Dupalaki™

Ciprofibrate

Presentation

Dupalaki™ Tablet: Each Tablet contains Ciprofibrate BP 100 mg.

Description

Dupalaki™ is a preparation of ciprofibrate. Ciprofibrate is a new derivative of phynoxyisobutyric acid which has a marked hypolipidemic action. It reduces both LDL and VLDL and hence the levels of triglyceride and cholesterol associated with these lipoprotein fractions. It also increases the levels of HDL cholesterol. The mechanism of action of Ciprofibrate is not entirely clear. It includes increased VLDL catabolism, but may also be influenced by reduced synthesis of VLDL or direct effect on the LDL receptor.

Indications

Ciprofibrate is indicated for- an adjunct to diet, exercise and weight reduction followed by

- Treatment of severe hypertriglyceridemia with or without low HDL cholesterol.
- Mixed hyperlipidemia when a statin is contraindicated or not tolerated.

Dosage and Administration

Adults: The recommended dose is Ciprofibrate 100 mg per day. This dose should not be exceeded.
Elderly Patients: As like adults but precautions should be taken for Age more than 70 years.
Use in case of impaired renal function: In moderate renal impairment (creatinine clearance 30-80ml/min/1.73m2) it is recommended that dosage be reduced to one tablet every other day. Patients should be carefully monitored. Ciprofibrate should not be used in severe renal impairment(creatinine clearance ,30ml/min/1.73m2).
Use in children: Not recommended since safety and efficacy in children has not been established.
Method of administration: for oral use.

Drug Interactions

Other fibrates: as like other fibrates, the risk of rhabdomyolysis and myoglobinuria may be increases if Ciprofibrate is used in combination with other fibrates.
Not recommended combination with HMG CoA reductase inhibnitors: As with other fibrates, the risk of myopathy, rhabdomyolysis and myoglobinuria may be increased if Ciprofibrate is used in combination with HMG CoA reductase inhibitors. The benefits of combined use should be carefully weighed against the risks.
Oral anticoagulant therapy: Ciprofibrate is highly protein bound and therefore likely to displace other drugs from plasma protein binding sites. This may increase the effects of drugs like phenytoin, tolbutamide and other sulphonylurea derivatives and coumarin-like anticoagulants.Ciprofibrate has been shown to potentiate the effect of warfarin, indicating that concomitant oral anticoagulant therapy should be given in reduced dosage.
Oral hypoglycaemics: Although Ciprofibrate may potentiate the effect of oral hypoglycaemics, available data do not suggest that such an interaction may be clinically significant.
Oestrogens: Oestrogens can raise lipid levels. Although a pharmacodynamics interaction may be suggested, no clinical data are currently available.

Use in Fertility, Pregnancy and Lactation

Fertility: There are no data on the effects of Ciprofibrate on fertility in humans.
Pregnancy: There are insufficient data from the use of Ciprofibrate in pregnant women. Animal studies have demonstrated neonatal thrombosis. The potential risk for humans is unknown. Ciprofibrate is contraindicated during pregnancy.
Lactation: Ciprofibrate is contraindicated during breast feeding.It is not known if Ciprofibrate is excreted into breast milk.

Contraindications

Hypersensitivity to the active substance or to any of the excipients *Severe hepatic impairment *Severe renal impairment (creatinine clearance <30 ml/min/1.73 m2) *Pregnancy and lactation or when pregnancy is suspected *Concurrent use with another fibrate * Previous phototoxicity caused by fibrates.

Precautions & Warnings

Special warnings: Patient with rare heriditery problems of galactose intolerance, the lapp latose deficiency or glucose-galactose malabsorption should not take this medicine.
Myalgia/myopathy: Patients should be advised to report unexplained muscle pain,tenderness or weakness immediately

Overdose

Symptoms: Overdose with Ciprofibrate has been rarely reported. Some cases of overdose are known, but in these cases, no adverse reactions specific to overdose have been observed. In the worst case, after ingestion of 2800mg Ciprofibrate for 3 days, rhabdomyolysis observed.
Treatment: There is no specific antidotes to Ciprofibrate. Treatment of overdose should be symptomatic. The usual measures should be taken to prevent further absorption of the drug from the gastro-intestinal trac. Gastric lavage and appropriate supportive care may be instituted if necessary. Ciprofibrate is non-dialysable.

Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

Commercial Pack

Dupalaki™ Tablet: Each commercial box contains 3 blister strips of 10 tablets.

Manufactured by
Incepta Pharmaceuticals Ltd
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