Package leaflet: Information for the patient

Citalopram Teva 10 mg film-coated tablets
Citalopram Teva 20 mg film-coated tablets
Citalopram Teva 40 mg film-coated tablets

citalopram

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 Teva film-coated tablets is and what it is used for

Citalopram Teva film-coated tablets belongs to a group of antidepressants known as selective serotonin reuptake inhibitors (SSRIs).

Citalopram Teva film-coated tablets is used for the treatment of depression (major depressive episodes).

2 What you need to know before you take Citalopram Teva film-coated tablets

Do NOT take Citalopram Teva film-coated tablets
- If you are allergic to citalopram or any of the other ingredients of this medicine (listed in section 6).
- If you are taking, or have taken in the last 2 weeks an antidepressant medicine of the type called monoamine oxidase inhibitors (MAOIs) e.g. selegiline or moclobemide.
- If you are treated with linezolid (an antibiotic medicine) unless you are under close observation and monitoring of blood pressure.
- If you are born with or have had an episode of abnormal heart rhythm (seen at ECG; an examination to evaluate how the heart is functioning).
- If you take medicines for heart rhythm problems or that may affect the heart's rhythm. Also refer to the section "*Other medicines and Citalopram Teva film-coated tablets*" below.

Warnings and precautions
Talk to your doctor or pharmacist before taking Citalopram Teva film-coated tablets if you:

- Suffer from diabetes, treatment with Citalopram Teva film-coated tablets may alter control of your sugar levels.
- Suffer from epilepsy or seizures, as seizures are a potential risk with antidepressant drugs.
- Receive electro-convulsive therapy.
- Have a history of mania/hypomania, Citalopram Teva film-coated tablets should be used with caution and should be discontinued when you enter a manic phase.
- Have kidney or liver problems. Citalopram Teva film-coated tablets is not recommended for use in patients with severe kidney problems.
- Have a bleeding disorder or if you are pregnant (see "Pregnancy, breast-feeding and fertility"), Citalopram Teva film-coated tablets may cause bleeding.
- Are using medicinal products that effect the clotting of blood (see section "Other medicines and Citalopram Teva film-coated tablets").
- Have a stomach ulcer or have had any bleeding in the stomach or intestine in the past.
- Suffer from low blood potassium or magnesium levels.
- Suffer from psychosis with depressive episodes.
- Experience 'serotonin syndrome'. A combination of symptoms, such as agitation, tremor, muscle contractions and hyperthermia may indicate the development of this condition. Treatment with Citalopram Teva film-coated tablets should be discontinued immediately.
- If you suffer or have suffered from heart problems or have recently had a heart attack.
- If you have a low resting heart-rate and/or you know that you may have salt depletion as a result of prolonged severe diarrhoea and vomiting (being sick) or usage of diuretics (water tablets).
- If you experience a fast or irregular heartbeat, fainting, collapse or dizziness on standing up which may indicate abnormal functioning of the heart rate.
- If you have problems with your eyes, such as certain kinds of glaucoma.
- During the first few weeks of treatment symptoms such as restlessness, and an inability to sit or stand still may develop in patients taking anti-depressants. In patients who develop these symptoms, increasing the dose could be harmful.
- Citalopram Teva film-coated tablets should be discontinued in any patients who develop fits (epilepsy) or if their frequency of fits increase. Citalopram should be avoided in patients with unstable (uncontrolled) epilepsy. Patients with controlled epilepsy should be carefully monitored.
- Citalopram Teva film-coated tablets should not be used at the same time as medicines which have a serotonergic effect including pain killers and medicines used to treat migraines (see "Other medicines and Citalopram Teva film-coated tablets").
- Citalopram Teva film-coated tablets should be used with caution in patients with low sodium levels.

Medicines like Citalopram Teva film-coated tablets (so called SSRIs/SNRIs) may cause symptoms of sexual dysfunction (see section 4). In some cases, these symptoms have continued after stopping treatment.

