OF INTAKE

Citalopram should be taken as a single oral dose, either in the morning or in the evening. The film-coated tablet(s) can be taken with or without food, but with fluid.

DURATION OF TREATMENT

The effect of *Citalopram* is not felt straight away. It will take at least two weeks before you notice any improvement. After you are free of symptoms, *Citalopram* should be taken for another 4-6 months.

DISCONTINUATION OF THERAPY

Please see “If you stop taking *Citalopram*”.

If you take more *Citalopram* than you should

If you think that you or anyone else may have taken too many film-coated tablets contact your doctor or nearest hospital casualty department immediately.

The following symptoms may occur: feeling sleepy, coma, inability of the body to move (stupor), seizure, increased heartbeat, increased sweating, nausea, vomiting, blue discolouration of the lips, tongue, skin and mucous membranes (caused by a lack of oxygen in the blood) and accelerated breathing.

Also a serotonin syndrome may occur (symptoms see “Take special care with *Citalopram*”).

If you forget to take *Citalopram*

If you forget to take a dose, take the next dose at the usual time. Do not take a double dose to make up for a forgotten dose.

If you stop taking *Citalopram*

Do not stop using *Citalopram* until your doctor tells you. *Citalopram* should be withdrawn slowly, it is advised that the dose is gradually reduced over a period of at least 1-2 week. It is important that you follow the instructions of your doctor. Discontinuation of treatment with *Citalopram* particularly if abrupt, may result in the appearance of withdrawal symptoms like dizziness, sensory disturbances (including paraesthesia and electric shock sensations), sleep disturbances (including insomnia and intense dreams), agitation or anxiety, nausea and/or vomiting, tremor, confusion, sweating, headache, diarrhoea, palpitations, emotional instability, irritability and visual disturbances. Talk to your doctor, if such withdrawal symptoms occur after you stopped taking *Citalopram*.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, *Citalopram* can cause side effects, although not everybody gets them.

Side effects observed with *Citalopram* are in general mild and transient. They are most prominent during the first weeks of treatment and usually attenuate as the depressive state improves.

The frequencies are defined as

very common	<i>affects more than 1 user in 10</i>
common	<i>affects 1 to 10 users in 100</i>
uncommon	<i>affects 1 to 10 users in 1,000</i>
rare	<i>affects 1 to 10 users in 10,000</i>
very rare	<i>affects less than 1 user in 10,000</i>
not known	<i>frequency cannot be estimated from the available data</i>

VERY COMMON

- feeling sleepy, sleeplessness, agitation, nervousness, headache, tremor, dizziness
- difficulties of the eyes to adjust to various distances

- heart racing (palpitations)
- nausea, dry mouth, constipation, diarrhoea, increased sweating
- feeling weak and tired (asthenia)

COMMON

- weight loss, weight gain
- sleep disorders, impaired concentration, abnormal dreaming, memory loss, anxiety
- decreased libido
- increased or decreased appetite
- apathy
- confusion
- migraine
- sensation of tingling or numbness of the skin with no apparent cause (paraesthesia)
- impaired vision
- increased heartbeat, drop in blood pressure as a result of standing up from a sitting or lying position (sometimes accompanied by dizziness), high or low blood pressure
- rhinitis, sinusitis
- digestive disorders, vomiting, abdominal pain, flatulence, increased salivation
- rash, itching
- difficulty in passing urine, increased urine output (polyuria)
- ejaculatory disorders, delayed or inhibited orgasm in women, painful menstrual periods, impotence
- taste abnormalities
- feeling tired, yawning

UNCOMMON

- euphoria
- increased libido
- extrapyramidal disorder (lack of movement, stiffness, shaking)
- seizures
- ringing in the ears (tinnitus)
- decreased heartbeat
- coughing
- abnormal liver function tests
- sensitivity to light
- muscular pain
- allergic reactions
- sudden loss of consciousness (lasting from a few seconds to several minutes [syncope])
- general feeling of being unwell (malaise)

RARE

- bleeding (e.g. vaginal, gastrointestinal, ecchymosis and other forms of skin bleeding or bleeding in the mucous membranes)
- feeling restless and feeling like you can not sit or stand still (see „Take special care with *Citalopram*“)
- predominantly in elderly patients a lower than normal level of sodium in the blood and an inappropriate secretion of a hormone of the brain regulating the water balance of the body (syndrome of inappropriate anti-diuretic hormone secretion [SIADH])
- serotonin syndrome
Tell your doctor immediately, if some of the following symptoms are developing during therapy with *Citalopram*, because then you may have something called serotonin syndrome. The symptoms include: **feeling restless, feeling shaky, sudden movements of the muscles and fever**. If this happens, your doctor will stop treatment with *Citalopram* immediately.

VERY RARE

- seeing and hearing things which are not there (hallucinations), overactive behaviour or thoughts (mania), feeling detached from yourself (depersonalisation), panik attacks (all these symptoms mentioned so far may be due to the underlying disease)
- irregular heartbeat
- angioedema (sudden swelling of the skin and mucosa due to fluid retention [e.g. of the throat and tongue], breathing difficulties and/or itching and rash). Stop taking *Citalopram* and see your doctor immediately if these symptoms occur.
- joint pain
- abnormal production of breast milk in men and women
- anaphylactoid reactions (severe hypersensitivity reactions which may result in shock [strong decrease in blood pressure, paleness, agitation, weak and fast pulse, clammy skin, and decreased consciousness] due to a sudden widening of the blood vessels).

NOT KNOWN

- suicidal thoughts/behaviour (see “Take special care with *Citalopram*“).
Cases of people developing thoughts of harming or killing themselves, or showing such behaviour have been reported during the use of citalopram or shortly after stopping treatment.
- long-lasting, mostly painful erection.

WITHDRAWAL SYMPTOMS SEEN ON DISCONTINUATION

See “If you stop taking *Citalopram*“.

An increased risk of bone fractures has been observed in patients taking this type of medicines.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE *Citalopram*

Keep out of the reach and sight of children.

Do not use *Citalopram* after the expiry date which is stated on the outer carton and <blister or bottle> after EXP. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment

6. FURTHER INFORMATION

What *Citalopram* contains

The active substance is citalopram.

20 mg

Each film-coated tablet contains 20 mg citalopram (as hydrobromide).

40 mg

Each film-coated tablet contains 40 mg citalopram (as hydrobromide).

The other ingredients are:

Tablet core: mannitol, microcrystalline cellulose, colloidal silica (anhydrous), magnesium stearate
 Tablet coating: hypromellose, macrogol 6000, titanium dioxide (E171).

What *Citalopram* looks like and contents of the pack

20 mg

Round, white film-coated tablets with a break-line and diameter of 8 mm.
 The tablets can be divided to equal halves.

40 mg

Round, white film-coated tablets with a break-line and diameter of 10 mm.
 The tablets can be divided to equal halves.

Packs of 10, 14, 20, 28, 30, 50, 56, 98, 100, 100x1, 250 and 500 film-coated tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

<To be completed nationally>

This medicinal product is authorised in the Member States of the EEA under the following names

20 mg

Germany: Citalopram-CT 20 mg Filmtabletten
 Luxembourg: citalopram 20 von ct
 Netherlands: Citalopram 20 ct, filmomhulde tabletten 20 mg

40 mg

Germany: Citalopram-CT 40 mg Filmtabletten
 Luxembourg: citalopram 40 von ct
 Netherlands: Citalopram 40 ct, filmomhulde tabletten 40 mg

This leaflet was last approved in

<To be completed nationally>