PATIENT LEAFLET IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986

The medicine is dispensed with a doctor's prescription only

Citalopram Teva 20 mg

Film-coated tablets

Composition:

Each film-coated tablet contains:

Citalopram (as hydrobromide) 20 mg

For information regarding inactive ingredients and allergens, see section 2 - "Important information about some of the ingredients of the medicine" and section 6 - "Additional information".

- **Read the entire leaflet carefully before using the medicine.** This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
- **It is advisable to let a family member or another person close to you read this leaflet.**
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar.

Warning: suicidal thoughts and behavior

Antidepressant and anti-anxiety medicines increase the risk for suicidal behavior and thoughts in children, adolescents and young adults up to the age of 25.

At the beginning of treatment with the medicine, patients of all ages and their relatives should pay attention to behavioral changes such as: worsening of depression, suicidal thoughts, aggression and the like.

If such changes occur, refer to the doctor immediately.

1. What is the medicine intended for?

Therapeutic activity: For the treatment of depression and panic disorder.

Citalopram Teva belongs to a class of antidepressant medicines called selective serotonin reuptake inhibitors (SSRI). These medicines increase serotonin levels in the brain. Disturbances in the serotonin system in the brain are considered an important factor in the development of depression and related illnesses.

Therapeutic class: Selective serotonin reuptake inhibitors (SSRI).

2. Before using the medicine

Do not use Citalopram Teva if:

- You are sensitive (allergic) to the active ingredient or to any of the additional ingredients the medicine contains (see the inactive ingredients in section 6). Consult the doctor if you think you may be sensitive.
- You are being treated at the same time with medicines from the class of monoamine oxidase inhibitors (MAOIs) such as: phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine, moclobemide (used to treat depression); selegiline (for the treatment of Parkinson's disease); linezolid (an antibiotic). Even if you have finished taking one of the following medicines from the class of monoamine oxidase inhibitors: phenelzine, iproniazid, isocarboxazid, nialamide or tranylcypromine, you must wait two weeks before you begin taking Citalopram Teva tablets.
  Wait one day after stopping to take moclobemide. After you stop taking Citalopram Teva, wait one week before taking any medicine from the class of monoamine oxidase inhibitors.
- You have suffered from birth or have suffered in the past from episodes of abnormal heart rhythm (can be seen in ECG; a test to assess heart function).
- You are taking medicines for the treatment of heart rhythm problems or medicines that may affect your heart rhythm (see the "Drug interactions" section below).

Special warnings regarding the use of the medicine

Before treatment with Citalopram Teva, tell the doctor if you have any medical problems, and especially if you have:

- A history of bleeding disorders or if you have suffered in the past from bleeding in the stomach or intestines, or if you are pregnant (see the section "Pregnancy, breastfeeding and fertility")
- Liver disease
- Kidney disease
- Diabetes (the dosage of antidiabetic medicines may need to be adjusted)
- Epilepsy or a history of seizures or convulsions
- Manic or panic disorder
- Low levels of sodium in the blood
- You are being treated with electroconvulsive therapy (ECT)
- You suffer or have suffered in the past from impaired heart function or if you have recently had a heart attack
- Low resting heart rate and/or if you know that you may develop a decrease in blood salt levels, as a result of prolonged severe diarrhea and vomiting or as a result of taking diuretic medicines
- You have had a rapid or irregular heart rate, fainting, collapse or dizziness when transitioning to a standing position, which may indicate abnormal functioning of the heart rate
- Or you have had eye problems in the past, such as certain types of glaucoma (increase in intraocular pressure)

Please consult the doctor even if the conditions detailed above have happened to you at any time in the past.

Please note

- Some patients with manic-depressive illness may enter into a manic phase. This phase is characterized by unusual and rapidly changing ideas, happiness which is inappropriate for the situation and excessive physical activity. If you experience these effects – refer to the doctor.
- Symptoms such as restlessness, difficulty in sitting or standing still may occur during the first weeks of treatment. Refer to the doctor immediately if you notice these symptoms.
- Medicines like Citalopram Teva (called SSRI/SNRI) may cause symptoms of sexual dysfunction (see section 4). In some cases the symptoms persisted even after stopping treatment.