You should not discontinue treatment with Citalopram Teva film-coated tablets abruptly due to the withdrawal effects that might occur (see section 3).

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.

Children and adolescents
Citalopram Teva film-coated 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 Teva film-coated tablets 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 Teva film-coated tablets. Also, the long-term safety effects concerning growth, maturation and cognitive and behavioural development of Citalopram Teva film-coated tablets in this age group have not yet been demonstrated.

Other medicines and Citalopram Teva film-coated tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.
DO NOT TAKE Citalopram Teva film-coated 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. phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g. sparfloxacin, moxifloxacin, erythromycin IV, pentamidine, anti-malarial treatment particularly halofantrine), certain antihistamines (astemizole, mizolastine). If you have any further questions about this you should speak to your doctor.
- If you take monoamine oxidase inhibitors (MAOIs), e.g. phenelzine, isocarboxazid or tranylcypromine do not take Citalopram Teva film-coated tablets for 14 days after discontinuation of treatment with a so called irreversible MAOI. Do not take Citalopram Teva film-coated tablets for the time specified after discontinuation of treatment with a reversible MAOI (e.g. moclobemide), as stated in the patient information leaflet of the reversible MAOI. Do not take MAOIs for 7 days after discontinuation of treatment with Citalopram Teva film-coated tablets. Do not use Citalopram Teva film-coated tablets if you are taking more than 10 mg/day of the MAO selegiline.
- If you take pimozide (an antipsychotic medicine). Citalopram Teva film-coated tablets must not be taken together with pimozide due to the influence of this combination to the heart function.

Talk to your doctor or pharmacist if you are taking, or have previously taken any of the following:

- Other medicinal products with serotonergic effects such as sumatriptan, other triptans or tryptophan (see "Warnings and precautions").
- An anticoagulant (to prevent blood clotting), e.g. warfarin, acetylsalicylic acid, dipyridamole or ticlopidine.
- Medicines that lower the seizure threshold i.e. neuroleptics, mefloquine or bupropion.
- Herbal preparations containing St John's wort (*Hypericum perforatum*).
- Pain-relief and inflammation medicines called non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, ketoprofen or diclofenac.
- Medicines used to treat pain, such as tramadol, buprenorphine (see "Warnings and precautions").
- Medicines used to treat depression, e.g. fluoxetine, fluvoxamine, paroxetine, sertraline, venlafaxine.
- Medicines used to treat migraine, e.g. sumatriptan and other triptans (see "Warnings and precautions").
- Medicines used to treat heart failure, e.g. metoprolol.
- Medicines for psychiatric illness, e.g. lithium, risperidone or chlorpromazine.
- Medicines for stomach ulcers, e.g. omeprazole, esomeprazole, lansoprazole or cimetidine.
- Fluconazole (used to treat fungal infections)
- Medicines that decrease blood levels of potassium or magnesium as these conditions increase the risk of life-threatening heart rhythm disorder (QT prolongation, Torsades de Pointes).
- Linezolid (an antibiotic medicine).

Citalopram Teva film-coated tablets with food, drink and alcohol
You are advised not to drink alcohol whilst taking Citalopram Teva film-coated tablets.
Citalopram Teva film-coated tablets 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 for advice before taking this medicine.

Pregnancy
There is only limited experience concerning the use of Citalopram Teva film-coated tablets during pregnancy. Do not take Citalopram Teva film-coated tablets 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 Teva film-coated tablets. When taken during pregnancy, particularly in the last 3 months of pregnancy, medicines like Citalopram Teva film-coated tablets 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 Teva film-coated tablets abruptly. If you are taking Citalopram Teva film-coated tablets 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 who will be able to advise you.
If you take Citalopram Teva film-coated tablets 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 Teva film-coated tablets 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 Teva film-coated tablets, 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 Teva film-coated tablets may affect your ability to drive a car or use machines. Do not drive or use machines until you know how Citalopram Teva film-coated tablets affects you. Please ask your doctor or pharmacist if you are unsure about anything.

