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

The medicine is dispensed with a doctor's prescription only

Escitalopram Teva 10 mg

Tablets

The active ingredient and its quantity:
Each tablet contains:
Escitalopram (as oxalate) 10 mg

Escitalopram Teva 20 mg

Tablets

The active ingredient and its quantity:
Each tablet contains:
Escitalopram (as oxalate) 20 mg

For information on the inactive ingredients, see section 2 – "Important information about some of the ingredients of the medicine" and section 6 – "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

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.

This medicine is not usually intended for use in children and adolescents under the age of 18.

Antidepressants and anti-anxiety medicines increase the risk of suicidal behavior and thoughts in children, adolescents and young adults up to the age of 25.
Upon commencement of treatment with the medicine, patients of all ages, and their relatives, must monitor behavioral changes, such as: worsening of depression, suicidal thoughts, aggressiveness and the like.
If such changes occur, refer to a doctor immediately.

1. WHAT IS THE MEDICINE INTENDED FOR?

Escitalopram Teva is an antidepressant from the selective serotonin reuptake inhibitors (SSRI) group. Medicines belonging to this group act on the serotonin system in the brain by increasing serotonin levels. Disruptions in the serotonin system are considered important factors in development of depression and diseases associated with depression. Escitalopram Teva is used to treat the following conditions:
depression
panic disorders
generalized anxiety
social anxiety
obsessive-compulsive disorder

A few weeks may pass until you start to feel better. Continue taking the medicine even if it takes time until your feeling improves. Talk to the doctor if you do not experience an improvement or if you feel worse.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (escitalopram) or to any of the additional ingredients contained in the medicine (see list of inactive ingredients in section 6 – "Further Information").
- You are taking other medicines from the non-selective, irreversible monoamine oxidase inhibitors (MAOI) group, such as: phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine. Wait 14 days after taking these medicines before beginning to use Escitalopram Teva, or wait 7 days after taking Escitalopram Teva before starting treatment with these medicines. Likewise, do not concomitantly take Escitalopram Teva with reversible monoamine oxidase A inhibitors (MAO-AI) (e.g., moclobemide to treat depression) or the non-selective and reversible monoamine oxidase inhibitor (MAOI) linezolid (an antibiotic), or irreversible monoamine oxidase B inhibitors (MAO-BI) (e.g., selegiline for treatment of Parkinson's). The combination with these medicines increases the risk of serotonin syndrome (see "Drug interactions" in section 2).
- You are suffering from heart rhythm disorders (as tested by ECG, a heart function test), or from a congenital defect in the electrical activity of the heart.
- You are taking medicines to treat heart rhythm disorders or which may have an effect on the heart rhythm (see "Drug interactions" in section 2).
- You are taking the medicine pimozide.

Special warnings regarding use of the medicine

Before treatment with Escitalopram Teva, tell the doctor if:

- You are pregnant or breastfeeding (see "Pregnancy, breastfeeding and fertility" section).
- You are suffering, or have suffered in the past, from epilepsy. Discontinue treatment with Escitalopram Teva if you have an epileptic attack for the first time or if there is an increase in the frequency of attacks (also see section 4 – "Side Effects").
- You are suffering, or have suffered in the past, from impaired liver or kidney function. The doctor may need to adjust the dosage of the medicine for you.
- You have diabetes. Treatment with Escitalopram Teva may affect your sugar level balance. The dosage of the insulin and/or other diabetes medicines may need to be adjusted.
- You have reduced blood sodium levels.
- You have a tendency to bleed easily or develop bruises or if you are pregnant (see Pregnancy, breastfeeding and fertility" section).
- You are receiving electroconvulsive therapy (ECT).
- You are suffering, or have suffered in the past, from coronary heart disease.
- You are suffering, or have suffered in the past, from heart function disturbances or if you have recently suffered from a heart attack.
- You have a low heart rate at rest and/or if you know you may develop a decrease in blood salts, as a result of prolonged diarrhea or vomiting or as a result of taking diuretics.
- You are suffering, or have suffered in the past, from symptoms which may be indicative of heart rhythm disorders such as: rapid or irregular heart rate, fainting, collapse or dizziness when getting up from sitting or lying down.
- You have or, previously had, eye problems, such as certain types of glaucoma (increased intraocular pressure).

