

Name of medicinal product

Belmalip 20 mg, film-coated tablets

[Full statement of the active substance(s) and excipients(s)]

The active ingredient is simvastatin. Each tablet contains 20 mg of simvastatin (INN). The rest of the components are lactose monohydrate, microcrystalline cellulose, pregelatinised starch, butylated hydroxyanisole (E320), ascorbic acid, citric acid, colloidal anhydrous silica, talc, magnesium stearate, hypromellose, red iron oxide (E172), yellow iron oxide (E172), triethyl citrate, titanium dioxide (E 171), povidone.

Manufacturer of the product is:

LABORATORIOS BELMAC S.A., Spain

Poligono Industrial Malpica calle C.4., 500 16-Zaragoza

1. WHAT IS Belmalip 20 mg AND WHAT IS IT USED FOR

[Pharmaceutical form and contents: pharmacotherapeutic group]

It is a lipid-lowering agent that reduces the level of cholesterol and fatty substances, called triglycerides, in the blood.

It is supplied in packs of 28 tablets. Each tablet contains 20 mg of simvastatin.

[Therapeutic indications]

This medicinal product is used to lower the amount of cholesterol and triglycerides in the blood. Cholesterol may produce coronary heart disease by obstructing the blood vessels that transport oxygen and nutrients to the heart. This obstruction or hardening of the arteries, is called atherosclerosis. Atherosclerosis may cause chest pain (called angina) and heart attack.

If you suffer from heart disease, your doctor has prescribed Simvastatin Belmac to prolong your life, reduce the risk of a heart attack or cerebrovascular accident and reduce the risk of having to undergo surgery in order to increase blood flow to the heart. Simvastatin Belmac also delays the progression of atherosclerosis and reduces the development of new atherosclerosis.

2. BEFORE YOU TAKE Belmalip 20 mg

[List of information necessary before taking the medicinal product]

[Contraindications]

Do not take Belmalip 20 mg

- if you are hypersensitive (allergic) to any of the ingredients of the product
- if you have diagnosed active liver disease
- if you are taking mibefradil, a drug for treatment of hypertension and angina
- if you are pregnant or breast-feeding.

[Appropriate precautions for use: special warnings]

Take special care with Belmalip 20 mg:

- if you consume large quantities of alcohol
- have a history of liver disease

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

Belmalip 20 mg is not recommended for children.

[Use by pregnant or breast-feeding women]

Pregnancy

Women of fertile age should only take Belmalip 20 mg when it is very unlikely that they will become pregnant. If you become pregnant whilst taking Belmalip 20 mg you should stop treatment and tell your doctor immediately.

Ask your doctor or pharmacist for advice before taking any medicine.

Breast-feeding

If you are breast feeding your baby you should not take Belmalip.

Ask your doctor or pharmacist for advice before taking any medicine.

[Effects on the ability to drive or to use machines]

Driving and using machines:

According to current information, simvastatin does not effect the capacity to drive or use machines.

Important information about some of the ingredients of Belmalip 20 mg:

Belmalip 20 mg contains butylated hydroxyanisole therefore it could irritate the eyes, skin and mucous membranes.

[Interaction with other medicinal products]

Taking other medicines:

Please inform your doctor or pharmacist if you are taking or have recently taken other medicines, even those not prescribed.

It is particularly important that your doctor knows if you are taking cyclosporin, mibefradil (a drug for the treatment of hypertension and angina), anticoagulants (drugs that prevent blood clots, such as warfarin, fenprocoumon or acenocumarol).

Antifungal agents (such as itraconazole or ketoconazole), fibric acid derivatives (such as bezafibrate, phenofibrate and gemfibrozil) the antibiotics erythromycin and clarithromycin, the anti-depressant nefazodone or high doses (> 1 g/day) of niacin or nicotinic acid.

3. HOW TO TAKE Belmalip 20 mg

[Instructions for proper use]

Follow these instructions unless your doctor has given you other indications.

The usual starting dose is 10 of 20 mg of simvastatin per day, taken as a single dose in the evening. Some Patients with mild to moderate hypercholesterolaemia may be treated with an initial dose of 5 mg of Belmalip. The doctor may adjust the dose to a maximum daily dose of 80 mg, taken as a single dose in the evening. The doctor may prescribe lower doses, especially if you are taking cyclosporin or suffer from certain kidney disorders. Continue taking Belmalip until your doctor tells you to stop treatment.

[Method and/or route (s) of administration]

Taken Belmalip 20 mg with a sufficient amount of liquid.

If the required initial dose is 5 mg, break the scored 10 mg tablet in two.

[Duration of treatment]

Your doctor will inform you how long you have to take Belmalip 20 mg. If you stop taking Belmalip your cholesterol levels may rise again.

[Symptoms in case of overdose and action to be taken]

If you take more Belmalip 20 mg than you should immediately inform your doctor or your pharmacist.

In case of overdose or inadvertent ingestion, consult the Toxicology Information Service.

[Actions to be taken when one or more doses have been missed]

If you forget to take Belmalip 20 mg.

Do not take a double dose to make up for forgotten individual doses. Continue with the prescribed treatment as usual.

4. POSSIBLE SIDE EFFECTS:

[Description of side effects]

Like all medicines, Belmalip 20 mg can have side effects.

In general, Belmalip 20 mg is well tolerated. In most cases the side effects have been mild and of short duration. The most frequent side effects are, digestive disorders. A feeling of weakness and headache are less frequent. Even less common are pain, sensitivity to pressure or weakness in the muscles, liver problems and hypersensitivity (allergic reactions which could have various symptoms, including joint pain, fever or difficulty in breathing).

Due to the fact that on rare occasions muscle problems are serious, consult your doctor immediately if you have pain, sensitivity to pressure or weakness in your muscles.

Other side effects could occur on rare occasions, some of which could be severe, in which case tell your doctor immediately.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

5. STORING Belmalip 20 mg

[Storage conditions and expiry date]

Store in the original packaging and not above 30° C.

Expiry date

Do not use Belmalip 20 mg after the expiry date stated on the box.

Keep Belmalip 20 mg out of reach and sight of children

This leaflet was approved on Mars (month and year) 2002

Also supplied as:

Belmalip 40 mg, pack of 28 tablets

Belmalip 10 mg, pack of 28 tablets.



Laboratorios **BELMAC**, S.A.

046exp/P1