Resmerom-80

Resmetirom 80 mg

COMPOSITION :

Resmerom-80 : Each film coated tablet contains Resmetirom INN 80 mg.

DESCRIPTION :

Resmerom is a thyroid hormone receptor-beta (THR-β) agonist indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

PHARMACOLOGY :

Resmerom works directly in the liver by stimulating THR-β to improve critical hepatic processes and reduce fibrosis. Resmerom is a partial agonist of THR-β, a nuclear receptor predominantly expressed in liver cells. Resmerom stimulates THR-β signaling, regulating the expression of genes that improve critical processes in the liver, such as lipid metabolism and mitochondrial biogenesis. Resmerom works to improve lipid metabolism (e.g., reduces intrahepatic triglycerides and free fatty acids) and reduces inflammation in the liver. This helps to address drivers of disease progression, reduce liver damage, and improve liver health.

INDICATIONS :

Resmerom is indicated in conjunction with diet and exercise for the treatment of adults with noncirrhotic nonalcoholic steatohepatitis (NASH) with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis).

DOSAGE AND ADMINISTRATION :

The recommended dosage of Resmerom is based on actual body weight. For patients weighing:

- <100 kg, the recommended dosage is 80 mg orally once daily.
- ≥100 kg, the recommended dosage is 100 mg orally once daily.

Administer Resmerom with or without food.

Dosage Modifications for CYP2C8 Inhibitors

Concomitant use of Resmerom with strong CYP2C8 inhibitors (e.g., gemfibrozil) is not recommended. If Resmerom is used concomitantly with a moderate CYP2C8 inhibitor (e.g., Clopidogrel), reduce the dosage of Resmerom:

- <100 kg, reduce the dosage of Resmerom to 60 mg once daily.
- ≥100 kg, reduce the dosage of Resmerom to 80 mg once daily.

OVERDOSAGE :

There is no information regarding the acute toxicity and overdosage of resmetirom.

CONTRAINDICATIONS :

None

WARNING AND PRECAUTIONS :

Hepatotoxicity: Monitor patients during treatment with Resmerom for elevations in liver tests and for the development of liver-related adverse reactions. Discontinue Resmerom and continue to monitor the patient if hepatotoxicity is suspected.

Gallbladder-Related Adverse Reactions: Cholelithiasis and cholecystitis were observed more often in Resmetirom -treated patients. . If cholelithiasis is suspected, gallbladder diagnostic studies and appropriate clinical follow-up are indicated. If an acute gallbladder event such as acute cholecystitis is suspected, interrupt Resmerom treatment until the event is resolved.

SIDE EFFECTS :

The most common side effects with Resmerom are diarrhea, nausea, pruritus, vomiting, constipation, abdominal pain, and dizziness. Diarrhea and nausea were the most common causes of treatment discontinuation.

DRUG INTERACTIONS:

Strong or Moderate CYP2C8 Inhibitors: Concomitant use not recommended (strong inhibitor [e.g., Gemfibrozil]); or reduce Resmerom dosage (moderate inhibitor [e.g., Clopidogrel]).

OATP1B1 and OATP1B3 Inhibitors: Concomitant use with OATP inhibitors (e.g., Cyclosporine) is not recommended.

Statins: Limit daily Rosuvastatin and Simvastatin dosage to 20 mg. Limit Pravastatin and Atorvastatin dosage to 40 mg.

CYP2C8 Substrates: Monitor patients more frequently for substrate related adverse reactions.

USE IN SPECIAL POPULATIONS :

Pregnancy :

There are no available data on Resmetirom use in pregnant women.

Lactation :

There is no information regarding the presence of Resmetirom in human or animal milk, the effects on the breast-fed infant, or the effects on milk production.

Geriatric Use :

Numerically higher incidence of adverse reactions has been observed in patient's β 65 years of age compared to younger adult patients.

Renal Impairment :

Resmetirom has not been studied in patients with severe renal impairment.

Hepatic Impairment :

Avoid use in patients with decompensated cirrhosis (consistent with moderate to severe hepatic impairment). Moderate or severe hepatic impairment (Child-Pugh Class B or C) may increase the risk of adverse reactions. The safety and effectiveness have not been established in patients with cirrhosis.

STORAGE CONDITION :

Store below 30°C. Keep in dry place & protect from light. Keep out of the reach of children.

PACKING:

Resmerom-80 : Each bottle contains 30 Tablets.

Manufactured by
DRUG INTERNATIONAL LTD.
Tongi, Gazipur, Bangladesh