

STORVAS C TABLETS

Atorvastatin Calcium Tablets 10/20/40/80 mg

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What **STORVAS C TABLETS** is used for

STORVAS C TABLET belongs to a group of medicines known as statins, which are lipid (fat) regulating medicines.

STORVAS C TABLET is used in addition to diet to

- lower lipids known as cholesterol (total cholesterol), low-density lipoprotein cholesterol (LDL-C) and other fats (triglycerides) in the blood when a low fat diet and life style changes on their own have failed.
- Increase the level of high density lipoprotein cholesterol (HDL-C) which is beneficial for health.

STORVAS C TABLET can lower the risk for heart attack, stroke, certain types of heart surgery, and chest pain in patients who have heart disease or risk factors for heart disease such as:

- Age, smoking, high blood pressure, low HDL-C, heart disease in the family.

STORVAS C TABLET can lower the risk for heart attack or stroke in patients with diabetes and risk factors such as:

- Eye problems, kidney problems, smoking, or high blood pressure

Cholesterol:

Everyone has cholesterol in their blood. It is a type of blood fat needed by the

body for many things, such as building the cell lining, making bile acids (which help to digest food) and some hormones.

Your body makes cholesterol, but it also comes from food. Normally the body balances the cholesterol it makes with the cholesterol it gets from food. This means if more cholesterol comes from food, less is made by the body. However, if you eat a diet high in fat, your body may not keep this balance and your cholesterol levels rise. High cholesterol is more likely to occur with certain diseases or if you have a family history of high cholesterol.

When you have high levels of cholesterol, it may 'stick' to the inside of your blood vessels instead of being carried to the parts of the body where it is needed. Over time, this can form hard areas, called plaques, on the walls of blood vessels, making it more difficult for the blood to flow. This blocking of your blood vessels can lead to coronary heart disease (such as heart attack and chest pain) and stroke.

Other factors that will increase the risk of heart disease include high blood pressure, diabetes, increased weight, lack of exercise, smoking or a family history of heart disease.

There are different types of cholesterol, called low-density lipoprotein (LDL) and high-density lipoprotein (HDL). LDL cholesterol is the 'bad' cholesterol that can block your blood vessels. HDL cholesterol, on the other hand, is the 'good' cholesterol that is thought to remove the bad cholesterol from the blood vessels.

Triglycerides:

Triglycerides are an energy source for the body. However, as with cholesterol, too much triglycerides can be a problem.

How **STORVAS C TABLETS** works

STORVAS C TABLETS contain active substance atorvastatin.

STORVAS C TABLETS works by reducing the amount of cholesterol made by the liver. In terms of good and bad cholesterol, **STORVAS C TABLETS** reduces the bad cholesterol and raises the good cholesterol.

Ask your doctor if you have any questions about why **STORVAS C TABLET** has been prescribed for you. Your doctor may have prescribed it for another reason.

This medicine is available only with a doctor's prescription.

Before you use **STORVAS C TABLETS**

When you must not use it

Do not take **STORVAS C TABLETS** if you have an allergy to:

- any medicine containing atorvastatin
- any of the ingredients of **STORVAS C TABLETS**, listed at the end of this leaflet
- if you have active liver disease;
- if you have had any unexplained abnormal blood tests for liver function;
- if you are a woman of child-bearing capacity and not using any type of reliable contraception;
- if you are pregnant or trying to become pregnant;
- if you are breast-feeding. The active ingredient in atorvastatin may pass into breast milk and affect your baby.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue or other parts of the body
- rash, itching or hives on the skin.

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. If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine talk to your doctor.

Before you start to use it

Tell your doctor if you have allergies to

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any other medicines, foods, preservatives or dyes.

You should continue on a standard cholesterol-lowering diet.

Tell your doctor if you have or have had any of the following medical conditions:

- if you have a history of liver disease, your doctor should perform a liver function test before initiating you on treatment;
- if you have had repeated or unexplained muscle aches or pains, a personal history or family history of muscle problems;
- if you have had previous muscular problems during treatment with other lipid-lowering medicines (e.g., other '-statin' or '-fibrate' medicines);
- if you have muscle weakness with minimal inflammation
- if you have kidney problems;
- if you have had a previous stroke with bleeding into the brain, or have small pockets of fluid in the brain from previous strokes;
- if you have diabetes;
- if you regularly drink a large amount of alcohol
- if you have or have had myasthenia (a disease with general muscle weakness including in some cases muscles used when breathing), or ocular myasthenia (a disease causing eye muscle weakness) as statins may sometimes aggravate the condition or lead to the occurrence of myasthenia.

