

PACKAGE INSERT

TARDEN 10 mg - 20 mg - 40 mg, film-coated tablet

It is taken orally.

- **Drug substance:** Atorvastatine calcium trihydrate equivalent to 10 mg- 20 mg- 40 mg atorvastatine.
- **Excipients:** Calcium carbonate, microcrystalline cellulose, lactose granule, croscarmellose sodium, hydroxypropylcellulose, polysorbate 80, magnesium stearate, opadry white YS-1R-7002 (HPMC 2910 / hypromellose, titanium dioxide, macrogol / PEG 8000), opadry clear YS-1-7006 (HPMC 2910 / hypromellose, macrogol / PEG 400, macrogol / PEG 8000).

Please read this PACKAGE INSERT carefully before you start to use the medicine since it contains information that is important for you.

- *Keep this package insert. You may need to read it later.*
- *If you have additional questions, please consult your physician or pharmacist.*
- *This medicine is personally prescribed for you, do not give it to others.*
- *Tell your physician that you are using this medicine when you apply to a doctor or a hospital during the use of this medicine.*
- *Please comply with the information in this package insert exactly. Do not use higher or lower dose of the medicine than the one recommended to you.*

In This Package Insert:

1. **What is TARDEN and what is it used for?**
2. **Things to take into consideration before using TARDEN**
3. **How to use TARDEN?**
4. **What are the possible side effects?**
5. **How to store TARDEN?**

1. What is TARDEN and what is it used for?

Each film coated tablet contains atorvastatine calcium trihydrate equivalent to 10 mg, 20 mg or 40 mg atorvastatine and titanium dioxide as colorant and they are presented in blister packaging containing 30 tablets.
TARDEN 10 mg is an oval, white film coated tablet notched '10' on one side.
TARDEN 20 mg is an oval, white film coated tablet notched '20' on one side.
TARDEN 40 mg is an oval, white film coated tablet notched '40' on one side.

TARDEN belongs to the drug group named lipid (fat) regulators, also known as statins.

It is used for lowering levels of fat-based substances known as cholesterol and triglycerides. Cholesterol, which is required for normal growing process, is a naturally occurring substance. However, when blood cholesterol is highly increased, it may be stored in the walls of blood vessels and cause vessel stenosis (constriction) and ultimately occlusion (blockage).

This is one of the most common causes of cardiac diseases. High cholesterol levels are known to increase the risk of cardiac disease.

TARDEN is used to lower the levels of lipids known as cholesterol and triglycerides when low-fat diet or lifestyle changes fail on their own. Although your cholesterol levels are normal, if you have increased risk of cardiac disease, TARDEN may be used for decreasing the risk. You need to continue cholesterol-lowering diet during treatment.

2. Things to take into consideration before using TARDEN

DO NOT USE TARDEN in the following cases:

- If you have childbearing potential and you don't use a suitable birth control method
- If you are pregnant, you are trying to get pregnant or breastfeeding
- If your physician will recommend stopping TARDEN administration 1 month before, if you are planning to have children
- If you have a history of reaction towards TARDEN or similar medicines lowering blood lipids or their excipients
- If you have or have a history of a disorder affecting your liver
- If you had inexplicable abnormal results in your liver function tests
- If you drink excessive amounts of alcohol.

TAKE SPECIAL CARE WHILE USING TARDEN in the following cases:

- If you have kidney problems or a history of kidney problems
- If you or other members of your family has blood disorders
- If you had muscle problems (muscle pain, weakness etc.) during treatment with other lipid-lowering drugs (e.g. statins or fibrates)
- If you drink high amounts of alcohol constantly
- If you have intolerance to some sugars
- If you have significant respiratory distress
- If you have hypothyroidism (producing less than required amount of thyroid hormone in the body)
- If you are older than 70 years old
- If you have risk factors in connection with diabetes
- If you have diabetes or have a risk of developing diabetes, your physician will monitor you closely while using this medicine. If you have high blood sugar and lipid levels, you are overweight and have high blood pressure; you may have a risk of developing diabetes.

If any of those apply to you, your physician will need to perform blood tests before and during treatment with TARDEN for estimating your risks regarding muscular system side effects.

If you have a history of strokes, tell this to your physician and he/she will take this into consideration while determining most suitable treatment and dose for you.

If these cautions apply to you, even for any previous period, please consult your physician.

Taking TARDEN with food and drinks

While using TARDEN, do not drink more than one or two small glasses of grapefruit juice in a day, because drinking high amounts of grapefruit juice may change the effects of TARDEN.

Pregnancy

Please consult your physician or pharmacist before using this medicine.

