

NOMASHTM

(Resmetirom)

Tablet

نومیش

COMPOSITION:

NOMASH TABLET 60 MG:

Each film coated tablet contains:
Resmetirom 60 mg.

Product Specs.: Innovator

NOMASH TABLET 80 MG:

Each film coated tablet contains:
Resmetirom 80 mg.

Product Specs.: Innovator

NOMASH TABLET 100 MG:

Each film coated tablet contains:
Resmetirom 100 mg.

Product Specs.: Innovator

INDICATIONS:

Resmetirom is a thyroid hormone receptor-beta (THR-beta) 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). This indication is approved under accelerated approval based on improvement of NASH and fibrosis. Continued approval dependent on confirmatory trial results.

POSOLGY:

The recommended dosage of Resmetirom 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.

SPECIAL POPULATIONS:

Paediatric population: Safety and effectiveness in children have not been established.

Geriatric population: Patients aged 65 and older may experience more adverse reactions, though effectiveness is similar to younger adults.

Renal impairment: No dose adjustment is needed for mild or moderate renal impairment. Use in severe renal impairment has not been studied.

Hepatic impairment: Avoid in decompensated cirrhosis (moderate to severe impairment).

Mild hepatic impairment does not require dose adjustment.

Safety and effectiveness in NASH patients with cirrhosis are not established.

Body weight: Higher body weight may result in lower drug exposure, but dosage adjustment is not required.

METHOD OF ADMINISTRATION:

- Oral use
- Tablets can be administered with or without food.

CONTRAINDICATIONS: Resmetirom is contraindicated in patients with a history of hypersensitivity to active substance or to any excipient of the product.

SPECIAL WARNINGS AND PRECAUTIONS FOR USE:

Hepatotoxicity:

- Some patients taking Resmetirom may develop serious liver problems.
- Symptoms to watch for include fatigue, nausea, vomiting, pain in the right upper abdomen, jaundice (yellowing of skin or eyes), fever, rash, or unusual blood test results.
- In rare cases, liver enzymes (ALT, AST) and bilirubin can rise to very high levels.
- If liver problems are suspected, stop taking Resmetirom immediately and monitor liver tests closely.
- Once liver tests return to normal, your doctor will carefully weigh the risks and benefits before deciding if you should restart the medication.
- If liver tests do not return to normal, further evaluation for autoimmune-like liver disease may be needed.

Gallbladder-Related Adverse Reactions:

- Resmetirom may increase the risk of gallstones, inflammation of the gallbladder (acute cholecystitis), and gallstone-related pancreatitis.
- If you develop upper abdominal pain, nausea, vomiting, fever, or other signs of gallbladder problems, your doctor may temporarily stop Resmetirom and perform appropriate tests.
- Treatment may resume once the issue is resolved and your doctor approves it.

DRUG INTERACTIONS:

Effects of Other Drugs on Resmetirom:

CYP2C8 inhibitors: Resmetirom levels increase with strong or moderate CYP2C8 inhibitors.

- Avoid strong inhibitors (e.g., gemfibrozil).
- Reduce dose with moderate inhibitors (e.g., clopidogrel).

OATP1B1/1B3 inhibitors: Increase Resmetirom exposure.

- Avoid use with OATP inhibitors (e.g., cyclosporine).

Effects of Resmetirom on Other Drugs:

Statins:

Resmetirom increases statin levels.

- Limit rosuvastatin/simvastatin to 20 mg daily, atorvastatin/pravastatin to 40 mg daily.
- CYP2C8 substrates:** Resmetirom (a weak inhibitor) increases their exposure.
- Monitor closely for substrate-related adverse effects.

FERTILITY, PREGNANCY & LACTATION:

Pregnancy: There are no or limited amount of data from the use of Resmetirom in pregnant women. Therefore, Resmetirom should be used during pregnancy only if the potential benefit justifies the potential risk to the foetus. However, there are risks to the mother and fetus related to underlying maternal NASH with liver fibrosis, such as increased risks of gestational diabetes, hypertensive complications, preterm birth, and postpartum hemorrhage.

Breast-feeding: The effects of Resmetirom on a breastfed infant or on milk production are unknown.

ADVERSE EFFECTS:

Following adverse reactions have been reported with the use of Resmetirom:

- Hepatotoxicity
- Gallbladder-related adverse reactions
- Urticaria
- Rash
- Diarrhea
- Nausea
- Pruritus
- Vomiting
- Constipation
- Abdominal pain
- Dizziness

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Resmetirom is a partial thyroid hormone receptor-β (THR-β) agonist that primarily targets the liver. It activates THR-β more strongly than THR-α, helping reduce liver fat (intrahepatic triglycerides) while limiting activity in tissues like the heart and bone.

PHARMACOKINETIC PROPERTIES:

Absorption:

- Resmetirom reaches steady levels in 3–6 days.
- Peak levels occur about 4 hours after a dose.
- Food has no meaningful effect on overall exposure but may lower and delay the peak slightly.

Distribution:

- Resmetirom is highly protein-bound (>99%).
- The apparent volume of distribution is 68 L.

Metabolism:

- Resmetirom is mainly broken down by the liver enzyme CYP2C8.
- MGL-3623 is a major metabolite with a 28-times lower potency for THR-β than Resmetirom.

Elimination:

About 67% of the dose is eliminated in the feces (mostly as metabolites).

About 24% is eliminated in the urine.

Only very small amounts of unchanged drug are excreted.

OVERDOSE: In the event of overdose, appropriate supportive treatment should be initiated according to the patient's clinical signs and symptoms.

INSTRUCTIONS:

- Store below 30°C.
- Protect from heat, sunlight & moisture.
- Keep out of the reach of children.
- To be sold on the prescription of a registered medical practitioner only.

PRESENTATION:

NOMASH TABLET 60 MG	:	Pack of 3 x 10 tablets.
NOMASH TABLET 80 MG	:	Pack of 3 x 10 tablets.
NOMASH TABLET 100 MG	:	Pack of 3 x 10 tablets.

Manufactured by:
Wimits Pharmaceuticals Pvt. Ltd.
Plot No. 129, Sundar Industrial Estate, Raiwind Road, Lahore, Pakistan.

FOR FURTHER INFORMATION PLEASE CONTACT:



Marketed by:
CCL Pharmaceuticals (Pvt.) Ltd.
62 Industrial Estate, Kot Lakhpat, Lahore, Pakistan.

ہدایات:
۳۰ درجہ سینٹی گریڈ سے کم درجہ حرارت پر رکھیں۔
گرمی، دھوپ اور نمی سے بچائیں۔
بچوں کی پہنچ سے دور رکھیں۔
صرف مستند ڈاکٹر کے نسخہ پر فروخت کریں۔