If any of these apply to you, your doctor will need to carry out a blood test before and possibly during your atorvastatin treatment to predict your risk of muscle related side effects. The risk of muscle related side effects e.g. rhabdomyolysis is known to increase when certain medicines are taken at the same time.

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

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines, including any that you get without a prescription from your pharmacy, supermarket or

health food shop. Some medicines and **STORVAS C TABLETS** may interfere with each other. These include:

- grapefruit juice
- medicines used to alter the way your immune system works (e.g. cyclosporine);
- certain antibiotics or antifungal medicines (e.g., erythromycin, clarithromycin, rifampin, fusidic acid, azole antifungals like itraconazole);
- if you need to take fusidic acid to treat a bacterial infection your doctor may advise you to temporarily stop using **STORVAS C TABLETS**. If you need to take fusidic acid for long periods along with this medicine, your doctor will consider on a case by case basis and under close medical supervision;
- other lipid lowering medicines (e.g., fibrates, colestipol, niacin);
- antivirals called protease inhibitors used in the treatment of HIV (e.g., tipranavir/ritonavir, lopinavir/ritonavir, saquinavir/ritonavir, darunavir/ritonavir, fosamprenavir, fosamprenavir/ritonavir, nelfinavir, efavirenz) and hepatitis C (telaprevir, boceprevir, glecaprevir/pibrentasvir, elbasvir/grazoprevir);
- some medicines used for angina (chest pain) or high blood pressure (e.g. diltiazem), medicines to regulate your heart rhythm (e.g. digoxin);
- medicine used in the treatment of other viral infections (cytomegalovirus) (e.g. letermovir);
- other medicines known to interact with **STORVAS C TABLETS** include oral contraceptives, colchicine (used to treat gout) and antacids (containing magnesium or aluminium for indigestion);

Consult your doctor if you get muscle weakness, tenderness or pain.

These medicines may be affected by **STORVAS C TABLETS**, or may affect how well it works. You may need different amounts of your medicines, or you may need to take

different medicines.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking **STORVAS C TABLETS**.

How to use STORVAS C TABLETS

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to use

Your doctor or pharmacist will tell you how much and how often you should take **STORVAS C TABLETS**. This may depend on your condition and whether or not you are taking any other medicines.

The usual dose range of atorvastatin is 10 to 80 mg once a day. Your dose may be increased or decreased, if necessary by your doctor until you are taking the amount you need. The maximum dose of atorvastatin is 80 mg once daily.

How to take it

STORVAS C TABLETS tablets should be swallowed whole with a glass of water, and can be taken at any time of day, with or without food. However, try to take your tablet at the same time every day.

When to use it

Atorvastatin can be taken at any time of the day. However, your dose of atorvastatin should be taken at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you to remember when to take it. Atorvastatin can be taken with or without food.

How long to use it

You should take atorvastatin tablet as long as your doctor tells you.

If you forget to use it

If it is almost time for your next dose, skip the dose you missed and take your next dose when you are meant to. Otherwise, take it as soon as you remember, and then go back to taking your tablets as you would normally.

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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 **STORVAS C TABLETS**. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using STORVAS C TABLETS

Things you must do

Keep all of your doctor's appointments so that your progress can be checked. Your doctor will ask you to have your liver function tested from time to time while you are taking atorvastatin to make sure the medicine is working and to prevent unwanted side effects.

Your cholesterol and triglyceride levels also need to be checked regularly while you are taking this medicine.

If you become pregnant while you are taking atorvastatin, stop taking it and contact your doctor immediately. If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking atorvastatin.

You should avoid alcohol while you are taking **STORVAS C TABLETS**.

Things you must not do

- Do not stop taking the medicine unless advised by your doctor.
- Do not take any new medicines without consulting your doctor.
- Do not give **STORVAS C TABLETS** to anyone else, even if they have the same symptoms or condition as you.
- Do not take more than one or two small glasses of grapefruit juice per day because large quantities of grapefruit juice can change the effects of **STORVAS C TABLETS**.
- Do not drink too much alcohol while taking **STORVAS C TABLETS**.

