PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) – 1986
The medicine is dispensed with a doctor's prescription only

Pravalip 10;20;40

Tablets

Composition:
Each **Pravalip 10** tablet contains:
Pravastatin Sodium 10 mg
Each **Pravalip 20** tablet contains:
Pravastatin Sodium 20 mg
Each **Pravalip 40** tablet contains:
Pravastatin Sodium 40 mg
For information on inactive and allergenic ingredients see section 2 "Important information about some of the ingredients of the medicine" and section 6 "Further Information".

Read the leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.
This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them, even if it seems to you that their ailment is similar.
The medicine is not intended for children and adolescents under 18 years of age.

1. WHAT IS THE MEDICINE INTENDED FOR?
- Reduction of blood cholesterol and triglyceride levels.
- Reduction of the risk of myocardial infarction and extension of life expectancy in patients who have high cholesterol level with no evidence of coronary disease.
- Reduction of the risk of overall mortality by lowering mortality due to heart diseases, and reduction of the risk of heart attack in patients with atherosclerosis and average or high cholesterol level.

Further information:
Pravalip is used to reduce high levels of "bad" cholesterol and to increase levels of "good" cholesterol in the blood when changes in diet and physical activity have failed to adequately do this. While cholesterol is essential for the proper functioning of the body, if its levels in the blood are too high, it can accumulate on the walls of the arteries. Eventually, blood vessels may become blocked. This condition is called hardening of the arteries (atherosclerosis). This condition may lead to chest pain (angina pectoris), when a blood vessel in the heart is partially blocked, heart attack (myocardial infarction), when a blood vessel in the heart is completely blocked, stroke (cerebrovascular accident), when a blood vessel in the brain is completely blocked. Most of the cholesterol is produced by the liver, and only a small amount of cholesterol comes from the diet. Most of the cholesterol is produced by the body at night.
Although you may be on a low-fat diet, blood tests can show that the blood fat (including cholesterol) levels are still high. A high cholesterol level is generally identified as contributing to the risk for heart disease.
Additional factors, such as pre-existing heart disease, high blood pressure, diabetes, being overweight, lack of physical activity and smoking, can also significantly increase the risk of development or progression of heart disease.

Therapeutic group:
Statins (or HMG-CoA reductase enzyme inhibitors). This group lowers the amount of cholesterol and triglycerides (fats) in the blood.

2. BEFORE USING THE MEDICINE

Do not use the preparation if:
- You are sensitive (allergic) to the active ingredient pravastatin, or to any of the additional ingredients contained in the medicine (see section 6 – "Further Information").
- You suffer from an active liver disease.
- You are pregnant, or there is a possibility that you will become pregnant, or if you are breastfeeding (see "Pregnancy and breastfeeding").

Special warnings regarding use of the medicine
Before treatment with Pravalip, tell the doctor if:
- You have kidney problems.
- You are over 70 years of age.
- You have suffered in the past from liver problems.
- You suffer from an underactive thyroid (hypothyroidism).
- You suffer from a hereditary muscle disorder or you have a family history of similar problems.
- You have suffered in the past from side effects affecting the muscles while taking another medicine to reduce cholesterol, e.g., a statin (a medicine that inhibits the HMG-CoA reductase enzyme) or a fibrate (e.g., gemfibrozil).
- During the course of treatment you experience unexplained muscle cramps or pain – inform the doctor immediately.
- You suffer from alcohol abuse problems (regular consumption of large amounts of alcohol).
- You are using or have used in the last 7 days a medicine called fusidic acid (a medicine for bacterial infection), orally or by injection. The combination of fusidic acid with **Pravalip** can lead to serious muscle problems (rhabdomyolysis).

If any of the conditions described above apply to you, the doctor will order blood tests for you before, and most likely during, treatment. These blood tests will be used to assess the risk of muscle-related side effects.
The doctor will order blood tests for you before you begin to take **Pravalip**, and if you have symptoms of liver problems during the treatment with **Pravalip**. The objective of the test is to check your liver function. Your doctor may want you to perform blood tests to check how your liver is functioning after beginning treatment with **Pravalip**.
In addition, before the treatment with **Pravalip**, tell the doctor if:
- You suffer from severe respiratory failure.

If you suffer from diabetes or are at risk of developing diabetes, the doctor will monitor your tests frequently. If you have high blood sugar and fat levels, you are overweight and have high blood pressure, you are almost certainly at risk of developing diabetes.
In addition, tell the doctor if you experience prolonged muscle weakness. Additional tests and medicines may be necessary to diagnose and treat this condition.

