

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.

Antidepressant medicines increase the
risk of suicidal behavior and thoughts in
children, adolescents and young adults.
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
level. 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 pimoziide.

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 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 also tramadol
and other similar medicines (opioids, used
to relieve severe pain). These medicines
may increase the risk of side effects.

- Cimetidine, lansoprazole and omeprazole
(for treatment of gastric ulcer), famotidine
(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) due to a possible risk of a lowered
threshold for seizures.

- 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 effect on heart rhythm,

such as class IA and III anti-arrhythmias,
antipsychotics (e.g., phenothiazine
derivatives, pimoziide, haloperidol), tricyclic
antidepressants, certain antimicrobial
agents (e.g., sparfloxacin, moxifloxacin,
erythromycin administered intravenously,
pentamidine, anti-malarials particularly
halofantrine), certain antihistamines
(for 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

Escitalopram Teva 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). The
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 the 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 (frequency cannot be
estimated from the available data):

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);
Cases of rhabdomyolysis (skeletal
muscle break downs) were reported post
marketing of the preparation. Contact the
doctor immediately if you experience an
unexplained muscle pain, tenderness or
muscle weakness.

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
(frequency cannot be estimated from the
available data):

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,
abnormal platelets (thrombocytopenia),
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, increased blood levels of the
hormone prolactin, 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, measuring 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".