Things to be careful of

Driving and using machines

Normally this medicine does not affect your ability to drive or operate.

Side effects

Like all medicines, **STORVAS C TABLETS** can cause side effects, although not everybody gets them. If you experience any of the following serious side effects, stop taking your tablets and tell your doctor immediately or go to the nearest hospital's accident and emergency department.

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

Frequent side effects:

- inflammation of the nasal passages;
- increase in blood sugar levels (if you have diabetes continue careful monitoring of your blood sugar levels);
- pain in the throat, nose bleed;
- diarrhoea, indigestion, nausea, wind;
- painful, swollen joints, pain in the hands or ankles, muscle pain and cramps;
- blood test results that show your liver function may be abnormal, increase in blood creatine phosphokinase (an enzyme indicating muscle damage).

Other possible side effects:

- nightmares;
- blurred vision;
- ringing in the ears;
- stomach pain, belching;
- hepatitis (liver inflammation);
- cholestasis (yellowing of the skin and whites of the eyes);
- skin rash and itching (hives);
- muscle fatigue, neck pain;
- feeling unwell, fever;
- urine tests that are positive for white blood cells.
- autoimmune disease presenting with weakness of the muscles close to the core of the body with cellular injury to the muscle cells but with minimal inflammation (immune-mediated necrotizing myopathy)
- reduction in blood platelets which increases the risk of bleeding or bruising;
- allergic reactions (including

serious allergic reaction which causes difficulty in breathing or dizziness);

- tendon injury;
- weight gain;
- reductions in sensation to pain or touch; loss of memory, dizziness, change in sense of taste;
- pancreatitis (inflammation of the pancreas leading to stomach pain);
- severe skin reactions which can cause blisters, sores, and ulceration, swelling of the area beneath the skin;
- muscle weakness, inflammation or pain and particularly, if at the same time, you feel unwell or have a high temperature it may be caused by an abnormal muscle breakdown (rhabdomyolysis), autoimmune disease presenting with weakness of the muscles close to the core of the body with cellular injury to the muscle cells but with minimal inflammation (immune-mediated necrotizing myopathy), inflammation of the muscles (myositis), back pain;
- chest pain, swelling especially in the ankles, fatigue;
- cognitive impairment (e.g. memory loss/impairment, forgetfulness, amnesia, confusion);
- increase in blood sugar levels such as HbA1c (average blood sugar for two or three months) and fasting blood sugar
- myasthenia gravis (a disease-causing general muscle weakness including in some cases muscles used when breathing);
- ocular myasthenia (a disease-causing eye muscle weakness).

Please talk to your doctor if you experience weakness in your arms or legs that worsens after periods of activity, double vision or drooping of your eyelids, difficulty swallowing, or shortness of breath.

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.moh.gov.my (Consumers -> Reporting -> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)).

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After using STORVAS C TABLETS

Date of Revision: October 2024

Storage

Store below 30°C, protect from moisture

Serial No.: NPRA(R2/2)241101/1366

Disposal

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

Product description

STORVAS C 10

White to off-white film-coated capsule shaped tablets debossed 'SB' on one side and other side "1" and "0" on either side of breakline.

STORVAS C 20

White to off-white film-coated capsule shaped tablets debossed 'SB' on one side and other side "2" and "0" on either side of breakline.

STORVAS C 40

White to off-white film-coated capsule shaped tablets debossed 'SB' on one side and other side "4" and "0" on either side of breakline.

STORVAS C 80

White to off-white film-coated capsule shaped tablets debossed 'SB' on one side and other side "8" and "0" on either side of breakline.

Ingredients:

Calcium Carbonate, Lactose,
Microcrystalline Cellulose,
Croscarmellose Sodium, Hydroxypropyl
Cellulose L, Polysorbate 80, Purified
Water, Magnesium Stearate, Opadry OY
S 58910 White

MAL NO:

STORVAS C 10: MAL11060015AZ

STORVAS C 20: MAL11060016AZ

STORVAS C 40: MAL11060017AZ

STORVAS C 80: MAL11060020AZ

Manufacturer and Registration Holder

RANBAXY (M) SDN. BHD.

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