

XOLSTAT

Rosuvastatin Calcium Tablet (5/10/20 mg)

What is in this leaflet

1. What **XOLSTAT** is used for
2. How **XOLSTAT** works
3. Before you use **XOLSTAT**
4. How to use **XOLSTAT**
5. While you are using it
6. Side Effects
7. Storage and disposal of **XOLSTAT**
8. Product description
9. Manufacturer and Product registration holder
10. Date of revision

What **XOLSTAT** is used for

XOLSTAT is used along with diet to:

- lower the level of bad cholesterol (LDL) and fat (triglycerides) and increase the level of good cholesterol (HDL) in the blood.
- slow the buildup of fatty deposits (plaque) in the walls of blood vessels
- reduce the risk of heart attack or stroke if you are elderly and have additional risk factor for having a heart disease or stroke such as high blood pressure, low HDL, smoking, or family history of early heart disease.

How **XOLSTAT** works

XOLSTAT belongs to a group of medicines known as statins. It reduces the 'bad' cholesterol and increases the 'good' cholesterol in your blood.

For most people, high cholesterol does not affect the way they feel because it does not produce any symptoms. However, if it is left untreated, fatty deposits can build up in the walls of your blood vessels causing them to narrow.

Sometimes, these narrowed blood vessels can get blocked which can cut off the blood supply to the heart or brain leading to a heart attack or a stroke. By lowering your cholesterol levels, you can reduce your risk of having a heart attack, a stroke or related health problems.

Ask your doctor if you have any questions about why **XOLSTAT** has been prescribed for you.

Before you use **XOLSTAT**

- When you must not use it

Do not take **XOLSTAT** if you:

- have ever had an allergic reaction to **XOLSTAT**, or to any of its ingredients.
- have liver disease
- have repeated or unexplained muscle aches or pains
- take a drug called cyclosporin (used after organ transplants)
- are pregnant or intend to become pregnant. Women should avoid becoming pregnant while taking **XOLSTAT** by using suitable contraception.
- are breast-feeding currently.

Do not take **XOLSTAT** if any of the above applies to you.

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. The expiry date refers to the last day of that month.

- Before you start to use it

Talk to your doctor or pharmacist before taking **XOLSTAT**:

- you have problems with your kidneys
- you have liver problems
- you have or had repeated or unexplained muscle aches or pains, a personal or family history of muscle problems, or a previous history of muscle problems when taking other cholesterol-lowering medicines. Tell your doctor immediately if you have unexplained muscle aches or pains especially if you feel unwell or have a fever.
- if you regularly consume large amounts of alcohol
- if your thyroid gland is not working properly
- if you are an elderly person (more than 70 years old)
- if you take other medicines called fibrates (such as gemfibrozil, bezafibrate) to lower your cholesterol
- you are of Asian origin that is Japanese, Chinese, Filipino, Vietnamese, Korean and Indian. Your doctor needs to choose the

right start dose of **XOLSTAT** to suit you

- you are taking certain medicines known as protease inhibitors (lopinavir/ ritonavir or atazanavir/ ritonavir), used to treat certain viral infections.
- if you are taking or have taken in a medicine called fusidic acid (a medicine for bacterial infection), orally or by injection. The combination of fusidic acid and **XOLSTAT** can lead to serious muscle problems (rhabdomyolysis).
- you have serious problems with your breathing. Interstitial lung disease has been reported with some statins (medicines of the same type as atorvastatin). It is a disorder that results in progressive scarring of lung tissue that eventually affects the ability to breathe and get enough oxygen into the bloodstream. Its presenting features can include shortness of breath, persistent cough and deterioration in general health (fatigue, weight loss and fever)
- If you have or develop diabetes mellitus (characterized by high blood sugar levels, increased thirst, increased urination etc.)

