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Simvastatin 10mg, 20mg and 40mg Tablets

- Please read this leaflet carefully before you start taking your medicine.
- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- This medicine has been prescribed for you personally and you should not pass it on to others. It may harm them, even if their symptoms are the same as yours.

ALPHARMA

In this leaflet:

1. What Simvastatin is and what it is used for
2. Before you take Simvastatin
3. How to take Simvastatin
4. Possible side effects
5. Storing Simvastatin

Your medicine is called Simvastatin 10mg, 20mg and 40mg tablets referred to throughout the leaflet as Simvastatin.

- The active substance in this medicine is simvastatin which is available in 3 strengths. The peach coloured oval shaped tablets contain 10mg simvastatin, the tan coloured oval tablets contain 20mg simvastatin and the brick red coloured tablets contain 40mg of simvastatin.
- The other ingredients are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, butylated hydroxyanisole (E320), ascorbic acid, anhydrous citric acid, colloidal anhydrous silica, talc, magnesium stearate, hypromellose, red iron oxide (E172), yellow iron oxide (E172), triethylcitrate, titanium dioxide (E171), povidone.
- Simvastatin 10mg tablets are supplied in blister packs of 28 tablets. Simvastatin 20mg tablets and Simvastatin 40mg tablets are supplied in blister packs of 14 tablets. Two blister packs per carton.

The Marketing Authorisation Numbers are PL 20395/0004-6
The Marketing Authorisation Holder and Manufacturer is: Relonchem Limited, 27 Old Gloucester Street, London, England WC1 3XX.

1.WHAT SIMVASTATIN IS AND WHAT IT IS USED FOR

Simvastatin belong to a group of medicines called 'HMG-CoA reductase inhibitors'. These medicines work by reducing the amount of cholesterol and fatty substances, called triglycerides, in the blood. Cholesterol is vital for the body to function. Sometimes cholesterol can build up in the blood stream and become deposited in the walls of the blood vessels. There it forms plaques which will eventually block the blood vessels similar to scale furring up of a water pipe. Your doctor has done some blood tests, which shows that you have high amounts of cholesterol and fatty substances in your blood even though you have been following a low fat diet. Your doctor may have prescribed Simvastatin because you have a high risk of developing heart disease. It is generally accepted that if you have high amounts of cholesterol in your blood it adds to your risk of heart disease. Other factors such as existing heart disease, high blood pressure, high blood sugar (diabetes), increased weight, lack of exercise, smoking and a diet high in fat increase your risk further to the development of heart disease.
Cholesterol may cause coronary heart disease by obstructing the blood vessels that carry oxygen and nutrients to the heart. This obstruction or hardening of arteries, is called atherosclerosis. Atherosclerosis may cause chest pain (called angina) and heart attack. If you suffer from coronary heart disease, your doctor has prescribed simvastatin to prolong your life. Simvastatin can decrease the risk of heart attack and decrease the risk of having to undergo surgery in order to increase blood flow to the heart. Simvastatin also delays the progression of atherosclerosis and reduces the development of new atherosclerosis.

2. BEFORE YOU TAKE SIMVASTATIN

Make sure it is safe for you to take Simvastatin.

Do not take Simvastatin:

- if you think you may be pregnant
- if you are planning to become pregnant. You should stop taking Simvastatin at least one month before trying to become pregnant
- if you discover you are pregnant while taking Simvastatin you should stop taking Simvastatin immediately
- if you are a woman who could bear children unless you are using a reliable form of contraception other than the pill (you may want to discuss this with your doctor)
- if you are breast feeding
- if you are hypersensitive (allergic) to any of the ingredients
- if you have active liver disease
- if you are taking mibefradil, a drug for the treatment of hypertension and angina
- if you have a rare inherited disease called porphyria.

It is important to talk to your doctor if you have any other following conditions:

- persistent muscles aches or pains
- have a history of liver disease. Your doctor may want to do a simple blood test to check your liver is working properly before you take simvastatin.

Tell your doctor of your present and past medical problems and any allergies you have.