Special information relating to your illness

As with other medicines used to treat depression or related illnesses, improvement is not achieved immediately. After starting treatment with Citalopram Teva, it may take several weeks before you feel an improvement.

At the beginning of treatment, some patients experience increased anxiety, which disappears later in the treatment. Therefore, it is very important to follow the doctor's instructions exactly, and not to stop the treatment or change the dosage before consulting the doctor.

Suicidal thoughts or worsening of the depression or panic disorder

If you suffer from depression and/or panic disorders, you can sometimes have suicidal thoughts or thoughts of harming yourself.

These thoughts may be increased at the beginning of antidepressant treatment, as it takes time until the antidepressant effect of the medicine is felt. Usually two weeks, but sometimes longer. You may be more likely to think like this if:

- You have had suicidal thoughts or thoughts of harming yourself in the past.
- You are a **young adult.** Information from clinical trials has shown an increased risk of suicidal behavior in young adults (under 25 years of age) suffering from psychiatric illness who have been treated with antidepressants.

If you experience suicidal thoughts or thoughts of harming yourself at any time, **refer to your doctor immediately or go to the hospital.**

It is advisable to tell a relative or close friend that you are suffering from depression or panic disorder and ask them to read this leaflet.

Ask them to tell you if they think your depression or panic disorder is getting worse or if they are concerned about changes in your behavior.

Children and adolescents under the age of 18

Citalopram Teva is not usually intended for use in children and adolescents under 18 years of age. You should know that in patients under the age of 18 years who take medicines from this class, there is an increased risk of side effects such as suicide attempts, suicidal thoughts and hostility (especially aggression, rebellious behavior and anger). Despite this, your doctor may prescribe this medicine to patients under the age of 18 years if he thinks it is in their best interest.

If the doctor has prescribed the medicine to a patient under the age of 18 years and you would like to discuss it – go back to the doctor.

Report to your doctor if any of the side effects listed above have occurred or worsened in patients under the age of 18 years taking Citalopram Teva. Furthermore, the long-term safety effects of Citalopram Teva in this age group have not yet been studied in terms of growth, maturation, and cognitive-behavioral development.

Drug interactions

If you are taking or have recently taken other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist. Medicines may affect the action of other medicines, and this may sometimes cause serious side effects. Tell your doctor or pharmacist if you are taking, have taken in the past or might take any medicines, including other antidepressants (see in section 2 "Do not use Citalopram Teva if").

- The herbal preparation St. John's Wort (Hypericum perforatum) – do not take it concomitantly with Citalopram Teva.
- Monoamine oxidase inhibitors (MAOI) – do not take these medicines concomitantly with Citalopram Teva (see in section 2 "Do not use Citalopram Teva if").

Tell the doctor if you are taking any of the following medicines:

- Linezolid (an antibiotic).
- Sumatriptan (for the treatment of migraine) or tramadol (for pain relief). Refer to the doctor if you feel unwell when taking these medicines together with Citalopram Teva.
- Lithium (for the prevention and treatment of mania) and tryptophan (for the treatment of depression).
- Pimozide (a neuroleptic). Do not take pimozide concomitantly with Citalopram Teva.
- Imipramine and desipramine (medicines for the treatment of depression).
- Medicines containing selegiline (used for the treatment of Parkinson's disease).
- Cimetidine, lansoprazole and omeprazole (for the treatment of stomach ulcer), fluconazole (used for the treatment of fungal infections), fluvoxamine (for the treatment of depression) and ticlopidine (used to reduce the risk of stroke). These medicines may cause an increase in the levels of citalopram in the blood.
- Mefloquine (for the treatment of malaria).
- Bupropion (for the treatment of depression).
- Medicines known to affect the platelets (e.g. anticoagulants used to treat or prevent the formation of blood clots; aspirin and non-steroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and diclofenac used as pain relievers, as well as antipsychotic medicines and tricyclic antidepressants).
- Metoprolol, a beta blocker used to treat migraine, certain heart diseases and hypertension. The effect of each of the medicines may be increased, decreased or altered.
- Neuroleptic medicines (for the treatment of schizophrenia).