Citalopram Teva film-coated tablets contains lactose and sodium
If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.
This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially ‘sodium-free’.

3 How to take Citalopram Teva film-coated tablets

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

Citalopram Teva film-coated tablets 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 with a drink of water or other fluid.
Citalopram Teva film-coated tablets does not work immediately. An antidepressant effect should not be expected for at least 2 weeks. Treatment should continue until you are free of symptoms for 4-6 months. Citalopram Teva film-coated tablets should be withdrawn slowly. It is advised that the dose is gradually reduced over a 1-2 week period. Do not stop taking Citalopram Teva film-coated tablets even if you begin to feel better, unless you are told to do so by the doctor. Never change the dose of your medicine without talking to your doctor first.

40 mg
If the prescribed dosage cannot be achieved with this product, other medicines containing citalopram are available.

The recommended dose is:

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

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.

Use in children and adolescents
Citalopram Teva film-coated tablets should not be used in the treatment of children and adolescents under 18 years of age (see "Warnings and precautions").

Liver problems
Patients with mild to moderate liver problems should receive a starting dose of 10 mg per day. Patients with liver complaints should not receive more than 20 mg per day. Such patients should be clinically monitored. Caution and extra careful dosing is advised in patients with severe liver problems.

Kidney problems
In patients with mild to moderate kidney problems no dosage adjustment is required. The use of Citalopram Teva film-coated tablets in patients with severe kidney problem is not recommended as no information is available in these patients.

Withdrawal symptoms seen on discontinuation
Abrupt discontinuation should be avoided. When stopping treatment with Citalopram Teva film-coated tablets the dose should be gradually reduced over a 1-2 week period in order to reduce the risk of withdrawal reactions (see section "If you stop taking Citalopram Teva film-coated tablets" and "Possible side effects").

If intolerable symptoms occur following a decrease in the dose upon discontinuation of treatment, then resuming the previously prescribed dose may be considered. Subsequently, your doctor may continue decreasing the dose, but at a more gradual rate.

If you take more Citalopram Teva film-coated tablets than you should
If you have taken more Citalopram Teva film-coated tablets than you should, talk to a doctor or pharmacist immediately.

Symptoms of an overdose include: sleepiness, a condition of near unconsciousness with apparent mental inactivity, reduced ability to respond to stimulation or coma, seizures, ECG changes (e.g. prolonged QT interval), irregular heartbeat, feeling sick, vomiting, discolouration of the skin, sweating, hyperventilation. Features of serotonin syndrome may occur (see 'Possible side effects'), particularly when other substances are co-ingested.

If you forget to take Citalopram Teva film-coated tablets
If you miss a dose, do not take a double dose to make up for a forgotten dose.

If you stop taking Citalopram Teva film-coated tablets
Do not stop taking Citalopram Teva film-coated tablets 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.

Withdrawal reactions include: dizziness, pins and needles, electric shock sensations, numbness, sleeplessness, intense dreams, agitation, anxiety, feeling sick or being sick, shaking, confusion, sweating, headache, diarrhoea, faster heartbeat (palpitations), emotional instability, irritability and visual disturbances. Most of the withdrawal reactions are mild and self-limiting in nature but may be severe in some patients.

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.
A few people may develop a severe allergic reaction. This is a very rare but serious side effect. **If you experience any of the following symptoms stop taking Citalopram Teva film-coated tablets and tell your doctor immediately or go to your nearest casualty department:**

- Swelling of the lips, face and neck (allergic reaction) leading to severe difficulty in swallowing or breathing.
- Shock (strong decrease of blood pressure, paleness, agitation, weak and fast pulse, clammy skin, decreased consciousness) caused by a sudden strong vascular dilatation as a result of severe allergy to certain substances (anaphylactic reactions).
- Fast, irregular heartbeat, fainting which could be symptoms of a life-threatening condition known as Torsades de Pointes.

