**COMPOSITION**

Livacol® Tablet: Each film coated tablet contains Obeticholic Acid INN 5 mg.

**PHARMACOLOGY**

Obeticholic acid is an agonist for Farnesoid X receptor (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 choleretic, thus reducing hepatic exposure to bile acids.

**INDICATION**

Livacol® is indicated for the treatment of primary biliary cholangitis (PBC) 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**

The starting dose and dosage titration for primary biliary cholangitis patient.

<table>
<thead>
<tr>
<th>Staging/Classification</th>
<th>Non-Cirrhotic or Compensated Child Pugh Class A</th>
<th>Child-Pugh Class B or C or Patients with a Prior Decompensation Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>Starting Dosage for first 3 months</td>
<td>5 mg once daily.</td>
<td>5 mg once weekly.</td>
</tr>
<tr>
<td>Dosage Titration after first 3 months, for patients who have not achieved an adequate reduction at least in ALP and/or bilirubin and who are tolerating Livacol</td>
<td>10 mg once daily.</td>
<td>5 mg twice weekly (at least 3 days apart). Titrated to 10 mg twice weekly (at least 3 days apart) based on response and tolerability.</td>
</tr>
<tr>
<td>Maximum Dosage</td>
<td>10 mg once daily.</td>
<td>10 mg twice weekly (at least 3 days apart)</td>
</tr>
</tbody>
</table>

Management and dose adjustment for severe pruritus

For Non-Cirrhotic or Child-Pugh Class A patients:
- Reducing the dosage of Obeticholic acid to:
  - 5 mg every other day, for patients intolerant to 5 mg once daily
  - 5 mg once daily, for patients intolerant to 10 mg once daily
- Temporarily interrupting Obeticholic acid dosing for up to 2 weeks followed by restarting at a reduced dosage.
- Continue to increase the dosage to 10 mg once daily, as tolerated, to achieve optimal response.

For Child-Pugh Class B or C or Decompensated Cirrhotic patients:
- Reducing the dosage of Obeticholic acid to:
  - 5 mg once weekly, for patients intolerant to 5 mg twice weekly
  - 10 mg once weekly, for patients intolerant to 10 mg twice weekly
- Temporarily interrupting Obeticholic acid dosing for up to 2 weeks followed by restarting at a reduced dosage if applicable.
- Continue to increase the dosage to 10 mg twice weekly, as tolerated, to achieve optimal response.

Consider discontinuing treatment with Obeticholic acid for patients who continue to experience persistent, intolerable pruritus.

**SIDE EFFECT**

Most common adverse reactions (≥ 5%) are: pruritus, fatigue, abdominal pain and discomfort, rash, oropharyngeal pain, dizziness, constipation, arthralgia, thyroid function abnormality, and eczema.

**STORAGE**

Store below 30°C. Protected from light & moisture. Keep the medicine out of the reach of children.

**HOW SUPPLIED**

Livacol® Tablet: Each box contains 20 Tablets in Alu-Alu Blister pack.