

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**  
This medicine is dispensed with a doctor's prescription only

<b>Repaglinide Teva 0.5 mg tablets</b>	<b>Repaglinide Teva 1 mg tablets</b>	<b>Repaglinide Teva 2 mg tablets</b>
<b>Composition:</b> Each Repaglinide Teva 0.5 mg tablet contains: repaglinide 0.5 mg	<b>Composition:</b> Each Repaglinide Teva 1 mg tablet contains: repaglinide 1 mg	<b>Composition:</b> Each Repaglinide Teva 2 mg tablet contains: repaglinide 2 mg

For information about inactive ingredients and allergens see section 6 'Additional information'.  
**Read the entire leaflet carefully before you start using this medicine.** This leaflet contains concise information about this medicine. Keep this leaflet; you may need to read it again. If you have any further questions, consult your doctor or pharmacist.  
This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their signs of illness are the same as yours.  
If you develop any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4. This medicine is not intended for adolescents under 18 years old and adults over 75 years old.

**1. What is this medicine intended for?**

Repaglinide Teva is an oral antidiabetic medicine containing repaglinide which helps your pancreas produce more insulin and thereby lower your blood sugar (glucose) level.  
**Type 2 diabetes** is a disease in which your pancreas does not produce enough insulin to control the sugar level in your blood or when your body does not respond normally to the insulin it produces.  
Repaglinide Teva is used to treat type 2 diabetes in adults whose blood sugar level cannot be controlled by changing their diet, or by weight reduction or exercise. Repaglinide Teva can be given with metformin, another medicine for diabetes.  
Repaglinide Teva has been shown to effectively lower blood sugar levels, which helps to prevent complications from your diabetes.  
**Therapeutic group:** meglitinide diabetes medicines.

**2. Before using this medicine**

<b>Do not use this medicine if:</b> <ul style="list-style-type: none"><li>• You are sensitive (allergic) to repaglinide or to any of this medicines other ingredients (see section 6 'Additional information').</li><li>• You have type 1 diabetes.</li><li>• The acid level in your blood rises (diabetic ketoacidosis).</li><li>• You have a severe liver disease.</li><li>• You take gemfibrozil (a medicine used to lower increased level of fats in the blood).</li><li>• You are pregnant or breastfeeding.</li></ul>
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**Special warnings about using this medicine**  
**Before you start taking Repaglinide Teva, tell your doctor if:**

- you have problems with liver function. Repaglinide Teva is not recommended in patients with mild to moderate liver disease. Do not take Repaglinide Teva if you have a severe liver disease (see section 2 'Before using this medicine', under 'Do not take this medicine if').
- you have kidney disease. Repaglinide Teva should be taken with extra caution.
- you are about to have major surgery or you have recently suffered a severe illness or infection. In any of these cases, diabetic control may be lost.
- you are under 18 or over 75 years old, Repaglinide Teva is not recommended. It has not been studied in these age groups.

Talk to your doctor if any of these apply to you. Repaglinide Teva may not be a suitable treatment for you. Your doctor will advise you.  
**Children and adolescents**  
Do not take this medicine if you are under 18 years old.

**If you get hypoglycemia (low blood sugar level)**  
You may get a hypo (short for hypoglycemia) if your blood sugar level gets too low. This may happen:

- if you take too much Repaglinide Teva.
- if you exercise more than usual.
- if you are taking other medicines or have liver or kidney problems (see other sections under section 2 'Before using this medicine').

**The warning signs of a hypo** may come on suddenly and can include: cold sweat; cool pale skin; headache; rapid heart-beat; nausea; feeling very hungry; temporary changes in vision; drowsiness; unusual tiredness and weakness; nervousness or tremor; feeling anxious; feeling confused; difficulty concentrating.  
**If your blood sugar level is low or you feel a hypo coming on:** eat sugar tablets or a high sugar food or drink, then rest.  
**When the symptoms of hypoglycemia have disappeared or when your blood sugar levels are under control** continue Repaglinide Teva treatment.  
**Tell people you have diabetes and that if you pass out (become unconscious)** due to a hypo, they must turn you on your side and get medical help straight away. They must not give you any food or drink if you are unconscious. It could choke you.

