Information For the User Obeticholic acid (10mg)

Obewise 10

Obewise 10 Tablet

Composition:

Each tablet contains:

Obeticholic Acid – 10 mg

Description:

Obewise 10 Tablet contains Obeticholic Acid, a farnesoid X receptor (FXR) agonist used in the treatment of primary biliary cholangitis (PBC), a chronic liver disease that affects bile ducts. It helps regulate bile acid metabolism, reducing liver inflammation and preventing disease progression.

Pharmacological Action:

Obeticholic Acid activates FXR, a nuclear receptor that controls bile acid synthesis and transport. By reducing bile acid accumulation in hepatocytes, it decreases liver inflammation, fibrosis, and cholestatic injury.

Indications:

• Primary biliary cholangitis (PBC) as monotherapy or in combination with ursodeoxycholic acid (UDCA) for patients who have an inadequate response to or cannot tolerate UDCA.

Dosage & Administration:

- Recommended starting dose: 5 mg once daily.
- May be increased to 10 mg daily based on patient response and tolerability.
- To be taken orally, with or without food.

Contraindications:

- Complete biliary obstruction.
- Severe hepatic impairment without dose adjustments.
- Hypersensitivity to Obeticholic Acid or any excipients.

Warnings & Precautions:

- Regular liver function monitoring is required due to the risk of hepatotoxicity.
- Pruritus may occur and may require dose modification or symptomatic treatment.
- Use caution in patients with cirrhosis, as decompensated cirrhosis may require adjusted dosing.

Adverse Effects:

- Pruritus, fatigue, abdominal pain
- Increased liver enzymes
- Nausea, diarrhea, or constipation

Drug Interactions:

- Bile acid sequestrants may reduce the absorption of Obeticholic Acid and should be administered separately.
- CYP3A4 inhibitors may affect the metabolism of Obeticholic Acid, requiring monitoring.

Storage Conditions:

- Store in a cool, dry place below 25°C.
- Keep away from direct sunlight and moisture.

Conclusion:

Obewise 10 Tablet is an effective therapy for primary biliary cholangitis, aiding in the regulation of bile acid metabolism and reducing disease progression. Regular monitoring is essential for optimal treatment outcomes.

Manufactured in India for:



(An ISO 9001: 2015 Certified Co.)

Plot no.: 367-FF, Industrial Area Phase-I,

Panchkula-134113

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