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ALPHARMA

Simvastatin is not recommended for children.

Taking other medicines:
Please check with your doctor before taking Simvastatin if you are taking or have recently taken any other medicines even if not prescribed. Some medicines may occasionally interfere with Simvastatin including the following:

- immunosuppressants e.g.ciclosporin
- antifungal agents (such as itraconazole orketoconazole)
- other cholesterol lowering agents such as fibric acid derivatives (benzafibrate, phenofibrate and gemfibrozil)
- antibiotics erythromycin and clarithromycin
- the anti-depressant nefazodone
- high doses (> 1g/day) of niacin if nicotinic acid
- HIV protease inhibitors used in the treatment of HIV infections (indinavir, nelfinavir, ritonavir or saquinavir)
- blood thinning agents such as warfarin
- digoxin used in the treatment of heart conditions
- amiodarone a drug used to treat an irregular heartbeat
- mibefradil, verapamil and diltiazem (drugs used to treat high blood pressure, angina or other heart conditions)

Taking Simvastatin with food and drink:
Grapefruit juice has one or more components that alter the metabolism of some medications including Simvastatin. Large volumes of grapefruit juice (more than 1 litre) may have adverse effects, however typical consumption (one 250ml glass daily) is unlikely to cause problems. If you are unsure ask your doctor for advice.
Your doctor will have told you to keep alcohol to a minimum. If you are concerned about how much alcohol you can drink you should discuss this with your doctor.
Driving and using machines:
According to current information, Simvastatin does not affect the capacity to drive or use machines.
Important information about some of the ingredients of Simvastatin.
These tablets contain Lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. HOW TO TAKE SIMVASTATIN

Your doctor will decide what is the right dose for you to take and how long you will need to continue taking the medicine. Check the label and if you're not sure ask your doctor or pharmacist.
Usual Dose:
The usual starting dose is 10mg daily for high cholesterol levels and 20mg daily for coronary heart disease, taken as a single dose in the evening. Your doctor may adjust the dose to a maximum daily dose of 80mg, taken as a single dose in the evening. Your doctor may prescribe lower doses, especially if you are taking ciclosporin or suffer from certain kidney disorders. Continue taking Simvastatin until your doctor tells you to stop treatment. Take your tablet whole with a glass of water. Your doctor will inform you how long to take Simvastatin. If you stop taking Simvastatin your cholesterol levels may rise again.
While Taking Your Medicine
If you take more Simvastatin than you should:
Contact your doctor or pharmacist immediately or go to your nearest casualty department.
If you forget to take Simvastatin:
If you forget to take a tablet, wait until the next dose is due then continue as before. Do not take a double dose to make up for forgotten individual doses.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Simvastatin can have side effects in some people.
The most common side effects are stomach upsets (such as feeling or being sick, stomach pain, constipation, diarrhoea and flatulence), rash, itchiness, weakness, headache or indigestion. Other possible but less common side effects include dizziness, hair loss, pancreatitis (which may include acute and persistent gastric pain, feeling sick or being sick and a temperature), abnormal sensations in the arms and legs, muscle cramps, urticaria (small pale or reddened swellings) and thrombocytopaenia/eosinophilia (problems with blood which may result in fever, sore throat, unusual bleeding/bruising).
Rarely a few patients have experienced liver disease, muscle disease presenting as aches and pains or an allergic reaction which may include swelling of the face or neck, muscle and joint pains, joint and blood vessel inflammation, urticaria, a high temperature, flushing, difficulty in breathing or tiredness.
If you experience any of these side effects or you have any other unusual symptoms or feelings, stop taking the tablets and consult your doctor immediately. If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING SIMVASTATIN

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN. STORE IN THE ORIGINAL PACKAGING.

Do not store above 30°C. Do not use after the expiry date stated on the carton. Any unused medicine should be returned to your doctor or pharmacist. If you notice any visible signs of deterioration in the tablets, take them to your pharmacist for advice before taking it.

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Front Side

Back Side

Simvastatin 10, 20 & 40mg

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