This leaflet format has been determined by the Ministry of Health and the content thereof has been checked and approved in June 2016
PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Diltiazem Teva® 30 mg

Tablets

The active ingredient and its quantity:
Each tablet contains:
Diltiazem hydrochloride 30 mg

Diltiazem Teva® 60 mg

Tablets

The active ingredient and its quantity:
Each tablet contains:
Diltiazem hydrochloride 60 mg

For the list of inactive ingredients, please see section 6.

Read this 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 the treatment of your ailment. Do not pass this medicine on to others. It may harm them even if it seems to you that their medical condition is similar.

1. WHAT IS THE MEDICINE INTENDED FOR?

The medicine is intended for the treatment of angina pectoris.

Therapeutic group:
Calcium channel blocker.

2. BEFORE USING THE MEDICINE:

Do not use the preparation in the following cases:

- If you are breastfeeding or are planning to breastfeed.
- If you have a known sensitivity to diltiazem or to any of the other ingredients of the medicine.
- If you are suffering from low blood pressure.
- If you are suffering from a very slow heart rate - less than 50 beats per minute.
- If you are suffering from heart failure or from problems with blood flow to the lungs - in these conditions, you may experience breathlessness and swelling of the ankles.
- If you are suffering from severe heart problems, including irregular heart rate (unless you have a pacemaker).
- If you are concomitantly receiving dantrolene injections (for use in cases of severe fever or severe muscle spasms - see "If you are taking, or have recently taken, other medicines" section).
- If you are taking a medicine that contains ivabradine for the treatment of certain heart diseases.

Special warnings regarding use of the medicine:
- If you are sensitive to any food or medicine, inform the doctor before taking this medicine.
- During the course of treatment with this medicine, blood pressure, and liver, kidney and heart function tests should be performed.

Before treatment with Diltiazem Teva®, tell the doctor if:
- You are suffering, or have suffered in the past, from impaired function of:
  - The heart and/or blood vessels
  - The liver
  - The kidney/urinary system
- You are suffering, or have suffered in the past, from mood changes, including depression
- You are suffering, or have suffered in the past, from intestinal problems
- You have diabetes
- You are due to undergo surgery

The doctor will monitor your condition very carefully (particularly at the beginning of treatment) in the following cases:
- If you are over 65 years of age
- If you are suffering from kidney or liver problems
- If you have diabetes

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 the following medicines:
- Aspirin and salicylates
- Anticoagulants
- Antidepressants – e.g., lithium or medicines from the TCA group (e.g., imipramine, amitriptyline)
- Antihypertensives – e.g., doxazosin, tamsulosin, atenolol, propranolol, acebutolol
- Antihypertensives from the ACE inhibitors group e.g., lizinopril or captopril
- Diuretics (e.g., furosemide or spironolactone)
- Medicines that act on the heart (e.g., digitalis, quinidine, amiodarone)
- Anesthetics
- Medicines to treat insomnia or anxiety (e.g., triazolam or midazolam)
- Beta blockers or other calcium channel blockers
- Medicines for ulcer (e.g., cimetidine, ranitidine)
- Carbamazepine, phenobarbital, phenytoin (for epilepsy)
- Theophylline (for asthma)
- Ciclosporin, tacrolimus and sirolimus (to prevent rejection of a transplanted organ)
- Rifampicin (for tuberculosis)
- Nitrates (to treat angina pectoris)
- Alpha blockers for treatment of hypertension (prazosin)
- Corticosteroids – to treat inflammation or to treat allergic reaction
- Benzodiazepines
- Buspirone
- Medicines to lower cholesterol (e.g., the statin family)
- Dantrolene – given for severe muscle spasms or severe fever
- Protease inhibitors (to treat HIV)
- Cilostazol (for blood circulation)
- Erythromycin – to treat infections

Pregnancy and breastfeeding:
If you are pregnant, your doctor will only prescribe this medicine for you if it is absolutely essential.
Do not take this medicine during pregnancy, unless the doctor has decided that the benefit to the woman outweighs the risk to the unborn baby.
If you are pregnant, think you are pregnant or are planning to become pregnant, consult a doctor before using the medicine.
Do not breastfeed during the course of treatment, since this medicine may pass into breast milk. Consult a doctor if you are breastfeeding or are planning to breastfeed.

Driving and use of machines:
Use of this medicine may cause dizziness and impaired alertness. If you experience these effects, do not drive or operate dangerous machinery or participate in any activity which requires alertness.

Important information about some of the ingredients of the medicine:
Diltiazem Teva® contains lactose monohydrate. If you have intolerance to lactose or to other sugars, inform the doctor before taking this medicine.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain.
The dosage and treatment regimen will be determined by the doctor only.

The usual dosage unless instructed otherwise by the doctor:

Adults:
Starting dosage: 30 mg, 4 times a day (before each meal and again at bedtime). The doctor may gradually increase the dosage (every day or two) up to 240 mg (in equal doses split into 3-4 times a day) until reaching the optimal response.

Patients over 65 years of age or with liver or kidney problems: The dosage will be adjusted by the doctor.

Children: Do not give this medicine to children.

Directions for use of the medicine:
- Swallow the tablet whole with a little water.
- Do not chew! Take the medicine one hour before eating or on an empty stomach.
- *Diltiazem Teva® 30 mg:* The tablet does not have a score line.
- *Diltiazem Teva® 60 mg:* The tablets can be halved on the score line.

