

VASCOR TABLET 20MG FILM COATED

Simvastatin (20mg)

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What VASCOR TABLET is used for

VASCOR TABLET helps to lower cholesterol.

VASCOR TABLET is used in people who have coronary heart disease (CHD) [plaque builds up in the coronary arteries] or who are at high risk of CHD (for example, if they have diabetes, a history of stroke, or other blood vessel disease).

VASCOR TABLET may be used in these people, regardless of their cholesterol level to:

- help prolong life by reducing the risk of a heart attack
- the reduce risk of stroke
- reduce the need for surgery to increase blood flow to the heart

How VASCOR TABLET works

VASCOR TABLET belongs to a group of medicines known as HMG-CoA reductase inhibitors. It works by reducing the amount of cholesterol made by the liver. VASCOR TABLET reduces the bad cholesterol (LDL-C)

and raises the good cholesterol (HDL-C).

Before you use VASCOR TABLET

- When you must not use it

Do not use VASCOR TABLET if you are allergic to simvastatin or any of the other ingredients listed at the end of the leaflet.

Symptoms of an allergic reaction may include skin rash, itchiness, short of breath, swelling of the tongue or face, or painful joints.

Do not used VASCOR TABLET if you have had muscle pain, tenderness or weakness from other medicines used to treat high cholesterol or triglycerides

- Before you start to use it

Before taking VASCOR TABLET, you must tell your doctor or pharmacist if you have, or have had, any of the following conditions:

- Active liver disease
- Kidney disease
- Drink alcohol regularly
- Allergic to any other medicines or any other substances, such as foods, preservatives or dyes.
- 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.

If you are not sure if you have, or have had, any of these conditions, you should raise those concerns with your doctors or pharmacist.

Pregnancy

Tell your doctor if you are pregnant, or likely to become pregnant during your course of

medication.

VASCOR TABELT should not be used during pregnancy since

there is possibility that it could interfere with foetus growth.

VASCOR TABLET should be discontinued immediately due to its potential hazard to the foetus.

Breast-feeding

Tell your doctor if you are breastfeeding, or likely to breastfeed during your course of medication.

It is not known whether VASCOR TABLET is excreted in human milk.

You should not breastfeed your infants if you are taking VASCOR TABLET.

- Taking other medicines

Tell your doctor or pharmacist before taking VASCOR TABLET.

Before using VASCOR TABLET, it is important to tell your doctor or pharmacist if you are taking any other medicines, obtained with or without a doctor's prescription.

The following medicines should not be taken with VASCOR TABLET:

- Potent CYP3A4 inhibitors (such as itraconazole, ketoconazole and posaconazole are used to treat fungal infections)
- Gemfibrozil (used to lower fats and raise "good" cholesterol in blood)
- Cyclosporine (used to prevent organ rejection after transplant)
- Danazol (used to treat endometriosis and fibrocystic breast disease)

Some medicines and VASCOR TABLET may interfere with each other. It is important to tell your doctor if you are taking these medicines:

- Fibrates (to lowers fat level in blood) other than gemfibrozil or fenofibrate)
- Amiodarone (used to treat types of irregular heartbeat)
- Calcium channel blockers such as Verapamil or Diltiazem, Amlodipine and Niacin (used to treat high blood pressure)
- Coumarin derivatives (used to prevent blood clots)
- Grapefruit juice

How to use VASCOR TABLET

- How much to use

Follow the instructions carefully. If you do not understand the instructions on the label, ask your doctor, or pharmacist for help.

For adults, the recommended dosage range is 5-80mg per day, taken in the evening, which may need to be increased up to 80 mg daily to have the best effect.

For patients at High Risk of Coronary Heart Disease (CHD) or with existing CHD, the recommended dosage of VASCOR TABLET starts at 40 mg daily in the evening.

For patients with Hyperlipidemia (Who are not in the risk categories above): You should be placed on a standard cholesterol-lowering diet before receiving VASCOR TABLET and should continue on this diet during treatment with VASCOR TABLET.

The recommended starting dose is 20mg per day given as a single dose a day in the evening. Anyone who require a large reduction in LDL-C (more than 45%) may be started at 40mg per day given as single dose in the evening.

For individuals with Homozygous Familial Hypercholesterolemia, the

recommended dosage is 40mg daily in the evening. The 80mg dose is recommended when benefits are expected to outweigh the potential risks.

For kidney insufficiency, the recommended dosage above 10mg/day should be carefully considered and if deemed necessary, implemented cautiously.

Uses in children:

VASCOR TABLET is not recommended for paediatric use. Safety and effectiveness in paediatric patients have not been established.