Attention:

Some patients suffering from manic depression may enter a state of mania, characterized by unusual ideas, which rapidly change, unexplained happiness and more physical activity than usual. If you experience these symptoms, refer to a doctor.

Symptoms such as restlessness or difficulty sitting or standing still may also occur in the first weeks of treatment. If they occur, report them immediately to the doctor.

Medicines such as Escitalopram Teva (called SSRI/SNRI) may cause symptoms of sexual function disturbances (see section 4 – "Side Effects"). In certain cases, the symptoms persisted even after discontinuation of the treatment.

Panic disorder

When treating panic disorders, 2-4 weeks usually pass before any improvement is felt. Some patients may experience increased anxiety at the beginning of treatment, which will disappear during the first or second week of treatment. Therefore, in cases of panic disorders, it is recommended to start treatment with a low dosage.

It is very important to strictly follow the doctor's instructions and not to stop treatment or change the dose without consulting the doctor.

Suicidal thoughts and worsening of depression or of anxiety disorder

Suicidal thoughts or thoughts of self-harm are common in psychiatric disorders, especially in patients suffering from depression and/or anxiety disorder. These thoughts may increase at the beginning of treatment with antidepressants, as the effect of these medicines takes time, usually two weeks, but sometimes longer. The chance of occurrence of such thoughts is higher if:

- You have had suicidal thoughts or thoughts of self-harm in the past.
- You are a young adult. Data from clinical trials show that there is increased risk of suicidal behavior among adults below the age of 25 with a psychiatric condition who were treated with antidepressants.

If you have suicidal thoughts or thoughts of self-harm at any time, **refer to your doctor or proceed to a hospital immediately. It is recommended that you tell a relative or close friend** that you are suffering from depression or from an anxiety disorder, and ask them to read this leaflet. You can ask them to tell you when they think there has been a worsening of your depression or your anxiety disorder, or if they are concerned about a change that has occurred in your behavior.

Children and adolescents

Escitalopram Teva is not usually intended for use in children and adolescents under the age of 18.

In patients under the age of 18 who have taken medicines from this group, there is an increased risk of side effects, such as suicide attempts, suicidal thoughts and hostility (particularly aggressiveness, rebellious behavior and anger). Despite this, your doctor can prescribe this medicine for patients under the age of 18 if he thinks that this is for their benefit.

If the doctor has prescribed the medicine for a patient under the age of 18 and you are interested in discussing it – refer to the doctor again.

Inform your doctor if some of the above listed side effects occurred or became worse in patients under the age of 18. Likewise, the long-term effects of Escitalopram Teva on growth, maturation and cognitive-behavioral development in this age group have not yet been tested.

Drug interactions

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. In particular, inform the doctor or pharmacist if you are taking:

- Do not use with non-selective monoamine oxidase inhibitors (MAOI) (such as: phenelzine, iproniazid, isocarboxazid, nialamide, tranylcypromine). If you took one of these medicines, you should wait 14 days before starting treatment with Escitalopram Teva. After discontinuing treatment with Escitalopram Teva, you should wait 7 days before starting treatment with these medicines.
- Do not use together with selective, reversible monoamine oxidase A inhibitors (MAO-AI), such as moclobemide (for treatment of depression).
- Do not use together with irreversible monoamine oxidase B inhibitors (MAO-BI), such as selegiline (to treat Parkinson's disease). They may increase the risk of side effects.
- Do not use together with the antibiotic linezolid.
- Lithium (for treatment of manic depression) and tryptophan.
- Imipramine and desipramine (for treatment of depression).
- Sumatriptan and similar medicines (for treatment of migraine) and tramadol (to relieve severe pain). These medicines may increase the risk of side effects.
- Cimetidine, lansoprazole and omeprazole (for treatment of gastric ulcer), fluconazole (for treatment of fungal infections), fluvoxamine (for treatment of depression) and ticlopidine (to reduce risk of stroke). These medicines may increase the concentration of escitalopram in the blood.
- St. John's wort (*Hypericum perforatum*, a herbal medicine for treatment of depression).
- Aspirin (acetylsalicylic acid) and non-steroidal anti-inflammatory drugs (NSAIDs) (medicines to relieve pain or thin the blood, anticoagulants). These medicines may increase the tendency for bleeding.
- Warfarin, dipyridamole and phenprocoumon (blood thinners, anticoagulants): the doctor will monitor your blood coagulation time at the start of treatment and at the end of treatment with Escitalopram Teva, to makes sure that the dosage of the blood-thinner medicine you are taking is appropriate.
- Medicines that may lower your sensitivity threshold for convulsions: mefloquine (for treatment of malaria), bupropion (for treatment of depression) and tramadol (for treatment of severe pain), neuroleptic preparations (medicines for treatment of schizophrenia and psychoses), and antidepressants (from the tricyclic antidepressant group, and SSRIs).
- Flecainide, propafenone and metoprolol (for treatment of heart and vascular diseases), clomipramine, nortriptyline (antidepressants) and risperidone, thioridazine and haloperidol (antipsychotics). It may be necessary to adjust the dosage of Escitalopram Teva.
- Medicines that lower blood potassium or magnesium levels, as such conditions increase the risk of life-threatening arrhythmias.