Do not take Citalopram Teva if you are taking medicines for the treatment of heart rhythm disorders or medicines that may have an effect on your heart rhythm, such as class IA and class III antiarrhythmic medicines, antipsychotic medicines (for example phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial medicines (for example sparfloxacin, moxifloxacin, intravenous erythromycin, pentamidine, antimalarial medicines and in particular halofantrine), certain antihistamines (astemizole, mizolastine). Refer to the doctor if you have any further questions about this.

Use of the medicine and food

The medicine may be taken with or without food.

Use of the medicine and alcohol consumption

As with all antidepressants, it is recommended to avoid drinking alcohol during treatment with the medicine, even though no increase in the effect of alcohol has been observed as a result of taking Citalopram Teva.

Pregnancy, breastfeeding and fertility

Pregnancy

If you are taking Citalopram Teva near the end of your pregnancy, you may have an increased risk of heavy vaginal bleeding shortly after giving birth, especially if you have a history of bleeding disorders. Your doctor or midwife should be aware that you are taking Citalopram Teva so that they can advise you.

Consult the doctor or pharmacist before using any medicines. If you are pregnant, think you may be pregnant, or are trying to become pregnant, tell the doctor.

Do not use Citalopram Teva when you are pregnant, unless you have consulted your doctor and discussed with him the risk compared to the benefit of taking this medicine. Make sure your midwife and/or doctor know you are taking Citalopram Teva. Taking medicines like Citalopram Teva during pregnancy, and especially in the last three months of pregnancy, may increase the risk of a serious condition in babies called persistent pulmonary hypertension of the newborn (PPHN) that causes rapid breathing and makes the baby's skin appear bluish. These signs usually appear in the first 24 hours after birth. If you notice these signs in your baby, refer to your midwife and/or doctor immediately.

Furthermore, if you are taking Citalopram Teva during the last three months of pregnancy and until birth, you should be aware that the following effects may occur in the newborn: seizures (convulsions), body temperature that is too high or too low, feeding difficulties, vomiting, low blood sugar level, stiff or floppy muscles, heightened reflexes, tremor, nervousness, irritability, fatigue, constant crying, Somnolence or sleeping difficulties. Refer to the doctor immediately if your baby shows any of these signs.

Breastfeeding

Consult the doctor or pharmacist before taking any medicines. If you are breastfeeding, consult the doctor. Do not breastfeed while using the medicine, as small amounts may pass into breast milk.

Fertility

Animal studies have shown that citalopram, the active ingredient in Citalopram Teva, reduces sperm quality. Theoretically, this may affect fertility, however impact on fertility has not yet been observed in humans.

Driving and operating machinery

Citalopram Teva usually does not affect the ability to perform daily activities, however, if you feel dizzy or sleepy at the beginning of treatment with the medicine, you must exercise caution when driving a vehicle or operating dangerous machinery or in any activity that requires alertness, until these symptoms pass.

Important information about some of the ingredients of the medicine

Citalopram Teva contains lactose. If you have been told by your doctor that you have an intolerance (sensitivity) to certain sugars, consult your doctor before taking this medicine.

This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.

3. How should you use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use the medicine.

The dosage and treatment regimen will be determined only by the doctor. The generally accepted dosage is:

For the treatment of depression: 20 mg per day. The doctor may increase the dosage up to 40 mg per day.

For the treatment of panic disorder: Initial dosage of 10 mg per day for the first week of treatment, after which the dosage will be increased to 20 mg per day. The doctor may increase the dosage up to 40 mg per day.

The elderly (above the age of 65): A reduction to half the recommended dosage is required – 10 mg to 20 mg per day. Maximum dosage of 20 mg per day.