If any of these conditions applies to you now or has in the past, talk to your doctor before taking this medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including

- cyclosporin (used after organ transplants)
- fibrates such as gemfibrozil, fenofibrate
- other cholesterol lowering drug such as nicotinic acid, ezetimibe
- azole antifungals such as itraconazole, ketoconazole, fluconazole (medicines used to treat fungal infections)
- erythromycin (an antibiotic used to treat infections)
- warfarin (or any other drug used for thinning the blood)
- antacid preparation containing aluminium and magnesium hydroxide used for indigestion remedies (used to neutralise acid in your stomach)

- protease inhibitors (used to treat certain viral infections) such as lopinavir/ritonavir or atazanavir/ritonavir
- any of the following drugs used to treat viral infections, including HIV or hepatitis C infection, alone or in combination: ritonavir, lopinavir, atazanavir, sofosbuvir, voxilaprevir, ombitasvir, paritaprevir, dasabuvir, velpatasvir, grazoprevir, elbasvir, glecaprevir, pibrentasvir.
- oral contraceptive pill or hormone replacement therapy
- colchicine (a medicine used to treat gout)

The effects of these medicines could be changed by XOLSTAT or they could change the effect of XOLSTAT.

How to use XOLSTAT

Follow all directions given to you by your doctor or pharmacist carefully.

- How much to use

Your doctor or pharmacist will tell you how much and how often you should take XOLSTAT.

Make sure you continue with the recommended low-fat diet even while taking XOLSTAT.

Usual recommended dose:

The dose range for rosuvastatin is 5 to 40 mg orally once daily. Your treatment must start with the 10 mg to 20 mg once daily, even if you have taken a higher dose of a different statin before. The choice of your start dose will depend upon:

- Your cholesterol level.
- The level of risk you have of experiencing a heart attack or stroke.
- Whether you have a factor that may make you more sensitive to possible side effects.

Depending on your condition and ethnic background, your doctor will decide the most appropriate starting dose for you.

Increasing the dose and maximum daily dose:

Your doctor may decide to increase your dose gradually that is right for

you. If you started with a 5 mg dose, your doctor may decide to double this to 10 mg then 20 mg and subsequently 40 mg if necessary. There will be a gap of four weeks between every dose adjustment.

The maximum daily dose of rosuvastatin is 40 mg. It is only for patients with high cholesterol levels and a high risk of heart attacks or stroke whose cholesterol levels are not lowered enough with 20 mg.

Your doctor may decide to give you the lowest dose (5 mg) if:

- You are of Asian origin (Japanese, Chinese, Filipino, Vietnamese, Korean and Indian).
- You are over 70 years of age.
- You have moderate kidney problems.
- You are at risk of muscle aches and pains (myopathy)

XOLSTAT is not recommended for use in children younger than 10 years of age.

It is important to go back to your doctor for regular cholesterol checks, to make sure your cholesterol has reached and is staying at the correct level.

- When to use it

You can take XOLSTAT at any time of day, with or without food.

Swallow each tablet whole with a drink of water. Take XOLSTAT tablet once daily

- How long to use it

You must take this medicine for as long as your doctor has told you to.

- If you forget to use it

Don't worry; just take your next scheduled dose at the correct time. Do not take a double dose to make up for the one you missed.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints.

- If you use too much (overdose)

Immediately telephone your doctor or the Poisons Information Centre for advice, or go to Accident and Emergency at the nearest hospital, if you think that you or anyone else may

have taken too much XOLSTAT. Do this even if there are no signs of discomfort or poisoning.

While you are using it

- Things you must do

Follow your doctor's instructions carefully. If you do not follow your doctor's instructions, your treatment may not help or you may have unwanted side effects.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking XOLSTAT.

Do not take XOLSTAT if you are pregnant or breast feeding. If you become pregnant while taking XOLSTAT stop taking it immediately and tell your doctor. Women should avoid becoming pregnant while taking XOLSTAT by using suitable contraception.

- Things you must not do

Do not stop taking your medicine to you because you feel better, unless advised by your doctor.

Do not give your medicine to anyone else, even if they have the same condition as you.

- Things to be careful of

Most people can drive a car and operate machinery while using XOLSTAT – it will not affect their ability. However, some people feel dizzy during treatment with XOLSTAT. If you feel dizzy, consult your doctor before attempting to drive or use machines.

XOLSTAT contains lactose monohydrate.