If you are pregnant or you are trying to get pregnant, do not use TARDEN.

If you notice you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Lactation

Please consult your physician or pharmacist before using this medicine.

If you are breastfeeding, do not use TARDEN.

Ability to drive and use machines

TARDEN administration is not expected to cause any negative side effects on the ability to drive and on the use of machines. If this medicine affects your ability to drive, do not drive. If you think your ability to use machines is affected, do not use them.

Important information about some of the ingredients of TARDEN

TARDEN contains lactose. If you have been told by your physician before that you have intolerance against some sugars, consult your physician before taking this medicinal product.

TARDEN contains sodium. If you are on a controlled sodium diet, take this into consideration.

Use with other medicines

Some medicines may change the efficiency of TARDEN or the efficiency of some medicines may be affected by TARDEN. That kind of interaction may reduce the efficiency of one or both of those medicines. It may increase the risk or severity of side effects including a significant, however rare muscle weakness condition also known as rhabdomyolysis. Your physician will take this into consideration while determining your TARDEN dose.

Some medicines that may interact with TARDEN:

- Medicines changing the performance of immune system such as cyclosporin or terfenadine, medicines effective against allergic disorders such as astemizole
- Medicines effective against certain infections or medicines effective against fungus diseases; e.g. erythromycin, clarithromycin, ketoconazole, itraconazole, rifampicin, fucidic acid
- Other lipid-regulating medicines such as gemfibrozile, fenofibrate, colestipol
- Some calcium channel blockers used for hypertension or angina (chest pain presenting with stenosis (constriction) / occlusion (blockage) of vessels feeding the heart); e.g. verapamil, diltiazem
- Medicines regulating cardiac rhythm; e.g. digoxin, amiodarone
- Medicines used in the treatment of AIDS (HIV) such as ritonavir, lopinavir, atazanavir, indinavir, darunavir, nelfinavir (protease inhibitors)
- Boceprevir (protease inhibitor) used in Hepatitis C treatment
- Other drugs known to interact with TARDEN; ezetimibe (lowers cholesterol), warfarin (decreases blood clotting), birth control pills, stiripentol (prevents epileptic seizures), cimetidine (used for ulcer and heart burn), phenazone (pain-killer), antacids (indigestion medicines containing aluminum and magnesium) and St.John'sWort.

If you are currently using a prescribed or non-prescribed medicine, or have used recently, please inform your physician or pharmacist about it.

3. How to use TARDEN

Instructions for proper use and dose/dosing intervals:

- Daily initiation dose of TARDEN is 10 mg for adults and children aged 10 and above.
- This dose may be increased by your physician until required dose intake is determined. Your physician will adjust the suitable dose for you by performing controls in 4 weeks or longer intervals at your convenience. The highest dose of TARDEN is 80 mg once a day dose in adults, while it is 20 mg once a day dose in children.
- Before starting TARDEN treatment, a standard cholesterol lowering diet should be started and this diet should be continued during TARDEN treatment.
- Use TARDEN in the way your physician has prescribed. If you are not certain, you should check with your physician or pharmacist.

Administration route and method:

- TARDEN tablets should be swallowed with water as a whole.
- Doses may be taken at any hour of the day, with or without food.
- Still, try to take your dose in the same time every day.

Various age groups:

Pediatric use:

Recommended initial dose is 10 mg in children aged 10 and above, and recommended maximum dose is 20 mg daily.

Geriatric use:

No difference was observed between elderly patients and all of the population in terms of safety and efficiency of TARDEN and reaching lipid treatment goals.

Special administration conditions:

Renal failure:

No dose adjustment is required in patients with renal failure.

Liver failure:

TARDEN should not be used in patients with active liver diseases. Care should be taken in patients with a history of liver disease. Periodic liver function tests should be performed before and after starting treatment with TARDEN.

If you have the impression that the effect of TARDEN is either very potent or very weak, please talk to your physician or pharmacist.

If you used more TARDEN than you should:

If you have taken more TARDEN than you should, consult your physician or pharmacist.

If you forget to use TARDEN

If you remember before your next dose that you forgot to take one dose, take your dose as soon as you remember.
Do not take double doses to make up the missed dose.

If you have further questions about effects that can be experienced upon the discontinuation of TARDEN treatment and the use of this medicine or if you wish to stop your treatment, consult your physician or pharmacist.

4. What are the possible side effects?

As with all medicines, there may be side effects in the individuals who are sensitive to any of ingredients of TARDEN.