Serotonin syndrome has been reported in patients treated with this type of antidepressant (SSRI). **Tell your doctor if you experience** high fever, trembling, muscle twitches and anxiety because these symptoms may indicate the development of this condition. **Treatment with Citalopram Teva film-coated tablets should be discontinued immediately.**

Cases of thoughts/behaviours of harming or killing yourself have been reported during Citalopram Teva film-coated tablets therapy or early after treatment has been stopped (see section 2 “Warnings and precautions”). If you have thoughts of harming or killing yourself at any time, contact your doctor or go to a hospital straight away.

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

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

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

- sleepiness, difficulty sleeping
- headache
- feeling your heart beat
- feeling sick, dry mouth
- increased sweating
- feeling of weakness (asthenia)

Common (may affect up to 1 in 10 people)

- reduction in weight, loss of appetite
- agitation, problems with concentration, abnormal dreaming (unusual and intense dreams), memory loss, anxiety, decreased sex drive, absence of emotion or enthusiasm, confusion, nervousness

- pins and needles or numbness
- tremor, dizziness, ringing in the ears (tinnitus), pain in muscles and joints
- runny and itchy nose, inflammation of the sinuses (pain and pressure in your face, which is worse when you lean forwards, blocked nose, sore throat and cough, headache, fever, earache, toothache or pain in your upper jaw)
- indigestion/heart burn, being sick, stomach pain, wind, increased saliva, diarrhoea, constipation
- problems with urination (e.g. controlling urination)
- inability to achieve orgasm in women, impotence (inability to get or maintain an erection), ejaculation failure
- itching
- fatigue, yawning

Uncommon (may affect up to 1 in 100 people)
- increase in weight, increase in appetite, absence of appetite
- a state of optimism, cheerfulness and well-being (euphoria), aggression, reduced emotions, indifference, hallucinations, mania, general feeling of discomfort or uneasiness
- fainting
- slowing of the heartbeat, fast heart beat
- coughing
- nettle rash, hair loss, rash, bruising easily, sensitivity to sunlight, dilatation of the eye pupil
- problems passing urine
- swelling of the arms and legs
- abnormally heavy and prolonged menstrual period

Rare (may affect up to 1 in 1,000 people)
- bleeding, e.g. from the vagina, stomach, skin and mucous membranes (the lubricated inner lining of the mouth, nasal passages, vagina and urethra)
- convulsions, involuntary movements, taste abnormalities
- unintentional and purposeless motions
- inflammation of the liver (hepatitis)
- lower amount of blood sodium, predominantly in the elderly (which causes hallucinations, confusion, fits, lack of energy and muscle cramps or weakness)
- fever

Not known (cannot be estimated from the available data)
- low levels of platelets in your blood (thrombocytopenia) which can increase bleeding or bruising
- panic attacks, grinding teeth, restlessness, inappropriate ADH secretion (characterised by an excessive production of urine)
- fits, impairment of voluntary movement, i.e. tremor, tics, changes in muscle tone, slowness of movement, involuntary and/or irregular muscle movements that occur in the facial area, restlessness of the arms and legs (akathisia)
- visual disturbance
- dizziness when suddenly standing up
- changes in electric recording heart (ECG QT interval prolonged)
- nosebleed
- bleeding in your stomach or intestine
- bleeding disorder including skin and mucosal bleeding (ecchymosis)

- sudden swelling of skin and mucosa
- abnormal liver function tests
- abnormal milk secretion from the breast (galactorrhoea)
- irregular menstrual bleeding
- heavy vaginal bleeding shortly after birth (postpartum haemorrhage), see “Pregnancy, breast-feeding and fertility” in section 2 for more information
- painful erections in men
- increased blood levels of the hormone prolactin
- low potassium levels in the blood

Since withdrawal reactions may occur when the treatment is stopped, it is advised to reduce the dose gradually at intervals of 1-2 weeks.