Drug interactions
If you are taking, or if you have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.
Especially if you are taking:
- Medicines from the fibrate group to lower cholesterol level, e.g., fenofibrate or gemfibrozil, a medicine that reduces the body's immune protection (ciclosporin, an immunosuppressant administered after an organ transplant) or another medicine to lower the level of cholesterol (nicotinic acid [vitamin B3]) – these medicines can disrupt the way **Pravalip** acts in the body.
- Medicines known to bind bile acid (a group of medicines that prevent bile acid from being reabsorbed into the digestive system, thereby promoting the conversion of cholesterol to bile acid and reducing the level of fats in the blood), e.g., cholestyramine, colestipol. If you are also taking a bile acid-binding medicine, see section 3 "How should you use the medicine?".
- A medicine to treat bacterial infections (erythromycin, clarithromycin or fusidic acid antibiotics). If you need to use oral fusidic acid to treat a bacterial infection, you will have to temporarily stop using **Pravalip**. The doctor will tell you when it is safe to resume **Pravalip** treatment. Use of **Pravalip** together with fusidic acid may rarely lead to muscle weakness, tenderness or pain (rhabdomyolysis). See further information regarding rhabdomyolysis in section 4 "Side effects".
- If you are taking a medicine called "vitamin K antagonist" to treat and prevent formation of blood clots, tell the doctor before taking **Pravalip**, since concomitant use of a vitamin K antagonist and **Pravalip** may increase blood test values used to monitor vitamin K antagonist treatment.

Taking **Pravalip** with any of the following medicines can increase the risk of muscle problems:
- Colchicine (used to treat gout).
- Nicotinic acid (used to lower high blood cholesterol level).
- Rifampicin (used to treat tuberculosis).
- Lenalidomide (used to treat a cancer called multiple myeloma).

Use of the medicine and food
Pravalip may be taken with or without food.
Use of the medicine and alcohol consumption
Limit alcohol consumption to a minimum. If you want to drink while using the medicine, drink small amounts of alcohol only. Even if you drank an alcoholic beverage once, do not stop using the medicine. If you are concerned about the amount of alcohol that you can drink while taking the medicine, consult with the doctor.
Pregnancy and breastfeeding
Do not use **Pravalip**:
- If you are pregnant, are planning to become pregnant or are breastfeeding (since this medicine passes into breast milk).
- If you might become pregnant, unless you are using reliable **non-hormonal** contraceptives (examples of hormonal contraceptives are, for example, pills or another hormonal preparation to prevent pregnancy). It is important that you consult the doctor about this.
- If you become pregnant during the course of treatment with **Pravalip**, stop taking this medicine as soon as you find out about it.

Driving and operating machinery
Pravalip may cause dizziness, blurred or double vision during the course of treatment.
If you experience these effects, do not drive and do not operate machinery. Make sure that you are fit to drive and operate machinery before setting out to do so.
Important information about some of the ingredients of the medicine
Patients with lactose intolerance must take note that **Pravalip** tablets contain a small amount of lactose. If you have been told by the doctor that you have an intolerance to certain sugars, refer to the doctor before taking this medicine.
This medicine contains less than 23 mg of sodium per tablet, and is therefore considered to be sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use the preparation according to the doctor's instructions.
Check with the doctor or pharmacist if you are uncertain about the dosage and treatment regimen of the preparation. The doctor will explain the importance of a low-fat diet in addition to taking **Pravalip**, and you should continue this diet throughout the course of treatment.
The dosage and treatment regimen will be determined by the doctor only. The usual dosage is generally:
- For treatment of high blood cholesterol and fat levels: 10-40 mg, once a day, preferably in the evening.
- For prevention of heart and blood vessel diseases: 40 mg, once a day, preferably in the evening.

Do not exceed the recommended dose.
Duration of treatment
The doctor will indicate the duration of **Pravalip** treatment. This medicine should be used regularly, and for the period of time as determined by the doctor, even if it is for a long time. Do not stop treatment on your own.
Method of administration
It is preferable to take the tablet with a glass of water.
The tablet may be taken with or without food.
If necessary, the tablet can be halved for immediate use. There is no information regarding crushing or chewing the tablet.
If you are taking bile acid-binding medicines (e.g., cholestyramine or colestipol), take **Pravalip** at least one hour before taking these medicines or four hours after taking these medicines, since the absorption of **Pravalip** may be affected by bile acid-binding medicines if taken close to each other.
Liver or kidney problems
If you have suffered in the past from liver problems or if you are suffering from kidney problems, the doctor may prescribe a lower dosage.
If you accidentally took a higher dosage or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.
If you forgot to take the medicine at the required time, take a dose as soon as you remember, unless it is almost time for you to take the next dose. Do not take a double dose to compensate for the forgotten dose.
Adhere to the treatment regimen as recommended by the doctor.
Even if there is an improvement in your health, do not stop treatment with the medicine without consulting the doctor.
Do not take medicines in the dark! Check the label and the dose each time you take medicine. Wear glasses if you need them.
If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS
As with any medicine, use of **Pravalip** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.
Stop taking the medicine and refer to a doctor immediately if:
- You suffer from sudden severe allergic reactions, including swelling of the face, lips, tongue or trachea, which can cause great difficulty in breathing. This is a very rare reaction, and when it occurs, it can be severe. If this happens, tell the doctor immediately.
- You suffer from breathing problems, including a persistent cough and/or shortness of breath or fever.