- **If severe hypoglycemia** is not treated, it can cause brain damage (temporary or permanent) and even death.
- **If you have a hypo** that makes you pass out, or many hypoglycemia events, talk to your doctor. The amount of Repaglinide Teva, your diet, or exercise may need to be adjusted.

**If your blood sugar level gets too high:**  
Your blood sugar level may get too high (hyperglycemia). This may happen:

- if you take too little Repaglinide Teva.
- if you have an infection or a fever.
- if you eat more than usual.
- if you exercise less than usual.

**The warning signs of blood sugar level that is too high** appear gradually. They include: increased urination; feeling thirsty; dry skin and dry mouth. Talk to your doctor. The amount of Repaglinide Teva, your diet or exercise may need to be adjusted.

**Other medicines and Repaglinide Teva**  
**If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.**  
You can take Repaglinide Teva with metformin, another medicine for diabetes, if your doctor prescribes it.  
If you take gemfibrozil (used to lower increased fat levels in the blood) you should not take Repaglinide Teva.  
Your body's response to Repaglinide Teva may change if you take other medicines, especially these:

- monoamine oxidase inhibitors (MAOI) (used to treat depression).
- beta blockers (used to treat certain heart conditions and high blood pressure).
- ACE-inhibitors (used to treat certain heart conditions).
- salicylates (such as aspirin).
- octreotide (used to treat cancer).
- nonsteroidal anti-inflammatory drugs (NSAID) (a type of painkiller).
- steroids (anabolic steroids and corticosteroids – used to treat anemia and inflammation).
- birth control pills.
- thiazides (diuretics).
- danazol (used to treat breast cysts and endometriosis).
- thyroid products (used to treat low levels of thyroid hormones).
- sympathomimetics (used to treat asthma).
- clarithromycin, trimethoprim, rifampicin (antibiotic medicines).
- itraconazole, ketoconazole (antifungal medicines).
- cyclosporine (used to suppress the immune system).
- deferasirox (used to reduce chronic iron overload).
- clopidogrel (prevents blood clots).
- phenytoin, carbamazepine, phenobarbital (used to treat epilepsy).
- Hypericum (St. John's wort) (herbal medicine).

**Particularly inform your doctor or pharmacist if you are taking any of these medicines.**  
**Using this medicine and food**  
Swallow the tablets with a glass of water immediately before or up to 30 minutes before each main meal.  
**Using this medicine and alcohol consumption**  
Alcohol can change the ability of Repaglinide Teva to lower your blood sugar level. Watch for signs of a hypo.  
Drinking alcohol can affect how the medicine works (alcohol can cause a serious drop in blood sugar level): Avoid drinking alcohol while you are being treated with this medicine.  
**Pregnancy and breastfeeding**  
If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Do not take Repaglinide Teva if you are pregnant or you are planning to become pregnant.  
Do not take Repaglinide Teva if you are breastfeeding.

**Driving and using machines**  
Your ability to drive or use a machine may be affected if your blood sugar level is low or high.  
Bear in mind that you could endanger yourself or others. Please ask your doctor whether you can drive a car if you:

- have frequent hypoglycemia incidents.
- have few or no warning signs of hypoglycemia.

**3. How to use this medicine?**

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure.  
Only your doctor will determine your dose and how you should take this medicine.  
**The usual starting dose** is 0.5 mg before each main meal.  
Swallow the tablets with a glass of water immediately before or up to 30 minutes before each main meal.  
Your doctor will adjust your dose, up to 4 mg, to be taken immediately before or up to 30 minutes before each main meal.  
The maximum recommended daily dose is 16 mg.

**Do not exceed the recommended dose.**

Do not crush/split/chew because this may cause the tablet to crumble and the accuracy of your dose will be affected.

**If you have accidentally taken a higher dose**  
If you take too many tablets, your blood sugar level may become too low, even causing a hypo. Please see the section 'If you get a hypo' on what a hypo is and how to treat it.  
**If you have taken an overdose, or if a child has accidentally swallowed some medicine,** immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

**If you forget to take the medicine**  
If you forget to take the medicine at the scheduled time, do not take a double dose. Take the next dose at the usual time and consult your doctor.