Sudden discontinuation may cause exacerbation of the angina pectoris.
Consult a doctor regarding the permissible degree of physical activity.

Tests and follow-up
You may be referred for blood and heart function tests during the course of treatment.

If you accidentally took a higher dosage, the following signs may appear: dizziness or weakness, blurred vision, chest pain, breathlessness, fainting, abnormal heart rate, loss of consciousness, impaired speech, confusion.

If you took an overdose or if a child 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.

If you forgot to take this medicine at the required time, take a dose as soon as you remember. However, if it is almost time for the next dose, skip the forgotten dose and continue as usual. Never take two doses together to compensate for a forgotten dose.
Adhere to the treatment as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with this medicine without consulting the doctor or pharmacist.
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 Diltiazem Teva® may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Stop the treatment and refer to the doctor or hospital immediately in the following cases:
- A severe allergic reaction – the signs can include rash, swallowing or breathing difficulties, swelling of the lips, face, throat or tongue.
- Skin rash that includes redness or lumps on the skin, swollen eyelids, swelling of the face, lips, throat or tongue, breathing or swallowing difficulties.
- Stevens-Johnson syndrome: blistering or peeling of the skin around the lips, eyes, mouth, nose and genitals, flu symptoms and fever.
- A skin reaction called toxic epidermal necrolysis - includes severe blistering of the skin and peeling of the skin, feeling generally unwell and fever, chills and muscle pain.
- A skin reaction called erythema multiforme - includes rash or red patches on the skin with a lighter center; itching and peeling or blistering in the center may occur. The rash is primarily on the palms or feet.

Inform the doctor immediately if you experience the following severe effects (immediate medical treatment may be necessary):

Side effects that occur frequently (frequency of 1-10 in 100 patients):
- Slow or irregular heart rate.
- Very fast, irregular heart rate or forceful heartbeats.

Side effects of unknown frequency:
- Rash caused by narrowing of the blood vessels (vasculitis).
- Shortness of breath, tiredness with swelling of the legs and ankles (may be a sign of heart failure).
- Muscle movement disorders of the muscle of the tongue, face, eyes and trembling.
- High fever, tiredness, lack of appetite, abdominal pain, nausea (may be signs of inflammation of the liver - hepatitis).
- Increased urine output, increased thirst, dry mouth or skin (can be signs of high blood sugar level – hyperglycemia).
- Hypersensitivity to the sun – use sun protection while using this medicine.
- Breast enlargement in men.

Inform the doctor immediately if you experience the following effects:

Side effects that occur very frequently (effects that occur in more than 1 patient in 10 patients):
- Swelling of the legs.

Side effects that occur frequently (frequency of 1-10 in 100 patients):
- Indigestion, abdominal pain, constipation and diarrhea.

Uncommon side effects (frequency of 1-10 in 1,000 patients):
- Dizziness, or fainting when standing or when rapidly transitioning from a sitting to standing position.

Rare side effects (frequency of 1-10 in 10,000 patients):
- Dry mouth.
- Itchy rash (urticaria).

Side effects of unknown frequency:
- Swelling of the gums.

Inform the doctor or pharmacist if the following effects worsen or last for more than a few days:

Side effects that occur frequently (frequency of 1-10 in 100 patients):
- Headache.
- Flushing.
- Nausea or vomiting.
- General unwell feeling.
- Weakness or tiredness.
- Dizziness.
- Skin redness.

Uncommon side effects (frequency of 1-10 in 1,000 patients):
- Insomnia.

Side effects of unknown frequency:
- Mood changes including depression.
- Bleeding or tendency to bruise more easily.

If a side effect occurs, if any of the side effects worsen, or if you are suffering from a side effect not mentioned in the leaflet, consult the doctor.

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://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine, and any other medicine, should 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.
- **Store in a dry place, below 25ºC.**
- Do not discard medicines into the waste water or waste bin. Ask the pharmacist how to dispose of medicines that are no longer in use. These measures will help protect the environment.

6. FURTHER INFORMATION:

In addition to the active ingredient, Diltiazem Teva® 30 mg also contains:
Lactose monohydrate, hydroxypropyl methylcellulose, povidone, magnesium stearate, hypromellose, titanium dioxide, macrogol, polysorbate 80, FD&C yellow #6, purified water.

Each tablet contains 139 mg lactose monohydrate.

In addition to the active ingredient, Diltiazem Teva® 60 mg also contains:
Lactose monohydrate, hydroxypropyl methylcellulose, povidone, magnesium stearate, hypromellose, titanium dioxide, macrogol, FD&C yellow #6, polysorbate 80, purified water.

Each tablet contains 278 mg lactose monohydrate.

What the medicine looks like and the contents of the package:
Diltiazem Teva® 30 mg: A light orange, round, coated tablet, with the numbers '93' and '318' debossed on one side and the other side is plain.
Diltiazem Teva® 60 mg: An orange, round, coated tablet, with a score line on one side of the tablet with the number '93' appearing on one side of it and the number '319' on the other side. The other side of the tablet is plain.

The package contains 30 tablets.

Name of Manufacturer and License Holder and its address:
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petah-Tikva.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Diltiazem Teva® 30 mg: 140.85.27958.00
Diltiazem Teva® 60 mg: 140.86.27957.00

This leaflet was checked and approved by the Ministry of Health in June 2016.

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