PACKAGE LEAFLET: INFORMATION FOR THE USER

<Pravastatin 10 mg Tablets and associated names>
<Pravastatin 20 mg Tablets and associated names>
<Pravastatin 40 mg Tablets and associated names>
Pravastatin sodium

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

In this leaflet:

1. WHAT <PRAVASTATIN> IS AND WHAT IT IS USED FOR

Pravastatin, the active substance of <Pravastatin>, belongs to a group of medicines called statins which work by reducing high cholesterol levels in the blood. Cholesterol is a fatty substance (lipid) that can cause narrowing of the heart muscle blood vessels (coronary heart disease).

<Pravastatin> is used:
- to lower a high cholesterol level in the blood when there is an insufficient response to diet, physical exercise, weight reduction *etc*.
- as a supplement to diet if you are at risk of narrowing of the blood vessels in your heart caused by too much cholesterol in your blood
- to reduce the chance of having another heart attack if you have had a heart attack or if you have chest pain attacks (unstable angina pectoris)
- to lower the fatty substances (lipids) in the blood following an organ transplant.

2. BEFORE YOU TAKE <PRAVASTATIN>

Do NOT take <Pravastatin>

- If you are allergic (hypersensitive) to pravastatin or any of the other ingredients of this medicine
- If you have current liver problems, including unexplained abnormal blood tests for "transaminases"
- If you are pregnant or there is a possibility that you may become pregnant or are breast-feeding.

Take special care with <Pravastatin>

Tell your doctor before you start to take this medicine:
- If you have kidney problems
- If you are over 70 years of age
- If you have suffered with liver problems in the past

- If you have an underactive thyroid gland
- If you have an hereditary muscle disorder or a family history of such problems
- If you have previously suffered from side effects affecting your muscles when taking another cholesterol-lowering medicine such as nicotinic acid (niacin), a statin or a fibrate e.g. gemfibrozil
- If you have problems with alcohol abuse (regularly drinking large amounts of alcohol).
- If you have severe respiratory failure

If you have suffered from any of these problems, your doctor will need to carry out a blood test before and possibly during <Pravastatin> treatment to assess your risk of developing muscle-related side effects.

While you are on this medicine your doctor will monitor you closely if you have diabetes or are at risk of developing diabetes. You are likely to be at risk of developing diabetes if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure.

<Pravastatin> is not generally recommended for use in children before puberty. It has also not been studied in patients with an often more severe form of hereditary high cholesterol called homozygous familial hypercholesterolaemia.

Statins such as <Pravastatin> may sometimes cause lung disease, especially when they are used over a long period of time. You should stop taking <Pravastatin> and contact your doctor if you develop shortness of breath, a dry, non-productive cough and your general health worsens, with tiredness, weight loss and fever.

Taking other medicines

Talk to your doctor if you are taking any of the following:
- a group of cholesterol-lowering medicines called fibrates e.g. fenofibrate or gemfibrozil
- ciclosporin (an immunosuppressant used after an organ transplant)
- medicines known as bile acid sequestrants (a class of medicines that prevents bile acids being reabsorbed from the digestive system, so promoting conversion of cholesterol into bile acids) e.g. colestyramine, colestipol (please see section 3, If you are also taking a bile acid sequestrant)
- the antibiotics erythromycin or clarithromycin.

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking <Pravastatin> with food and drink

- Keep alcohol intake to a minimum.

Pregnancy and breast-feeding

Do not take <Pravastatin>:
- If you are pregnant or breast-feeding, or if you are planning to become pregnant.
- If you are a woman who could become pregnant (unless you are using a reliable form of contraception). If you do become pregnant when taking <Pravastatin>, stop taking the tablets as soon as you become aware of it and contact your doctor immediately.

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

Driving and using machines

<Pravastatin> may cause dizziness, if affected do not drive or operate machinery.