Withdrawal reactions include: dizziness, pins and needles, electric shock sensations, numbness, sleeplessness, intense dreams, agitation, anxiety, feeling sick or being sick, shaking, confusion, sweating, headache, diarrhoea, faster heartbeat (palpitations), emotional instability, irritability and visual disturbances. Most of the withdrawal reactions are mild and self limiting in nature.

Any side effects that do occur will usually disappear after a few days.

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 HPRA Pharmacovigilance
Website: www.hpra.ie
By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Citalopram Teva film-coated 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 after EXP. The expiry date refers to the last day of that month.

Do not store above 25 °C.

10 mg / 20 mg
HDPE tablet container
The shelf-life after first opening of the tablet container is 100 days.

Do not throw away any medicines via waste water 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 Teva film-coated tablets contains

- The active substance is citalopram
  10 mg
  Each film-coated tablet contains 10 mg citalopram (as hydrobromide).
  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: copovidone, croscarmellose sodium (E466), glycerol (E422), lactose monohydrate, magnesium stearate (E470b), maize starch, microcrystalline cellulose (E460i).
  Tablet coating: hypromellose (E464), microcrystalline cellulose (E460i), macrogol stearate 40 (E431) and titanium dioxide (E171).

What Citalopram Teva film-coated tablets looks like and contents of the pack
10 mg
Round, white tablets with a diameter of 6 mm.
20 mg
Oval, white tablets with a break-line on one side and diameter of 8 mm.
The tablet can be divided into equal doses.
40 mg
Oval, white tablets with a break-line on one side and diameter of 11 mm.
The tablet can be divided into equal doses.

10 mg
The product is available in pack sizes of 10, 14, 20, 28, 30, 50, 56, 98 and 100 film-coated tablets in PVC/PVDC/Al blisters. 50 x 1 film-coated tablets in PVC/PVDC/Al perforated unit dose blisters. 100 and 250 film-coated tablets in HDPE tablet containers with child-resistant polypropylene screw cap with desiccant insert.
20 mg
The product is available in pack sizes of 10, 14, 20, 28, 30, 50, 56, 60, 98, 100 and 120 film-coated tablets in PVC/PVDC/Al blisters. 50 x 1 film-coated tablets in PVC/PVDC/Al perforated unit dose blisters. 100 and 250 film-coated tablets in HDPE tablet containers with child-resistant polypropylene screw cap with desiccant insert.
40 mg
The product is available in pack sizes of 10, 14, 20, 28, 30, 50, 56, 60, 98, 100 and 120 tablets per box, 50x1 unit dose blister.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder
Teva Pharma B.V
Swensweg 5
2031GA Haarlem
The Netherlands

Manufacturer
Teva Pharmaceutical Works Private Limited Company, Pallagi út 13, H-4042 Debrecen, Hungary

Pharmachemie B.V, Swensweg 5, 2031 GA Haarlem, The Netherlands.

This medicine is authorised in the Member States of the European Economic Area and in the United Kingdom (Northern Ireland) under the following names:

Belgium: Citalopram Teva 20 & 40 mg filmomhulde tabletten
Czech Republic: Citalopram Teva 10, 20 & 40 mg
Denmark: Citalopram Teva 20 mg & 40mg
Estonia: Citalopram-Teva 10, 20 & 40 mg
Ireland: Citalopram Teva 10, 20 & 40 mg film-coated tablets
Iceland: Oropram 10, 20 & 40 mg filmuhúðaðar töflur
Latvia: Citalopram Teva 20 mg
Lithuania: Citalopram-Teva 20 & 40 mg plėvele dengtos tabletės
The Netherlands: Citalopram 10, 20 & 40 PCH, filmomhulde tabletten 10, 20 & 40 mg
Norway: Citalopram TEVA tabletti, filmdrasjert 10, 20 & 40 mg
Slovakia: Citalopram Teva 10, 20 & 40 mg
Sweden: Citalopram Teva, 10, 20 & 40 mg filmdragerad tablett
United Kingdom (Northern Ireland): Citalopram 10 & 20 mg tablets

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