

# Frehepta™

Resmetirom INN 60 mg, 80 mg & 100 mg

## Presentation

Frehepta™ 60 tablet: Each tablet contains Resmetirom INN 60 mg.

Frehepta™ 80 tablet: Each tablet contains Resmetirom INN 80 mg.

Frehepta™ 100 tablet: Each tablet contains Resmetirom INN 100 mg.

## Description

Resmetirom is a thyroid hormone receptor-beta agonist (THR-β). THR-β is the major form of thyroid hormone receptor in the liver, and stimulation of THR-β in the liver reduces intrahepatic triglycerides.

## Indication

Resmetirom is a prescribed medicine to treat adults with metabolic dysfunction associated steatohepatitis (MASH) formerly known as nonalcoholic steatohepatitis (NASH) with moderate to advanced liver scarring (fibrosis grade 2-3).

## Dosage and Administration

The recommended dosage is based on actual body weight. According to the weight of the patients, the dosage will be-

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

≥100 kg, the recommended dosage is 100 mg orally once daily

Dosage modifications for patients already taking CYP2C8 Inhibitors (clopidogrel, montelukast and clotrimazole)-

<100 kg, reduce the dosage of Resmetirom to 60 mg once daily

≥100 kg, reduce the dosage of Resmetirom to 80 mg once daily.

Atorvastatin, Pravastatin, Rosuvastatin and Simvastatin: Limit the daily dosage.

Rosuvastatin/Simvastatin: Max 20 mg/day, Pravastatin/Atorvastatin: Max 40 mg/day

Concomitant use with strong CYP2C8 inhibitor (Gemfibrozil) and OATP1B1/1B3 inhibitors (e.g., cyclosporine) is not recommended.

Administer resmetirom with or without food.

## Contraindications

It is contraindicated in those who are hypersensitive to Resmetirom and patients with decompensated cirrhosis.

## Precautions

Patients with hepatotoxicity & gallbladder-related adverse reactions (Cholelithiasis and cholecystitis) should use Resmetirom cautiously.

## Side-effects

Resmetirom might cause diarrhea, nausea, pruritus, vomiting, constipation, abdominal pain, and dizziness etc.

## Drug interactions

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Concomitant use with strong CYP2C8 inhibitor (Gemfibrozil) and OATP1B1/1B3 inhibitors (e.g., cyclosporine) is not recommended.

Atorvastatin, Pravastatin, Rosuvastatin and Simvastatin: Limit the daily dosage.

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

## Overdosage

No data found.

## Use in pregnancy and lactation

If needed it can be used in pregnant or lactating mothers after consultation with a health care professional.

## Usage in Pediatric Patients

It is not known if Resmetirom is safe and effective in children (under 18 years old).

## Storage

Do not store above 30 °C. Keep away from light and out of the reach of children.

## Commercial Packaging

Frehepta™ 60 tablet: Each box contains 3 blister strips of 10 tablets.

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Frehepta™ 100 tablet: Each box contains 3 blister strips of 10 tablets.