OCABILE

For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.
Abbreviated Prescribing information for OCABILE (Obeticholic acid Tablets 5 mg and 10 mg)

[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

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. **DOSAGE AND ADMINISTRATION:**

As directed physician.

CONTRAINDICATION: Obeticholic acid tablet is contraindicated in patients with complete biliary obstruction.

WARNINGS & PRECAUTIONS: **Hepatic Decompensation and Failure in Incorrectly Dosed PBC Patients with Child-Pugh Class B or C or Decompensated Cirrhosis**

In post marketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in PBC patients with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when Obeticholic acid was dosed more frequently than the commended starting dosage of 5 mg once weekly. Reported cases typically occurred within 2 to 5 weeks after starting Obeticholic acid and were characterized by an acute increase in total bilirubin and/or ALP concentrations in association with clinical signs and symptoms of hepatic decompensation (e.g., ascites, jaundice, gastrointestinal bleeding, worsening of hepatic encephalopathy).. [Refer Prescribing information for more details]

DRUG INTERACTION:.

Bile Acid Binding Resins

Bile acid binding resins such as cholestyramine, colestipol, or colesevelam adsorb and reduce bile acid absorption and may reduce the absorption, systemic exposure, and efficacy of Obeticholic acid tablet. **Warfarin: The** International Normalized Ratio (INR) decreased following coadministration of warfarin and Obeticholic acid. Monitor INR and adjust the dosage of warfarin, as needed, to maintain the target INR range when co-administering Obeticholic acid and warfarin. **CYP1A2 Substrates with Narrow Therapeutic Index:** Obeticholic acid may increase the exposure to concomitant drugs that are CYP1A2 substrates. Therapeutic monitoring of CYP1A2 substrates with a narrow therapeutic index (e.g. theophylline and tizanidine) is recommended when co-administered with Obeticholic acid.

Inhibitors of Bile Salt Efflux Pump Avoid concomitant use of inhibitors of the bile salt efflux pump (BSEP) such as cyclosporine. Concomitant medications that inhibit canalicular membrane bile acid transporters such as the BSEP may exacerbate accumulation of conjugated bile salts including taurine conjugate of obeticholic acid in the liver and result in clinical symptoms. If concomitant use is deemed necessary, monitor serum transaminases and bilirubin. [Refer Prescribing information for more details]

ADVERSE REACTIONS:

The following clinically significant adverse reactions are described.

• Hepatic Decompensation and Failure in Incorrectly Dosed PBC Patients with Child-

Pugh Class B or C or Decompensated Cirrhosis.

- Liver-Related Adverse Reactions.
- Severe Pruritus
- Reduction in HDL-C

Pruritus, Fatigue, Abdominal pain and discomfort, Rash, Arthralgia, Oropharyngeal, Dizziness, Constipation, Peripheral Edema, Palpitations, Pyrexia, Thyroid function and Eczema. [Refer Prescribing information for more details]

MARKETED BY:

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(Additional information is available on request)