Important information about some of the ingredients of <Pravastatin>

<Pravastatin> contain a sugar called lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. HOW TO TAKE <PRAVASTATIN>

Always take <Pravastatin> exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure. Your doctor will have explained the importance of a low fat diet as well as taking <Pravastatin>.

Adults (including the elderly)

For high cholesterol
The usual dose is 10 - 40 mg once a day, preferably in the evening.

To prevent narrowing of the blood vessels in the heart or heart attack
The usual dose is 40 mg.

Following organ transplantation
The usual dose is 20 mg .

If you are also taking a bile acid sequestrant, such as colestyramine or colestipol, <Pravastatin> should be taken at least one hour before or four hours after you have taken the bile acid sequestrant. This is because the absorption of <Pravastatin> can be affected by these medicines if taken too closely together.

Liver or kidney problems
If you have either liver or kidney problems your doctor may prescribe a lower dose.

Children and teenagers aged 8 to 18 years with mild hereditary high cholesterol (heterozygous familial hypercholesterolaemia)
The usual dose is 10 to 20 mg per day for children aged 8 to 13 years and 10 to 40 mg per day for teenagers aged 14 to 18 years.

The tablets should be swallowed preferably with a glass of water. <Pravastatin> can be taken with or without food.

If you take more <Pravastatin> than you should

If you (or someone else) swallow a lot of the tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

If you forget to take <Pravastatin>

If you forget to take a dose, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. POSSIBLE SIDE EFFECTS

Like all medicines, <Pravastatin> can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the face or neck, muscle and joint pain, hives, fever, flushing, shortness of breath).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

Contact your doctor as soon as possible and stop taking <Pravastatin> if you develop:

- any unexplained or persistent muscle pain, tenderness, weakness or cramps, especially, if at the same time you feel unwell or have a high temperature.

In very rare cases this can progress to become a serious and potentially life threatening condition, called rhabdomyolysis.

The following side effects have been reported at the approximate frequencies shown:

Uncommon (affecting fewer than one person in 100 but more than one person in 1,000):

- skin reactions such as itching and rashes, or scalp and hair problems including hair loss
- muscle and joint pain
- dizziness, tiredness, headache and sleep disturbances (including insomnia and nightmares)
- problems with sight e.g. blurred or double vision
- bladder problems (painful or frequent urination, having to pass water at night) and sexual difficulties
- stomach and bowel problems such as indigestion, pain, feeling or being sick, diarrhoea or constipation and wind.

Very rare (affecting fewer than one person in 10,000):

- severe blistering rash with associated general illness
- liver problems such as hepatitis (inflammation of the liver)
- yellowing of the skin and whites of the eyes
- pancreatitis (inflammation of the pancreas)
- problems with touch including burning/tingling sensations or numbness, which may indicate damage to nerve endings
- isolated cases of tendon disorders or rupture
- increase in certain enzyme levels in the body.

The following side effects have been reported with some statins:

- memory loss
- depression
- exceptional cases of breathing problems including persistent cough and/or shortness of breath or fever (interstitial lung disease), especially with long-term therapy (see 'Take special care with <Pravastatin> in section 2 above)
- diabetes. This is more likely if you have high levels of sugars and fats in your blood, are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

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

5. HOW TO STORE <PRAVASTATIN>

- Keep out of the reach and sight of children.
- Do not use <Pravastatin> after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.
- Do not store above 30°C. Store in the original package in order to protect from moisture.
- Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. FURTHER INFORMATION

What <Pravastatin> contains

- The active substance is pravastatin sodium. Each tablet contains 10, 20 or 40 mg pravastatin sodium.
- The other ingredients are lactose anhydrous, povidone (PVP K-30), crospovidone, calcium hydrogen phosphate anhydrous (E341), sodium stearyl fumarate, cellulose microcrystalline (E460), croscarmellose sodium (E466), 10 mg: red iron oxide (E172), 20 mg: yellow iron oxide (E172), 40 mg: quinoline yellow (E104), brilliant blue FCF (E133).

