PIVAL®
Tablets

Dear patient,
Please read the following instructions carefully. They contain important information about the use of this medicine. If you have any further questions, please ask your doctor or pharmacist.

Information about PIVAL
Each tablet for oral administration of PIVAL 2 mg contains Pitavastatin calcium equivalent to 2 mg Pitavastatin
Each tablet for oral administration of PIVAL 4 mg contains Pitavastatin calcium equivalent to 4 mg Pitavastatin
The excipients are: lactose monohydrate, hydroxypropyl methylcellulose, magnesium stearate, titanium dioxide, and magnesium aluminium silicate.
PIVAL is a lipid-lowering agent. It inhibits (HMG-CoA) reductase enzyme, which is involved in the biosynthesis of cholesterol.
PIVAL is indicated as an adjunctive therapy to diet for the following conditions:
- Reduction of elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B), triglycerides (TG) and increase high-density lipoprotein cholesterol (HDL-C) for adult patients with primary hyperlipidemia or combined (mixed) dyslipidemia when response to diet and other non-pharmacological measures is inadequate.
- Reduction of elevated total cholesterol (TC), low-density lipoprotein cholesterol (LDL-C), apolipoprotein B (Apo B) for pediatric patients aged 8 years and older with heterozygous familial hypercholesterolemia (HeFH).

The way to take PIVAL
Take PIVAL as directed by your doctor. Do not discontinue the treatment without consulting your physician. PIVAL should be used in addition to a standard cholesterol-lowering diet restricted in saturated fat and cholesterol.
Doses should be individualized according to patient's characteristics, goal of therapy and response. The dose range is 1 mg to 4 mg orally once daily. PIVAL can administered with or without food, at the same time each day.
The usual starting dose is 2 mg once daily and the maximum daily dose is 4 mg once daily. Lipid levels should be analyzed after 4 weeks and the dosage is adjusted accordingly.
Patients with moderate and severe renal impairment as well as end stage renal disease receiving hemodialysis should receive a starting dose of Pitavastatin 1 mg once daily and a maximum dose of 2 mg once daily.

Duration of treatment
The duration of treatment will be decided by your doctor. Do not discontinue therapy without consulting your doctor; you may require continuous treatment for quite some time. You should be periodically reassessed to determine the need for maintenance therapy with an appropriate dose.

In case of overdose
In case of intake of high doses of this medication, inform your doctor at once and seek emergency medical attention. General measures should be adopted.

In case of missed dose

Take the missed dose as soon as you remember unless the next intake is near. Go on taking the next scheduled dose as directed. Do not take a double dose at once.

Contraindications

PIVAL is contraindicated in the following conditions:

- Patients with known hypersensitivity to Pitavastatin or to any of the excipients or other statins
- Patients with active liver disease or unexplained persistent elevations in serum transaminases
- Patients receiving concomitant cyclosporine
- During pregnancy, while breast feeding, and in women of child bearing potential not taking appropriate contraceptive precautions

Precautions

- Use caution in patients with mild to moderate hepatic impairment, and patients with pre-disposing factors for rhabdomyolysis.
- Creatine kinase levels should be measured in any patient reporting muscle pain, muscle tenderness or weakness especially if accompanied by malaise or fever.
- Liver function tests should be performed prior to initiating treatment with this drug and then periodically during treatment. Discontinue the treatment in case of a persistent increase in serum transaminases, hepatic dysfunction and/or hyperbilirubinemia or jaundice occurs.
- Patients with diabetes or at risk of hyperglycemia should monitor their blood glucose level regularly.
- Discontinue PIVAL if markedly elevated CK levels occur or myopathy is diagnosed or suspected.

Associations with other medications

Please inform your doctor if other medicines are being taken or have been taken recently.

- Co-administration of this drug with cyclosporine is contraindicated.
- In patients taking erythromycin, a dose of 1 mg Pitavastatin should not be exceeded.
- Co-administration of this drug with gemfibrozil should be avoided.
- A maximum dose of Pitavastatin 2 mg should be given for patients taking Rifampin.
- Caution should be used with other fibrates, niacin, and colchicine.
- PIVAL should be used with caution in patients taking drugs known to cause myopathy.

Adverse reactions

The most commonly reported adverse reactions include: Myalgia, back pain, pain in extremity, constipation and diarrhea.

Other reported adverse reactions include: arthralgia, headache, influenza, nasopharyngitis, hypersensitivity reactions, myopathy, rhabdomyolysis, immune-mediated necrotizing myopathy, hepatic dysfunction, laboratory changes and increase in HbA1c and fasting serum glucose levels.

Please inform your doctor if any adverse reaction appears or becomes bothersome.

Storage

Store at controlled room temperature (below 30°C), protected from light and humidity, beyond the reach of children. The expiry date is printed on the pack; don't use this medicine after this date.

Pack Presentation

PIVAL 2 mg, Pitavastatin calcium equivalent to 2 mg Pitavastatin**,** pack of 30 tablets
PIVAL 4 mg, Pitavastatin calcium equivalent to 4 mg Pitavastatin, pack of 30 tablets

Revision date: 11/2020

PIVT/002

Manufactured by Mediphar Laboratories -Lebanon