Stop taking TARDEN if you experience one of the conditions below and inform your physician or apply to the emergency department of the nearest hospital IMMEDIATELY:

- Angioneurotic edema (swelling on face, tongue and windpipe that may make breathing difficult). All of these highly serious side effects are observed very rarely. If you experience one of those, inform your physician immediately.
- Serious disease presenting with fever and peeling, swelling, blistering of skin, mouth, eyes, and genitals.
- Skin rash characterized with pink-red spots and possible blisters in soles of feet and palms.
- Rarely, muscle weakness and inflammation was observed in patients and very rarely it may turn into severe, life-threatening condition (rhabdomyolysis). If muscle weakness and sensitivity continue with fatigue and fever, or your muscle problems continue after your physician has recommended stopping TARDEN treatment, inform your physician immediately. In this case, your physician may perform more tests for determining the cause of your muscle problems.

Very rare cases affect less than 1 of 10.000 patients using TARDEN (This means that these side effects are not expected in 9.999 of 10.000 patients using TARDEN).

- If you experience unexpected or unusual bleeding, or you have bruises, these may be associated with liver symptoms. Your physician should perform blood tests for checking your liver if you have liver symptoms before starting treatment with TARDEN or during TARDEN treatment. If you experience the following symptoms indicating a liver problem, tell your physician as soon as possible.
 - o Fatigue or weakness
 - o Loss of appetite
 - o Upper abdominal pain
 - o Dark amber colored urine
 - o Yellowing of white parts of your eyes or skin
- Stevens-Johnson syndrome (serious blisters in skin, mouth, eyes and genitals), erythema multiform (red rash with spots), visual impairment, blurred vision, hearing loss, tendon injuries, liver failure, changes in taste, gynecomastia in men.

All of these are serious side effects.

If you have one of these symptoms, you may need urgent medical intervention or hospitalization.

All of these highly serious side effects are observed very rarely.

Other possible side effects:

Common conditions affect 1-10 of 10.000 patients using TARDEN

- Inflammation in nasal airways, throat ache, nosebleeds
- Allergic reactions
- Increases in blood sugar levels (if you have diabetes, continue monitoring your blood sugar levels carefully), increases in blood creatine kinase levels
- Headache
- Nausea, constipation, gas, indigestion, diarrhea
- Joint pain, muscle pain and back pain
- Blood test results indicating abnormal liver function.

Uncommon conditions affect 1-10 of 1000 patients using TARDEN

- Loss of appetite, weight gain, decreases in blood sugar levels (if you have diabetes, continue monitoring your blood sugar levels carefully)
- Nightmares, insomnia
- Stupor, feeling or tingling in fingers of hand and feet, decrease in sensitivity to pain or feeling, changes in taste, memory loss
- Blurry vision
- Ringing in ears (tinnitus) and/or inside the head
- Vomiting, belching, lower and upper abdominal pain, pancreatitis (pancreas inflammation causing abdominal pain)
- Hepatitis (liver inflammation)
- Rash and itching, urticaria, hair loss
- Neck pain, muscle fatigue
- Fatigue, feeling unwell, weakness, chest pain, swelling particularly in ankles (edema), increased heat
- Determination of white blood cells in urine analysis.

Rare conditions affect 1-10 of 10.000 patients using TARDEN

- Visual impairment
- Unexpected bleeding or bruises
- Jaundice (yellowing of white parts of the eyes or skin)
- Tendon injury.

Very rare conditions affect 1-10 of 100.000 patients using TARDEN

- An allergic reaction – symptoms; sudden wheezing and chest pain or chest tightness, swelling on eyelids, face, lips, mouth, tongue and throat, difficulty in breathing, collapse
- Loss of hearing
- Gynecomastia (Enlarged breasts in men).

Other side effects reported with statins (same type of medicines with TARDEN):

- Insomnia and sleeping disorders including nightmares, memory loss, confusion
- Sexual problems
- Depression
- Constant coughing and/or respiratory problems including shortness of breath
- Diabetes. If you have high blood sugar and lipid levels, you are overweight and have high blood pressure, diabetes becomes more possible. Your physician will monitor you while using this medicine.

If you encounter any side effect that is not included in this package insert, inform your doctor or pharmacist.

5. How to store TARDEN

Keep TARDEN out of the sight and reach of children and in its package.

Keep at room temperature below 25°C.

Use in line with expiry date

Do not use TARDEN after the expiry date indicated on the box.

If you notice defects in the product and/or packaging, do not use TARDEN.

Registration N° for TARDEN 10 mg film coated tablet : 194919/05

Registration N° for TARDEN 20 mg film coated tablet : 194920/05

Registration N° for TARDEN 40 mg film coated tablet : 194921/05

Produced by **Pharmaline - Lebanon**

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