Adhere to the treatment as recommended by your doctor.  
Even if your health improves, do not stop taking this medicine without consulting your doctor.

**If you stop taking this medicine**  
Be aware that the desired effect is not achieved if you stop taking Repaglinide Teva. Your diabetes may get worse. If any change of your treatment is necessary consult your doctor first.

**How you can contribute to the success of your treatment?**  
Adhere to the treatment as recommended by your doctor.

**Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.**  
**If you have any further questions about using this medicine, consult your doctor or pharmacist.**

**4. Side effects**

Like with all medicines, using Repaglinide Teva may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

**Hypoglycemia**  
The most frequent side effect is hypoglycemia which may affect up to 1 in 10 patients (see 'If you get a hypo' in section 2).  
Hypoglycemic reactions are generally mild/moderate but may occasionally develop into hypoglycemic unconsciousness or coma. If this happens, medical assistance is needed immediately.

**Allergy**  
Allergy is very rare (may affect up to 1 in 10,000 patients). Symptoms such as swelling, difficulty in breathing, rapid heartbeat, feeling dizzy, and sweating could be signs of an anaphylactic reaction. Contact a doctor immediately.

**Additional side effects**  
**Common side effects (may affect up to 1 in 10 patients):**

- stomach pain.
- diarrhea.

**Rare side effects (may affect up to 1 in 1,000 patients):**

- acute coronary heart disease (not necessarily related to the medicine).

**Very rare side effects (may affect up to 1 in 10,000 patients):**

- vomiting.
- constipation.
- visual disturbances.
- severe liver function problems, abnormal liver function such as increased liver enzymes level in your blood.

**Side effects of unknown frequency (the frequency of these effects has not been established yet):**

- hypersensitivity (such as rash, itchy skin, reddening of the skin, swelling of the skin).
- nausea.

**If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.**

**Reporting side effects**  
You can report side effects to the Ministry of Health by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page ([www.health.gov.il](http://www.health.gov.il)) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

**5. How to store the medicine?**

Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.  
Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.  
Do not throw away the medicine via wastewater or household waste. Ask your pharmacist how to throw away medicines that you no longer need. These measures will help protect the environment.

**Storage conditions: Store in a dry place below 25°C. Store in the original package to protect from light.**

**6. Additional information**  
**In addition to the active ingredient, this medicine also contains:** microcrystalline cellulose, calcium hydrogen phosphate anhydrous, pregelatinized starch, povidone, poloxamer, polacrillin potassium, meglumine, colloidal anhydrous silica, magnesium stearate.

Repaglinide Teva 0.5 mg tablets also contain: FD&C blue No. 2, Aluminium Lake 11-14%  
Repaglinide Teva 1 mg tablets also contain: ferric oxide yellow (E-172)  
Repaglinide Teva 2 mg tablets also contain: ferric oxide red

**What the medicine looks like and contents of the pack:**  
Each pack contains 90 tablets.

**Repaglinide Teva 0.5 mg**  
Light blue to blue, capsule-shaped tablet, debossed with "93" on one side of the tablet and "210" on the other side of the tablet.

**Repaglinide Teva 1 mg**  
Yellow to light yellow, capsule-shaped tablet, debossed with "93" on one side of the tablet and "211" on the other side of the tablet.

**Repaglinide Teva 2 mg**  
Mottled peach, capsule-shaped tablet, debossed with "93" on one side of the tablet and "212" on the other side of the tablet.

**Name and address of registration holder and manufacturer:**  
Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva.

**Registration number of the medicine in the National Drug Registry of the Ministry of Health:**  
**Repaglinide Teva 0.5 mg:** 142.17.32017  
**Repaglinide Teva 1 mg:** 142.18.32018  
**Repaglinide Teva 2 mg:** 142.19.32019

This leaflet was reviewed and approved by the Ministry of Health in April 2015 and revised in September 2019 in accordance with Ministry of Health guidelines.