Patients with liver function disorders: A reduced dosage is required – maximum dosage of 20 mg per day.

Children and adolescents (under the age of 18): Do not give Citalopram Teva to children and adolescents. For more information, see section 2 "Before using the medicine".

Do not exceed the recommended dose.

Method of use

Citalopram Teva should be taken once a day.

You can choose any time of the day to take the medicine, with or without food.

Do not chew the medicine (because it tastes bitter). The tablet should be swallowed with some water. Do not keep the medicine in your mouth beyond the time it takes to swallow it.

The tablet can be halved.

If you accidentally took a higher dosage

Overdose symptoms (some of which can be life-threatening): irregular heart rhythm, convulsions, change in heart rhythm, sleepiness, loss of consciousness, vomiting, tremor, drop in blood pressure, rise in blood pressure, nausea, serotonin syndrome (see section 4 "Side effects"), agitation, dizziness, dilated pupils, bluish skin, hyperventilation.

If you have taken an overdose or if a child has accidentally swallowed the medicine, immediately refer to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you, even if you do not feel the symptoms above.

Do not induce vomiting without an explicit instruction from the doctor!

This medicine should be taken at set intervals as determined by the treating doctor.

If you forget to take this medicine at the scheduled time, take a dose as soon as you remember; but never take two doses together. Follow the treatment as recommended by the doctor.

Duration of treatment

As with other medicines intended to treat depression and similar illnesses, improvement is not achieved immediately. After starting treatment with the medicine, it may take several weeks (about 2-4 weeks) before you feel an improvement in your condition. At the beginning of treatment, some patients may experience an increase in the feeling of anxiety, which will disappear later in the treatment. It is therefore important to take the medicine according to the doctor's instructions and not to stop taking the medicine or change the dosage, without consulting the doctor.

If you stop taking the medicine

Abrupt discontinuation of the medicine may lead to the following symptoms: dizziness, feeling of pin prickling, sleep disturbances (active dreams, nightmares, insomnia), feeling of anxiety, headache, nausea, vomiting, sweating, feeling nervous or restless, tremor, feeling confused or disoriented, emotional instability, diarrhea, visual disturbances, rapid and increased heartbeat (palpitations).

The duration of treatment with the medicine varies from patient to patient, and is usually at least 6 months. Patients with recurrent depression may be treated with the medicine for a longer period of time and even for several years.

Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor or pharmacist. Your illness may return. If discontinuation of treatment is decided, it should be done gradually to prevent the occurrence of side effects.

Do not take medicines in the dark! Check the label and the dose every time you take the medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. Side effects

As with any medicine, using Citalopram Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.

Some of the side effects detailed below may also be symptoms of your illness and may disappear as you start to feel better.

Severe side effects

Stop using Citalopram Teva and refer to the doctor immediately if the following symptoms occur:

- Breathing difficulties.
- Swelling of the face, lips, tongue or throat that may cause difficulty swallowing or breathing.
- Severe itching of the skin (with raised lumps).
- Rapid, irregular heart rate, fainting which may be symptoms of a life-threatening condition known as "torsades de pointes".

If you notice any of the following symptoms, refer to the doctor immediately as the dosage you are taking may need to be reduced or the treatment needs to be stopped:

- You have an epileptic seizure for the first time or if there is an increase in the frequency of epileptic seizures compared to the past.
- If your behavior changes because you feel elated or over excited.
- If you have high fever, nervousness, confusion, tremor or strong contraction of the muscles. These symptoms may be signs of serotonin syndrome (rare).
- Tiredness, confusion and muscle cramps. These may be signs of low blood sodium level (hyponatremia).

If you have suicidal thoughts or thoughts of harming yourself at any time, refer to the doctor or hospital immediately.

The following side effects are usually mild and go away after a few days of treatment.