If you have been told by your doctor that you have intolerance to some sugars, contact your doctor before taking this medicinal product.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking XOLSTAT.

Like all medicines XOLSTAT can cause side effects, although not everybody gets them.

Ask your doctor or pharmacist to answer any questions you may have.

Serious Side Effects

If any of the following happen, stop taking XOLSTAT and tell your doctor immediately or go to the casualty department at your nearest hospital.

- Difficulty in breathing, with or without swelling of the face, severe itching, lips, tongue and/or throat, difficulty in swallowing.
- Serious blistering condition of the skin, mouth, eyes and genitals (Stevens-Johnson syndrome)
- Unusual aches or pains in your muscles. As with other statins, a very small number of people have experienced unpleasant muscle effects and rarely these have become a potentially life threatening muscle damage known as rhabdomyolysis.

If you have muscle problems that do not go away even after your doctor has told you to stop taking XOLSTAT, please refer to your doctor. Your doctor may do further tests to diagnose the cause of your muscle problems.

Tell your doctor immediately if you notice any of the following:

- Muscle pain, weakness, rupture of tendons
- Inflammation of the pancreas (pancreatitis), which may show up as severe abdominal pain with nausea and vomiting.
- Jaundice (yellowing of the skin and eyes), hepatitis (abdominal pain or distention; dark urine and pale or clay-colored stools; fatigue; general itching)
- Kidney failure
- Diabetes mellitus (characterized by high blood sugar levels, increased thirst, increased urination etc.)
- Interstitial lung disease (shortness of breath, persistent cough and deterioration in general health, fatigue, weight loss and fever)
- Polyneuropathy (characterized by problems with sensation, coordination, or other body functions)

The above list includes serious side effects. You may need urgent medical attention or hospitalization.

Others side effect

Tell your doctor if you notice any of the following:

- Headache, Dizziness
- Stomach pain, Constipation, Feeling sick (nausea), Diarrhoea
- Depression
- Memory loss
- Sleep disturbance
- Cough
- Blood in the urine
- Breast enlargement in men

Laboratory tests

There may be changes in the results of certain laboratory tests:

- An increase in the amount of protein in the urine
- Increase in blood sugar
- Abnormalities in liver functions (GGT, ALP, bilirubin)
- Traces of blood in your urine
- Increase in Creatine Kinase (CK) levels
- Low blood platelet count

Tell your doctor or pharmacist if you notice anything that is making you feel unwell.

If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

Other side effects not listed above may also occur in some people.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of XOLSTAT

- Storage

Store below 30°C, protected from moisture.

- Disposal

Return any unused or expired medicine to your doctor, pharmacist or health care professional for safe disposal.

Product Description

- What XOLSTAT looks like

5 mg: Light yellow to yellow colored round film coated tablets with 'RT1' on one side and plain on the other side.

10 mg: Light pink to pink colored round film coated tablets with 'RT2' on one side and plain on the other side.

20 mg: Light pink to pink colored round film coated tablets with 'RT3' on one side and plain on the other side.

- Ingredients

Active ingredient:

Rosuvastatin calcium

Inactive ingredients:

5 mg: Lactose monohydrate, crospovidone, microcrystalline cellulose, sodium citrate, magnesium stearate, opadry yellow (hypromellose, titanium dioxide, polyethylene glycol / macrogol, yellow iron oxide).

10 MG & 20 MG: Lactose monohydrate, crospovidone, microcrystalline cellulose, sodium citrate, magnesium stearate, opadry pink (hypromellose, titanium dioxide, polyethylene glycol / macrogol, red iron oxide).

- Number MAL

XOLSTAT TABLETS	5 mg
MAL15045135ASZ	
XOLSTAT TABLETS	10 mg
MAL15045136ASZ	
XOLSTAT TABLETS	20 mg
MAL15045137ASZ	

Manufacturer and Product Registration Holder

RANBAXY (MALAYSIA) SDN. BHD.

Lot 23, Bakar Arang Industrial Estate, 08000 Sungai Petani, Kedah, Malaysia.

Date of Revision:

May 2023

Serial number

NPRA(R2/1)230426/1049