Inform the doctor immediately if:
- You develop unexplained or prolonged muscle pain, tenderness, weakness or spasms, especially if you feel unwell or have a high fever at the same time.
- In very rare cases, muscle problems can be serious (rhabdomyolysis), and may lead to severe, life-threatening kidney disease.

Effect on the skin and hair: rash.
Additional side effects
Uncommon side effects – effects that occur in 1-10 in 1,000 users
- Insomnia
- Dizziness
- Tiredness
- Headache or sleep disturbances
- Blurred or double vision
- Indigestion
- Nausea
- Vomiting
- Abdominal pain or discomfort
- Painful sensation in the chest due to stomach acidity
- Diarrhea
- Constipation
- Flatulence
- Itching
- Acne
- Urticaria
- Rash
- Scalp and hair problems (including hair loss)
- Bladder-related problems (painful or frequent urination, nocturia)
- Sexual function disturbances
- Muscle and joint aches

Very rare side effects – effects that occur in 1 user in 10,000
- Weakness, problems with sense of touch, including a burning or tingling sensation or numbness, which can indicate neural damage (especially if you use **Pravalip** for a long period of time)
- Serious skin disease (lupus erythematous-like syndrome).
- Liver or pancreas inflammation, jaundice (identified by yellowing of the skin and whites of the eyes)
- Very rapid death of liver cells (fulminant liver necrosis)
- Tendinitis, which may have complications and lead to tendon rupture
- Increased transaminases (a group of enzymes naturally found in the blood), which can be a sign of liver problems. The doctor may perform periodic tests to monitor the condition

Side effects of unknown frequency (effects whose frequency has not been determined yet)
- Constant muscle weakness
- Diabetes: the frequency will depend on the presence or absence of risk factors (fasting blood glucose level of 5.6 mmol/liter, BMI >30 kg/m^2, high triglyceride levels, history of high blood pressure)
- Dermatomyositis (a condition characterized by inflammation of the muscles and skin)
- Liver failure

The following side effects have been reported for several statins (unknown frequency)
- Nightmares
- Memory loss
- Depression
- Breathing problem, including a persistent cough or shortness of breath or fever
- Diabetes: occurrence of this side effect is more likely if you have high blood sugar and fat levels, you are overweight and have high blood pressure. Your doctor will monitor you while you are taking this medicine.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, consult with the doctor.
Side effects can be reported to the Ministry of Health by clicking on the link "Report Side Effects of Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il) that directs you to the online form for reporting side effects, or by entering the link: https://sideeffects.health.gov.il
Additionally, you can report to "Unipharm Ltd.".

5. HOW SHOULD THE MEDICINE BE STORED?
Avoid poisoning! This medicine, and any other medicine, should be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
Storage: Store below 25°C, in a place that is protected from light.
Do not dispose of medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION
In addition to the active ingredient, the medicine also contains:
Microcrystalline cellulose; Lactose; Magnesium oxide; Croscarmellose sodium; Magnesium stearate.
Each **Pravalip 10** tablet contains 29 mg lactose.
Each **Pravalip 20** tablet contains 58 mg lactose.
Each **Pravalip 40** tablet contains 116 mg lactose.
What the medicine looks like and contents of the package:
Pravalip 10, 20:
A round, white, biconvex tablet, with a break line on one side.
Pravalip 40:
An oblong, white, biconvex tablet, with a break line on one side.
The tablets are packaged in trays (blisters) that are inserted into a carton package. Each **Pravalip** package has **10, 20, 28** or **30** tablets.
Not all package sizes may be marketed.
Registration holder and address: Unipharm Ltd., P.O. Box 21429, Tel Aviv, 6121301.
Manufacturer and address: Unipharm Ltd., "Mevo Carmel" Industrial Park.
Registration number of the medicine in the National Drug Registry of the Ministry of Health:
Pravalip 10: 132 80 31134 01
Pravalip 20: 132 79 31135 01
Pravalip 40: 132 78 31136 01
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