Do not take Escitalopram Teva concomitantly with medicines to treat heart rhythm disorder or with medicines that may have an affect on heart rhythm, such as class IA and III anti-arrhythmias, antipsychotics (e.g., phenothiazine derivatives, pimozide, haloperidol), tricyclic antidepressants, certain antimicrobial agents (e.g., sparfloxacin, moxifloxacin, erythromycin administered intravenously, pentamidine, anti-malarials particularly halofantrine), certain antihistamines (for the treatment of allergy, astemizole, hydroxyzine, mizolastine). If you have further questions on this matter, refer to the doctor.

- SNRI and SSRI antidepressants may cause serotonin syndrome (rare), which includes symptoms such as nervousness, restlessness, confusion, sweating, high fever, increased reflexes, muscle spasms, tremors, increase in heart rate (see section 4 – "Side Effects"). The syndrome may occur at a higher frequency if you are concomitantly taking additional medicines that affect the nervous system (see above). Therefore, inform the doctor about any other medicine you are taking.

Use of the medicine and food

The medicine can be taken with or without food.

Use of the medicine and alcohol consumption

As with many medicines, it is recommended not to consume alcohol with Escitalopram Teva, although no interaction between Escitalopram Teva and alcohol is expected.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you are pregnant or are planning a pregnancy, consult with the doctor or pharmacist before using this medicine. Do not use Escitalopram Teva if you are pregnant or breastfeeding, unless you have consulted your doctor and discussed with him the risk versus benefit of taking this medicine.

If you took Escitalopram Teva during the last 3 months of pregnancy, the following signs may occur in a newborn baby: breathing problems, blue skin, seizures, change in body temperature, eating problems, vomiting, low blood sugar level, stiff or flaccid muscles, increased reflexes, tremor, jitteriness, irritability, exhaustion, persistent crying, sleepiness, sleeping difficulties. If your baby shows these signs, refer to the doctor immediately.

Make sure your midwife and/or doctor know that you are taking Escitalopram Teva. When taking medicines such as Escitalopram Teva during pregnancy, especially in the last 3 months of the pregnancy, there is an increased risk of a serious condition in babies called persistent pulmonary hypertension of the newborn (PPHN), which causes the baby to breathe faster and to appear blue. These symptoms usually appear during the first 24 hours after birth. If these symptoms occur in your baby, refer to the midwife and/or doctor immediately.

If you take Escitalopram Teva 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 Escitalopram so they can advise you.

If you used Escitalopram Teva during pregnancy, do not discontinue use abruptly. Escitalopram may pass into breast milk and therefore, it is not recommended to breastfeed while using the medicine.

Animal studies have shown that citalopram, a medicine similar to escitalopram, reduces sperm quality. Theoretically, this may affect fertility; however, no effect on human fertility has yet been shown.

Driving and use of machines

It is recommended not to drive a vehicle or operate dangerous machinery, or to engage in any activity that require alertness before knowing how Escitalopram Teva affects you.

Important information about some of the ingredients of the medicine

This medicine contains less than 1 mmol (23 mg) sodium per tablet and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the preparation dosage and treatment regimen.

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

Adults

Depression: The recommended dosage is generally 10 mg once a day (once-daily dosage). Your doctor may increase the dosage up to 20 mg per day.

Panic disorder: The starting dosage is 5 mg per day (once-daily dosage) for the first week, and afterwards, an increase in the dosage to 10 mg per day. Your doctor can increase the dosage up to 20 mg per day.

