

KARDAK TABLET

Simvastatin (10 mg, 20mg, 40 mg, 80 mg)

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What Kardak is used for

Kardak is used to treat:

- Coronary heart disease (CHD)
- Higher than normal levels of fats in the blood (hyperlipidaemia)
- An inherited condition causing high levels of cholesterol in the blood

How Kardak works

Kardak is a medicine used to lower levels of total cholesterol, “bad” cholesterol (LDL cholesterol) and any fatty substances called triglycerides in the blood. In addition, Kardak raises levels of “good” cholesterol (HDL cholesterol). You should stay on a cholesterol-lowering diet while taking this medicine.

Kardak is a member of the class of drug called statins.

Before you use Kardak

- When you must not use it

- If you are allergic (hypersensitive) to Kardak or any other Ingredients of Kardak Tablets.
- If you currently have a liver problem
- If you are pregnant or breast-feeding

- Before you start use it

- Tell your doctor about your medical conditions including allergies
- Tell your doctor if you drink large amount of alcohol
- Tell your doctor if you ever had liver disease. Kardak may not be right for you.
- Tell your doctor if you are due to have an operation. You may need to stop taking Kardak tablets for a short time.

- Your doctor should do a blood test before you start taking Kardak. This is to check how well your liver is working.

Talk to your doctor if any other following applies:

- you have kidney problems
- you have thyroid problems
- you are more than 70 years old
- you have ever had muscle problems during treatment with cholesterol-lowering medicines called “statins” or fibrates
- you or a close family member have a hereditary muscle disorder.

- Taking other medicines

It is particularly important to tell your doctor if you are taking any of the following medicines products. Taking Kardak with any of these medicinal products can increase the risk of muscle problems (some of these have already been listed in the above section “When you must not take it”)

- cyclosporine (a medicine often used in organ transplant individual)
- medicines like itraconazole, ketoconazole, fluconazole (medicines for fungal infections)
- fibrates like gemfibrozil and bezafibrate (medicines for lowering cholesterol)
- erythromycin, Clarithromycin, Telithromycin (medicines for bacterial infections)
- HIV protease inhibitors such as indinavir, nelfinavir, ritonavir and saquinavir (medicines for AIDS).
- Nefazodone (a medicine for depression)
- amiodarone (a medicine used for an irregular heart beat)
- verapamil, diltiazam, or delaviridine (medicines for high blood pressure, chest pain associated with heart disease, or other heart conditions)

As well as medicines listed above, tell your doctor or pharmacist if you are taking or recently taken any medicines, including those obtained without prescription. In particular, tell your

doctor if you are taking any of the following:

- medicines to prevent blood clots, such as warfarin phenprocoumon or acenocoumarol (anticoagulants)
- medicines to reduce cholesterol levels in people at risk of cardiovascular disease (fenofibrate)
- niacin (for lowering cholesterol) or niacin containing product.

How to use Kardak

- How much to use

Always take Kardak exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

You should stay on a cholesterol-lowering diet while taking Kardak.

The dose is 1 Kardak 5mg, 10mg, 40mg, or 80mg tablet by mouth once a day.

The 80mg dose is only recommended for adult with very high cholesterol levels and at high risk of heart disease problems who have not reached their cholesterol goal lower doses.

Your doctor will determine the appropriate tablet strength for you, depending on your condition, your current treatment and your personal risk status.

- When to use it

Take Kardak in the evening. Simvastatin film-coated tablets should be taken with water. The tablets can be taken either on an empty stomach or after meal.

- How long to use it

The usual starting dose is 10, 20 or, in some cases, 40mg a day.

- Your doctor may adjust your dose after at least 4 weeks to a maximum of 80 mg a day. Do not take more than 80 mg a day.
- Your doctor may prescribe lower doses, particularly if you are taking certain medicinal product

