Obetic
Tablet

DRUG INTERNATIONAL LTD.

Composition : **Obetic-5 Tablet:** Each film coated tablet contains Obeticholic Acid INN 5 mg.
Obetic-10 Tablet: Each film coated tablet contains Obeticholic Acid INN 10 mg.

Pharmacology : Obeticholic acid is an agonist for FXR, a nuclear receptor expressed in the liver and intestine. FXR is a key regulator of bile acid, inflammatory, fibrotic, and metabolic pathways. FXR activation decreases the intracellular hepatocyte concentrations of bile acids by suppressing de novo synthesis from cholesterol as well as by increased transport of bile acids out of the hepatocytes. These mechanisms limit the overall size of the circulating bile acid pool while promoting choleresis, thus reducing hepatic exposure to bile acids.

Indications : Obeticholic acid is indicated for the treatment of adult patients with primary biliary cholangitis (PBC) without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, Either in combination with Ursodeoxycholic Acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

Dosage and administration : The usual starting dosage for PBC patients without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension who have not achieved an adequate biochemical response to an appropriate dosage of Ursodeoxycholic Acid (UDCA) for at least 1 year or are intolerant to UDCA follows bellow:
Start with dosage of 5mg once daily for first 3 months. After 3 months, for patients who have not achieved adequate reduction in Alkaline phosphate (ALP) and/or total bilirubin and who are tolerating Obeticholic Acid incrase to the maximum dosage 10 mg once daily.
Management of patient with intolerable pruritus: Add an antihistamine or bile acid binding resin. Reduce the dosage to 5 mg every other day, for patients intolerable to 5 mg once daily, 5 mg once daily, for patients intolerant to 10 mg once daily. Temporarily interrupt dosing for up to 2 weeks followed by restart at a reduced dosage and titrate the dosage to 10 mg once daily based on biochemical response. Or, as directed by the registered physician.

Contraindication : It is contraindicated in patients with decompensated cirrhosis (eg., Child-Plugh Class B or C) or prior decompensation event, compensated cirrhosis with evidence of portal hypertension (eg., ascites, gastroesophegeal varices, persistent thrombocytopenia), complete biliary obstruction.

Precautions : **Hepatic Decompensation and Failure in Incorrectly Dosed PBC Patients with Child-Plugh Class B or C or Decompensated Cirrhosis:** Routinely monitor patients for progression of PBC disease, including liver-related complications, with laboratory and clinical assessments. Dosage adjustment, interruption, or discontinuation may be required. Discontinue in patients who develop complete biliary obstruction. **Severe Pruritus:** Management strategies include the addition of bile acid binding resins or antihistamines; dosage reduction and/or temporary dosing interruption. **Reduction in HDL-C:** Monitor for changes in serum lipid levels during treatment.

Side effects : The most common side effects include: pruritus, fatigue, abdominal pain and discomfort. Other side effects include rash, arthralgia, oropharyngeal pain, dizziness, constipation, abnormal thyroid function and eczema.

Use in pregnancy and lactation : The limited available human data on the use of obeticholic acid during pregnancy are not sufficient to inform a drug-associated risk. There is no information on the presence of obeticholic acid in human milk, the effects on the breast-fed infant or the effects on milk production.

Use in children : Safety and effectiveness in pediatric patients have not been established.

Drug Interactions : It may interact with following drugs: Bile Acid Binding Resins (eg. cholestyramine, colestipol, or colesevelam), Warfarin, CYP1A2 substrates with narrow therapeutic index (e.g. theophylline and tizanidine), Inhibitors of bile salt efflux pump (eg. cyclosporine).

Overdose : Adverse reactions related overdose include elevations in liver biochemical tests, ascites, jaundice, portal hypertension, and primary biliary cholangitis flare. In case of overdosage, patients should be carefully observed and supportive care administered, as appropriate.

Storage : Store bellow 30°C in a cool and dry place. Protect from light and moisture. Keep out of the reach of children.

Packing : **Obetic-5 Tablet:** Each box contains 2 x 10's tablets in blister pack.
Obetic-10 Tablet: Each box contains 1 x 10's tablets in blister pack.