- When to use it

Take VASCOR TABLET once a day after your evening meal. Take VASCOR TABLET at about the same time each evening.

- How long to use it

VASCOR TABLET helps lower your cholesterol. It does not cure your condition. Therefore, continue taking VASCOR TABLET as recommended by your doctor if you expect to lower your cholesterol and keep it down. You may have to take cholesterol lowering medicine for the rest of your life. If you stop taking VASCOR TABLET, your cholesterol levels may rise again.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it. Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed dose.

- If you use too much (overdose)

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.

While you are using VASCOR TABLET

- Things you must do

- Tell all the doctors, dentists and pharmacists treating you that you are taking VASCOR TABLET.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take more than the recommended dose unless your pharmacist or doctor tells you.
- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not give VASCOR TABLET to anyone else, even if they have the same symptoms or condition as you.

- Things to be careful of

Be careful driving or operating machinery until you know how VASCOR TABLET affects you.

Side effects

Like all medicines, VASCOR TABLET can cause side effects, although not everybody gets them. If side effects persist, do not take the medicine and refer to the doctor.

Tell your doctor if you notice any of the following side effects or notice any other effects not listed:

Common effects

- Stomach pain
- Constipation
- Flatulence

- Headaches
- Skin rashes
- Dizziness
- Blurred vision
- Indigestion
- Taste alteration
- Impairment of eye movement
- Facial paresis
- Tremor
- Vertigo
- Memory loss
- Abnormal skin sensation (tingling, chilling, burning or numb)
- Peripheral nerve palsy (symptoms include numbness, tingling and paralysis)
- Mental illness
- Anxiety
- Insomnia
- Depression

Rare effects

Hypersensitivity Reactions:

- Serious allergic reactions
- Rapid swelling
- Lupus erythematosus-like syndrome (autoimmune disease)
- Polymyalgia rheumatic (inflammatory disorders that causes muscle pain, and stiffness)
- inflammation of blood vessel
- Purpura (blood spot)
- Low level of platelets in blood
- Decrease in white cells in blood
- Hemolytic anemia (disorder where destruction of red blood cells in faster than they can be made)
- Joint pain
- Hives
- Physical weakness or lack energy
- Extreme sensitivity to sunlight
- Fever and chills
- Flushing
- Feeling discomfort, illness or unease
- Shortness of breath
- Toxic epidermal necrolysis (skin disorder)
- Erythema multiforme (recurring skin condition that

is considered to be a type of hypersensitivity reactions) including Steven-Johnson syndrome (painful red or purplish rash that spreads and blisters.)

Gastrointestinal:

- Inflammation of pancreas
- Inflammation of liver
- Jaundice
- Fatty change in the liver
- Cirrhosis (late stage of scarring of the liver)
- Liver cancer
- Anorexia
- Vomiting

Skin:

- Hair loss
- Itchy skin
- Variety of skin changes (e.g. nodules, discoloration, dryness of skin/mucous membranes, changes to hair or nails)

Reproductive:

- Swelling of breast tissue in males
- Loss of sex drive
- Erectile dysfunction

Eye:

- Cataracts (clouding of eye lens)
- Paralysis or weakness of the eye muscle

Cognitive impairment:

- Memory loss
- Forgetfulness
- Amnesia
- Memory impairment
- Confusion

Unknown frequency

- Myasthenia gravis (a disease causing general muscle weakness including in some cases muscles used when breathing).
- Ocular myasthenia (a disease causing eye muscle weakness)

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.

If you have muscle problems that do not go away even after your doctor has told you to

stop taking VASCOR TABLET, please refer to your doctor. Your doctor may further to diagnose the cause of your muscle problems.

Visit your doctor or pharmacist immediately if you experience any side effects after using this medicine.

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 VASCOR TABLET

- *Storage*

Store below 30°C. Protect from light. Keep out of reach of children.

- *Disposal*

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines. These measures will help to protect the environment.

Product description

- *What it looks like*

11mm, oval, scored and marked '20' on one side, and marked 'VAS' on the other side, orange film-coated tablet.

- *Ingredients*

- Active ingredient:
- Simvastatin (20mg)

- Other Ingredients:

- Microcrystalline cellulose
- Butylated hydroxyl anisole
- Ascorbic acid
- Citric acid anhydrous
- Starch
- Magnesium stearate
- Lactose monohydrate
- Opadry orange

MAL number

MAL20020688AZ

**Manufacturer and Product
Registration Holder**

Duopharma (M) Sdn. Bhd.
Lot. 2599, Jalan Seruling
59, Kawasan 3, Taman Klang
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Darul Ehsan, Malaysia

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