Fibrocon

Resmetirom

COMPOSITION

Fibrocon 60 Tablet: Each film coated tablet contains Resmetirom INN 60 mg.
Fibrocon 80 Tablet: Each film coated tablet contains Resmetirom INN 80 mg.
Fibrocon 100 Tablet: Each film coated tablet contains Resmetirom INN 100 mg.

PHARMACOLOGY

Resmetirom is a partial agonist of the Thyroid Hormone Receptor-beta (THR-β). THR-β is the major form of THR in the liver and stimulation of THR-β in the liver reduces intrahepatic triglycerides.

INDICATIONS

It 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). Avoid use of it in patients with decompensated cirrhosis.
Avoid the use of Resmetirom in patients with moderate to severe hepatic impairment (Child-Pugh Class B or C).

DOSAGE AND ADMINISTRATION

The recommended dosage of it is based on actual body weight.
For patients body weight:
• <100 kg, the recommended dosage is 80 mg orally once daily.
• ≥100 kg, the recommended dosage is 100 mg orally once daily.

Reduce the dosage if used concomitantly with a moderate CYP2C8 inhibitor (e.g., Clopidogrel).

For patients body weight:
• <100 kg, reduce the dosage of Resmetirom to 60 mg once daily.
• ≥100 kg, reduce the dosage of Resmetirom to 80 mg once daily.

Administer the tablet with or without food.

CONTRAINDICATIONS

There is no contraindication.

WARNING & PRECAUTION

Hepatotoxicity: Discontinue the product and continue to monitor the patient if hepatotoxicity is suspected.
Gallbladder-Related Adverse Reactions: Cholelithiasis and cholecystitis were observed more often in the patients. Gallbladder diagnostic studies and appropriate clinical follow-up are indicated if cholelithiasis is suspected. If an acute gallbladder event such as acute cholecystitis is suspected, interrupt the treatment with this product until the event is resolved.

SIDE EFFECTS

The most common side effects are diarrhea, nausea, pruritus, vomiting, constipation, abdominal pain and dizziness.

USE IN PREGNANCY & LACTATION

There are no available data on its use in pregnant women.
There is no information regarding the presence of this drug in human milk, the effects on the breast-feed infant or the effects on milk production.

USE IN CHILDREN & ADOLESCENTS

The safety and effectiveness of it have not been established in pediatric patients.

DRUG INTERACTIONS

Strong or Moderate CYP2C8 Inhibitors: Concomitant use is not recommended for strong inhibitors (i.e., Gemfibrozil) and to reduce the dosage of Resmetirom for moderate inhibitors (i.e. Clopidogrel).
OATP1B1 and OATP1B3 Inhibitors: Concomitant use is not recommended.
Atorvastatin, Pravastatin, Rosuvastatin and Simvastatin: Limit the daily statin dosage as recommended.
CYP2C8 Substrates: Monitor patients more frequently for substrate-related adverse reactions.

OVERDOSAGE

No data is available.

STORAGE

Store below 30°C temperature in a cool & dry place. Protect from light and moisture. Keep out of the reach of children.

HOW SUPPLIED

Fibrocon 60 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Fibrocon 80 Tablet: Each box contains 30 tablets in Alu-Alu blister pack.
Fibrocon 100 Tablet: Each box contains 20 tablets in Alu-Alu blister pack.

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NIPRO JMI Pharma

Manufactured by:
NIPRO JMI Pharma Ltd.
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