Very common side effects (occurring in more than one out of ten users):

- Somnolence
- Sleeping difficulties
- Headache
- Changes in your sleeping pattern
- Decreased body strength, weakness
- Excessive sweating
- Dry mouth (increases the risk of tooth decay, so you should brush your teeth more often than usual)
- Nausea

Common side effects (occurring in up to 1 out of 10 users):

Decreased appetite, agitation, reduced sex drive, anxiety, nervousness, confusion, abnormal dreams, reduced emotions, indifference (apathy), tremor, tingling or numbness in the hands or feet, dizziness, problems with the ability to concentrate, migraines, memory loss, ringing in the ears (tinnitus), palpitations, yawning, runny or stuffy nose, diarrhea, vomiting, constipation, abdominal pain, flatulence, drooling, itching, muscle and joint pain, problems with erection and ejaculation in men, difficulty reaching orgasm in women, tiredness, prickling in the skin, weight loss.

Uncommon side effects (occurring in up to 1 out of 100 users):

Skin bleeding (bruises), increased appetite, aggressiveness, hallucinations, mania, fainting, enlarged pupils, fast or slow heart rate, hives (a type of rash), hair loss, rash, sensitivity to sunlight, difficulty urinating, increased bleeding during menstruation, swelling of the limbs, weight gain.

Rare side effects (occurring in up to 1 out of 1,000 users):

Increased sex drive, convulsions, involuntary movements, disturbed taste, bleeding, cough, hepatitis, general bad feeling.

Side effects with unknown frequency (reported by some users):

Heavy vaginal bleeding shortly after birth. See more information in the section "Pregnancy, breastfeeding and fertility" that appears in section 2 of this leaflet.

Suicidal thoughts or thoughts of self-harm (see also in section 2 "Before using the medicine"), decreased platelets (thrombocytopenia) which increases the risk of bleeding or bruising, hypersensitivity (rash), hypokalemia: low level of potassium in the blood that can cause muscle weakness, twitching or abnormal heart rate, panic attack, teeth grinding, restlessness, unusual muscle movements or muscle stiffness, akathisia (involuntary movements), low blood pressure, nose bleeding, bleeding disorders including subcutaneous or mucosal bleeding, sudden swelling of the skin or mucous membranes, in men – painful erection, milk secretion in men and women who are not breastfeeding, irregular menstrual periods, abnormal liver function test results, an increased risk of bone fractures has been observed in patients taking this type of medicine, abnormal heart rate.

Medicines from the SSRI class may in rare cases increase the risk of bleeding, including bleeding in the stomach or intestines. Tell the doctor if you vomit blood or if you have black or blood-stained stools.

Also tell the doctor if you continue to have other symptoms of depression. These may include hallucinations, anxiety, mania or confusion.

The side effects usually disappear after a few days. If the side effects do not disappear or are bothersome, if one of the side effects worsens, or if you suffer from a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

Side effects may be reported to the Ministry of Health by clicking on the link "Report side effects due to medicinal treatment" found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: https://sideeffects.health.gov.il

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- **Store in a dry place below 25°C.**

Do not dispose of medicines in household trash or wastewater. Consult the pharmacist how to dispose of medicines no longer required. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient the medicine also contains:

Microcrystalline Cellulose (Avicel PH-101), Lactose Monohydrate, Maize Starch, Croscarmellose Sodium (Primellose® SF), Copovidone (Kollidon® VA 64), Magnesium Stearate, Hypromellose, Glycerol, Microcrystalline Cellulose, Titanium Dioxide (E-171), Macrogol Stearate 40.

What does the medicine look like and what are the contents of the package:

A white, film-coated, oval tablet, with a score line on one side.

Package sizes: 28, 30 tablets. Not all package sizes may be marketed.

Marketing authorization holder and address:

Teva Israel Ltd., 124 Dvora HaNevi'a St., Tel Aviv 6944020.

Name and address of the manufacturer:

Polpharma Pharmaceutical Works S.A., Gdansk, Poland.

The leaflet was revised in March 2022 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the national drug registry of the Ministry of Health:

136.19.31231

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