Social anxiety: The recommended dosage is usually 10 mg once a day (once-daily dosage). Your doctor can lower the dosage to 5 mg per day or increase the dosage up to 20 mg per day, according to your response to treatment with the medicine.

Anxiety disorder: The recommended dosage is usually 10 mg once a day (once-daily dosage). Your doctor can increase the dosage up to 20 mg per day.

Obsessive-compulsive disorder: The recommended dosage is usually 10 mg once a day (once-daily dosage). Your doctor can increase the dosage up to 20 mg per day.

Elderly (above the age of 65)

The recommended dosage is usually 5 mg once a day (once-daily dosage). Your doctor can increase the dosage up to 10 mg per day.

Children and adolescents

Escitalopram Teva is not usually intended for use in children and adolescents (see section 2 – "Before Using The Medicine").

Impaired kidney function

It is recommended that caution be exercised in patients with severe kidney function impairment. Take the medicine as prescribed by the doctor.

Impaired liver function

These patients should receive no more than 10 mg of the medicine per day. Take the medicine as prescribed by the doctor.

Patients known to be poor metabolizers of the CYP2C19 enzyme

Patients known to have this genotype should receive no more than 10 mg of the medicine per day. Take the medicine as recommended by the doctor.

Do not exceed the recommended dose.

How to use

Swallow the medicine with some water. The medicine can be taken with or without food. Do not chew or crush the tablet, since it has a bitter taste.

The tablet can be halved on the scoreline.

Duration of treatment

A few weeks may pass until you start to feel better. Continue taking the medicine even if it takes time until you feel better. Do not change the dosage without consulting the doctor.

Complete the treatment as recommended by the doctor. Premature discontinuation of treatment may cause the symptoms to recur. It is recommended to adhere to the treatment for at least 6 months after you feel better.

If you accidentally took an overdose or if a child accidentally swallowed the medicine, refer immediately to the doctor or proceed to a hospital emergency room, and bring the package of the medicine with you. Do so even if you do not feel bad. Possible symptoms of an overdose are: dizziness, tremor, nervousness, convulsions, coma, nausea, vomiting, changes in heart rate, decreased blood pressure, changes in body salt/fluid balance.

If you forgot to take this medicine at the required time, do not take a double dose. If you forgot to take the medicine and you remembered before going to sleep, take the forgotten dose immediately and continue as usual the following day. If you only remembered during the night or the following day, do not take the forgotten dose and continue as usual.

Adhere to the treatment as recommended by the doctor. Use this medicine at set intervals as determined by the attending doctor. Even if there is an improvement in your health, do not stop treatment with the medicine without consulting with the doctor or pharmacist.

If you stop taking the medicine:

Do not stop treatment with Escitalopram Teva before being instructed to do so by the doctor. When completing treatment, it is usually recommended to gradually lower the dosage of the medicine over several weeks. Abrupt discontinuation of the treatment may cause the common symptoms with discontinuation of Escitalopram Teva treatment. The risk of these symptoms occurring is higher when Escitalopram Teva is used for a long time or at a high dosage, or if the treatment is reduced too quickly. In most patients, these symptoms are mild or go away on their own within two weeks. However, in some patients, the symptoms can be severe or can persist for a longer period of time (2-3 months and more). If you experience the symptoms of treatment discontinuation on completion of treatment with Escitalopram Teva, consult the doctor. The doctor will probably ask you to take the medicine again and to lower the dosage more slowly.

Symptoms of treatment discontinuation include: dizziness (unsteadiness or loss of balance), feeling pins and needles ("prickling"), sensation of burning and electric current (less common), including in the head, sleep disturbances (vivid dreams, nightmares, inability to sleep), feeling anxiety, headaches, nausea, sweating (including night sweats), a feeling of restlessness or nervousness, tremor, confusion or disorientation, feeling emotional or irritable, diarrhea, visual disturbances, palpitations.

Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, use of Escitalopram Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

These effects usually pass after a few weeks of treatment. Note that some of the side effects may be symptoms of your illness and will therefore improve when you begin to feel better.

Refer to the doctor or proceed to a hospital immediately if the following symptoms occur:

Uncommon, frequency of up to 1 in 100 patients:
Unusual bleeding, including gastrointestinal bleeding.

