Abbreviated Prescribing Information

OCALIVA® ▼ (obeticholic acid)

Please refer to the Full Summary of Product Characteristics (SmPC) before prescribing

Presentation: OCALIVA supplied as film-coated tablets containing 5 mg and 10 mg obeticholic acid.

Indication: For the treatment of primary biliary cholangitis in combination with ursodeoxycholic acid (UDCA) in adults with an inadequate response to UDCA or as monotherapy in adults unable to tolerate UDCA.

Dosage and administration: Oral administration. Hepatic status must be known before initiating treatment. Obeticholic acid is contraindicated in patients with decompensated cirrhosis (incl. Child-Pugh B or C) or a prior decompensation event. The starting dose is 5 mg once daily for the first 6 months. Based on an assessment of tolerability after 6 months, the dose should be increased to 10 mg once daily if adequate reduction of alkaline phosphatase (ALP) and/or total bilirubin have not been achieved. No dose adjustment of concomitant UDCA is required in patients receiving obeticholic acid. For cases of severe pruritus, dose management includes reduction, temporal interruption or discontinuation for persistent intolerable pruritus; use of bile acid binding agents or antihistamines (see SmPC).

Moderate to Severe Hepatic Impairment: Obeticholic acid is contraindicated in patients with decompensated cirrhosis (e.g. Child-Pugh Class B or C) or a prior decompensation event. No dose adjustment required in Child Pugh Class A function. **Mild or moderate renal impairment:** No dose adjustments are required. **Paediatric population:** No data. **Elderly:** No dose adjustment required; limited data exists.

Contraindications: Hypersensitivity to the active substance or any excipients. Patients with decompensated cirrhosis (e.g. Child-Pugh B or C) or a prior decompensation event. Patients with complete biliary obstruction.

Special warnings and precautions for use: After initiation, all patients (including those at risk of hepatic decompensation - those with elevated bilirubin levels, evidence of portal hypertension, concomitant hepatic disease and/ or severe intercurrent illness) should be monitored for progression of PBC, including hepatic adverse events, with frequent clinical and laboratory assessments to determine whether obeticholic acid treatment discontinuation is needed. Hepatic failure, sometimes fatal or resulting in liver transplant has been reported with obeticholic acid treated PBC patients with either compensated or decompensated cirrhosis. Liver-related adverse events have been observed within the first month of treatment and have included elevations in alanine amino transferase (ALT), aspartate aminotransferase (AST) and hepatic decompensation.

Interactions: Following co-administration of warfarin and obeticholic acid, International Normalised Ratio (INR) should be monitored, and the dose of warfarin adjusted, if needed, to maintain the target INR range. Therapeutic monitoring of CYP1A2 substrates with narrow therapeutic index (e.g. theophylline and tizanidine) is recommended. Obeticholic acid should be taken at least 4-6 hours before or after taking a bile acid binding resin, or at as great an interval as possible.

Fertility, pregnancy and lactation: Avoid use in pregnancy. Either discontinue breast-feeding or discontinue/abstain from obeticholic acid therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman. No clinical data on fertility effects.

Undesirable effects: Very common (≥1/10) adverse reactions were pruritus, fatigue, and abdominal pain and discomfort. The most common adverse reaction leading to discontinuation was pruritus. The majority of pruritus occurred within the first month of treatment and tended to resolve over time with continued dosing. Other commonly (≥ 1/100 to < 1/10) reported adverse reactions are, thyroid function abnormality, dizziness, palpitations, oropharyngeal pain, constipation, eczema, rash, arthralgia, peripheral oedema, and pyrexia. Other adverse events are hepatic failure, bilirubin increase, jaundice, cirrhosis (frequency unknown). Please refer to the SmPC for a full list of undesirable effects.

Overdose: Hepatic adverse reactions were reported with higher than recommended doses of obeticholic acid. Patients should be carefully observed, and supportive care administered, as appropriate.

Legal category: POM

Marketing authorisation numbers: PLGB 48025/0004 & 0005. EU/1/16/1139/001, 002, 003 & 004.

Marketing authorisation holder:

For GB: Advanz Pharma Europe Limited, Capital House, 85 King William Street, London, EC4N 7BL, United Kingdom

For ROI & NI: ADVANZ PHARMA Limited, Suite 17, Northwood House, Northwood Avenue, Santry, Dublin 9, Ireland

Package Quantities and Basic NHS cost: OCALIVA 5 mg and 10 mg £2,384.04 per bottle of 30 tablets.

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Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard for the UK or http://www.hpra.ie/homepage/medicines/safety-information/reporting-suspected-side-effects for Ireland. Adverse events should also be reported to Advanz Pharma on +44 (0)330 100 3694 for the UK or +353 144 75 196 for Ireland or email: medicalinformation@advanzpharma.com