listed above or have certain kidney conditions. Keep taking Kardak unless your doctor tells you to stop. • If your doctor has prescribed Kardak along with any bile acid sequestrant (medicines for lowering cholesterol), you should take Kardak at least 2 hours before or 4 hours after taking the medicine. - <u>If you forget to use it</u> Do not take an extra dose; just take your normal amount of Kardak at the usual time next day. - <u>If you use too much (overdose)</u> Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.	including Kardak. Consuming grapefruits juice should be avoided. <i>Pregnancy and breast-feeding</i> Do not take Kardak if you are pregnant, trying to get pregnant or think you may be pregnant. If you are getting pregnant while taking Kardak, stop taking it immediately and contact your doctor. Do not take Kardak if you are breast-feeding, because it is not known if the medicine is passed into breast milk. Ask your doctor or pharmacist for advice before taking any medicine. - <u>Things to be careful of</u> <i>Driving and using machines</i> Kardak is not expected to interfere with your ability to drive or to use machinery. However, it should be taken into account that some people get dizzy after taking Kardak. Important information about some of the Ingredients of Kardak. Kardak tablet contain sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugar, contact your doctor before taking this medical product.	- Uncommon: indigestion, diarrhoea. - Rare: Vomiting. • Liver disorders - Rare: yellowing of the skin and whites of the eye, • Skin and subcutaneous tissue disorders - Uncommon: skin rash, itchiness. - Rare: thinning or loss of hair (Alopecia). • Musculoskeletal, connective tissue and bone disorders - Rare: Muscular weakness, muscle pain, muscular cramp, damaged skeletal muscle. - If you have muscle problems that do not go away even after your doctor has told you to stop taking Kardak, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems. • General disorders - Uncommon: general weakness. An apparent hypersensitivity syndrome occurs rarely. It is associated with some of the following symptoms: Swelling of the lower layer of the skin, lupus-like syndrome, stiffness of the body, decrease in blood platelets, abnormally high amounts white blood cell is found in either the blood or in body tissues, inflammation arthritis and joint pain, rash, photosensitivity, fever, flushing, difficulty in breathing and weakness.
While you are using it - <u>Things you must do</u> Always take Kardak exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. You should stay on a cholesterol-lowering diet while taking Kardak. Contact your doctor immediately if you experience unexplained muscle pain, tenderness, or weakness. This is because on rare occasion, muscle problem can be serious, including muscle breakdown resulting in kidney damage; and very rare deaths have occurred. The risk of muscle breakdown is greater at high doses of KARDAK and is greater in certain patients. - <u>Things you must not do</u> Taking Kardak with food and drink Grapefruit juice contains one or more components that alter how the body uses some medicinal products,	Side effects Like all medicine, Kardak can cause side effects, although not everybody gets them. If any of these serious side effects happen, stop taking the medicine and tell your doctor immediately or got to the emergency room at your nearest hospital. • Blood and lymphatic system - disorders - Rare: Anaemia (low red blood cells) • Nervous system disorders - Uncommon: Headache. - Rare: Tingling or numbness of the skin, peripheral neuropathy (damage of the nerves), dizziness. • Gastrointestinal disorders - Common: Constipation, abdominal pain, flatulence, nausea.	Tell your doctor or your pharmacist if you notice any other unwanted or unexpected side effects. You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by calling Tel: 03-78835490, or visiting the website npra.moh.gov.my (Public → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI).

Storage and Disposal of Kardak**- Storage**

Keep out of the reach and sight of children. Do not store above 30°C. Do not use Kardak tablets after the expiry date which is stated on the blister and carton after EXP. The expiry date refers to the last day of that month

- Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

Product Description**- What it looks like**

Kardak 10: Light pink coloured, round shaped, biconvex, film coated tablets, debossed with 'A' on one side and '01' on the other side.

Kardak 20: Light pink coloured, round shaped, biconvex, film coated tablets, debossed with 'A' on one side and '02' on the other side.

Kardak 40: Pink coloured, round shaped, biconvex, film coated tablets, debossed with 'A' on one side and '03' on the other side.

Kardak 80: Pink colored, capsule shaped, biconvex, film coated tablets, debossed with 'A' on one side and '04' on the other side.

- Ingredients**Active ingredients**

Simvastatin

Inactive ingredients

Ascorbic Acid, Lactose Monohydrate, Microcrystalline Cellulose, Pregelatinized Starch (Maize Starch), Citric Acid Monohydrate, Butyl Hydroxy Anisole, Isopropyl Alcohol, Magnesium Stearate, Purified Water.

- MAL number(s):

Kardak 10mg Tablets:
MAL12095091AZ

Kardak Tablet 20 mg:
MAL08010727AZ

Kardak Tablet 40 mg:
MAL08010726AZ

Kardak Tablets 80 mg:
MAL10070573AZ

Manufacturer

Aurobindo Pharma Limited (Unit III),
Survey No. 313 & 314,
Bachupally Village,
Quthubullapur Mandal,
Ranga Reddy District,
Telangana State, India.

Product Registration Holder

Unimed SDN BHD No.53 Jalan Tembaga
SD 5/2B, Bandar Sri Damansara, 52200
Kuala Lumpur.

Date of revision

23/07/2020

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