Rare, frequency of up to 1 in 1,000 patients:
Swelling of the skin, tongue, lips, throat or face, urticaria or breathing or swallowing difficulties (signs of a severe allergic reaction); High fever, nervousness or restlessness, confusion, tremor, strong muscle contraction may be symptoms of a rare condition called serotonin syndrome.

Unknown frequency:
Difficulty passing urine; Convulsions (also see "Special warnings regarding use of the medicine" in section 2); Yellowing of the skin and white area of the eyes, which are signs of liver function problems/ hepatitis; Rapid and irregular heartbeat, and fainting may be symptoms of a life-threatening condition called torsade de pointes (heart rate disorder); Thoughts of self-harm or suicidal thoughts (also see "Special warnings regarding use of the medicine" in section 2); Sudden swelling of the skin or mucous tissues (angioedema).

Additional side effects:

Occur very frequently (frequency of more than 1:10):
Nausea, headache.

Occur frequently (frequency of up to 1:10):
Nasal congestion (sinusitis), reduced or increased appetite, anxiety, restlessness, abnormal dreams, difficulty falling asleep, sleepiness, dizziness, yawning, tremor, tingling sensation in the skin, diarrhea, constipation, vomiting, dry mouth, increased sweating, muscle and joint pain, sexual function disturbances (delayed ejaculation, problem with erection, decreased sexual desire, difficulty achieving orgasm in women), fatigue, fever, weight gain.

Occur infrequently (frequency of up to 1:100):
Rash, itchy skin, teeth grinding, excitement, nervousness, panic attack, confusion, sleep disturbances, disturbances in sense of taste, fainting, enlarged pupils, visual disturbances, ringing in the ears (tinnitus), hair loss, heavy menstrual bleeding, abnormal menstrual cycle, reduction in weight, fast heart rate, swelling of the limbs, nosebleed.

Occur rarely (frequency of up to 1:1,000):
Aggressiveness, depersonalization, hallucinations, slow heart rate.

Side effects of unknown frequency:
Decrease in blood sodium level (the symptoms are malaise and nausea with muscle weakness or confusion), dizziness when getting up from sitting or from lying down due to low blood pressure, abnormal liver functions (increased liver enzymes in the blood), movement disorders (involuntary muscle movements), painful erection, bleeding (including bleeding of the skin and mucous tissues), abnormal ADH secretion, which causes the body to retain water and for the blood to thin, and to a reduction in the amount of sodium, milk discharge in men and in women that are not breastfeeding, mania, an increased risk of fractures has been observed in patients being treated with this type of medicine, changes in the heart rhythm (called prolongation of QT interval, which can be seen in an ECG test of the electrical activity of the heart). Heavy vaginal bleeding shortly after birth, see further information in "Pregnancy, breastfeeding and fertility" section that can be found in section 2 of the leaflet.

In addition, several side effects are known to occur when taking medicines which act similarly to escitalopram (the active ingredient of Escitalopram Teva), which are: akathisia (motor restlessness), loss of appetite.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.

Reporting side effects
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link:
https://sideeffects.health.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- Avoid poisoning! This medicine and any other medicine must be kept in a safe place out of the reach and sight of children and/or infants in order 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) that appears on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Store the medicine in the original package in order to protect from light and moisture, below 25°C.
- Do not discard medicines into the wastewater or waste bin. Ask the pharmacist how to dispose of medicines no longer in use. These measures will help to protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Microcrystalline cellulose, croscarmellose sodium, stearic acid, magnesium stearate, colloidal silicon dioxide, hypromellose, titanium dioxide, polyethylene glycol.

What the medicine looks like and the contents of the package:

Escitalopram Teva 10 mg: White, film-coated, round convex tablet, scored on one side and debossed with "10" on the other side.

Escitalopram Teva 20 mg: White, film-coated, round convex tablet, scored on one side and debossed with "9" on the left side of the score and "3" on the right side of the score. The other side of the tablet is debossed with "7463".

There are packages of 28 or 30 tablets.

Not all package sizes may be marketed.

Name of Manufacturer and License Holder and its Address:

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

The leaflet was revised in November 2021 according to MOH guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Escitalopram Teva 10 mg:
137.84.31381
Escitalopram Teva 20 mg:
137.85.31382

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