What <Pravastatin> looks like and contents of the pack

- Tablet
- 10 mg: Pink, mottled, round, shallow convex tablet, with breakline on both sides. The tablet can be divided into equal doses.
- 20 mg: Light yellow, round, shallow convex tablet, with breakline on both sides. The tablet can be divided into equal doses.
- 40 mg: Light green, round, shallow convex tablet, with breakline on both sides. The tablet can be divided into equal doses.
- <Pravastatin 10 mg Tablets> are available in pack sizes of 20, 28, 30, 50, 56, 84, 98, 100 and 200 tablets and in hospital packs of 50 x 1 unit dose tablets. Not all pack sizes may be marketed.
- <Pravastatin 20 mg Tablets> are available in pack sizes of 10, 20, 28, 30, 50, 56, 84, 98, 100 and 200 tablets and in hospital packs of 50 x 1 unit dose tablets. Not all pack sizes may be marketed.
- <Pravastatin 40 mg Tablets> are available in pack sizes of 14, 20, 28, 30, 50, 56, 84, 98, 100 and 200 tablets and hospital packs of 50 x 1 unit dose tablets. Not all pack sizes may be marketed.

Marketing Authorization Holder

<To be completed nationally>

Manufacturer

<To be completed nationally>
Teva UK Ltd, Brampton Road, Hampden Park, Eastbourne, East Sussex, BN22 9AG, United Kingdom

Pharmachemie B.V., Swensweg 5, Postbus 552, 2003 RN Haarlem, the Netherlands

TEVA Pharmaceutical Works Private Ltd. Co., Pallagi ùt 13, 4042 Debrecen, Hungary

Teva Santé, Rue Bellocier, 89107 Sens, France

TEVA PHARMA S.L.U , Poligono Malpica, Calle C, N°4, 50016 Zaragoza, Spain

This medicinal product is authorised in the member states of the EEA under the following names:

Belgium	Pravastatine TEVA 10 mg, tabletten
	Pravastatine TEVA 20 mg, tabletten
	Pravastatine TEVA 40 mg, tabletten
Denmark	Pravastatinnatrium Teva 20 mg Tabletter
	Pravastatinnatrium Teva 40 mg Tabletter
France	Pravastatine Teva 10 mg, comprimé
	Pravastatine Teva 20 mg, comprimé
	Pravastatine Teva 40 mg, comprimé
Germany	PRAVA-TEVA® 10 mg Tabletten
	PRAVA-TEVA® 20 mg Tabletten
	PRAVA-TEVA® 40 mg Tabletten
Ireland	Bystat 10 mg Tablets
	Bystat 20 mg Tablets
	Bystat 40 mg Tablets
Italy	Pravastatina Ratiopharm 10 mg Compresse
	Pravastatina Ratiopharm 20 mg Compresse
	Pravastatina Ratiopharm 40 mg Compresse
The Netherlands	Pravastatinenatrium 10 mg Pharmachemie tabletten, tabletten
	Pravastatinenatrium 20 mg Pharmachemie tabletten, tabletten
	Pravastatinenatrium 40 mg Pharmachemie tabletten, tabletten
Norway	Pravastatin Teva 10 mg Tabletter
	Pravastatin Teva 20 mg Tabletter
	Pravastatin Teva 40 mg Tabletter
Portugal	Pravastatina Teva 10 mg Comprimidos
	Pravastatina Teva 20 mg Comprimidos
	Pravastatina Teva 40 mg Comprimidos
Spain	Pravastatina Teva 10 mg, Comprimidos EFG
	Pravastatina Teva 20 mg, Comprimidos EFG
	Pravastatina Teva 40 mg, Comprimidos EFG
Sweden	Pravastatin Teva 10 mg tabletter
	Pravastatin Teva 20 mg tabletter
	Pravastatin Teva 40 mg tabletter

This leaflet was last approved in MM-YYYY.