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Rezdiffra (*resmetirom*)

An overview of Rezdiffra and why it is authorised in the EU

What is Rezdiffra and what is it used for?

Rezdiffra is a medicine used together with diet and physical activity to treat adults with metabolic dysfunction-associated steatohepatitis (MASH). MASH (also known as NASH, non-alcoholic steatohepatitis) is a disease caused by fat building up in the liver, resulting in inflammation and damage to the liver. Rezdiffra is used in adults with moderate or significant scarring of the liver (stage 2 or stage 3 fibrosis).

Rezdiffra contains the active substance resmetirom.

How is Rezdiffra used?

Rezdiffra can only be obtained with a prescription. It is available as tablets to be taken by mouth once a day.

Rezdiffra should not be used together with medicines such as gemfibrozil that strongly block the effects of CYP2C8, a liver enzyme that helps the body break down many medicines, as this could affect the breaking down of Rezdiffra. If Rezdiffra is used with moderate inhibitors of CYP2C8 (such as clopidogrel, deferasirox, and teriflunomide), its dose should be reduced.

For more information about using Rezdiffra, see the package leaflet or contact your doctor or pharmacist.

How does Rezdiffra work?

In patients with MASH, a protein called thyroid hormone receptor beta (THR-beta), which helps breakdown fat, does not work properly. The active substance in Rezdiffra, resmetirom, works by attaching to and activating THR-beta in liver cells. By activating THR-beta, resmetirom increases fat breakdown; this reduces the amount of fat stored in the liver which can help reduce inflammation and fibrosis, and improve liver function.

What benefits of Rezdiffra have been shown in studies?

A main study showed that Rezdiffra is effective at reducing MASH symptoms and liver fibrosis.

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The main study involved 917 adults with MASH and liver fibrosis stage F2 (moderate) or F3 (advanced) who received either Rezdiffra or placebo (a dummy treatment) for 12 months. The study looked at the proportion of patients with resolution of MASH symptoms, as measured by the improvement or disappearance of inflammation and ballooning (damage to liver cells), with no worsening of fibrosis. The study also measured improvements in patients' fibrosis without worsening of MASH symptoms.

After 12 months, depending on the dose, around 26 to 30% of patients who received Rezdiffra achieved MASH resolution with no worsening of fibrosis, compared with 10% of patients who received placebo. In addition, around 27 to 29% of patients who received Rezdiffra had an improvement of liver fibrosis and no worsening of MASH, compared with 17% of those who received placebo.

What are the risks associated with Rezdiffra?

For the full list of side effects and restrictions with Rezdiffra, see the package leaflet.

The most common side effects with Rezdiffra (which may affect more than 1 in 10 people) include diarrhoea and nausea (feeling sick). Diarrhoea typically occurs at start of treatment, is mild to moderate and resolves on average in 2 to 3 weeks.

Pruritus (itching) may affect up to 1 in 10 people. Cholecystitis (inflammation of the gallbladder, often caused by gallstones blocking the bile duct) and urticaria (itchy rash) may affect up to 1 in 1,000 people.

Why is Rezdiffra authorised in the EU?

At the time of approval, there was no authorised treatment for patients with MASH, a disease associated with serious and life-threatening symptoms, including cirrhosis (severe and permanent scarring of the liver) if left untreated. Rezdiffra has been shown to reduce the symptoms of the disease and fibrosis, which are considered meaningful health benefits. There are no data yet on whether these benefits will reduce advanced liver disease and liver transplantation, or improve survival. However, further long-term data will be provided to address these questions. In terms of safety, the most frequent side effects are acceptable.

Rezdiffra has been given conditional authorisation for use in the EU. This means that it has been authorised on the basis of less comprehensive data than are normally required because it fulfils an unmet medical need. The European Medicines Agency considers that the benefit of having the medicine available earlier outweighs any risks associated with using it while awaiting further evidence.

The company must provide further data on Rezdiffra. It must submit further results from two ongoing studies comparing Rezdiffra with placebo in patients with MASH and moderate to advanced liver fibrosis. Every year, the Agency will review any new information that becomes available.

What measures are being taken to ensure the safe and effective use of Rezdiffra?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Rezdiffra have been included in the summary of product characteristics and the package leaflet.

As for all medicines, data on the use of Rezdiffra are continuously monitored. Suspected side effects reported with Rezdiffra are carefully evaluated and any necessary action taken to protect patients.

Other information about Rezdiffra

Rezdiffra received a conditional marketing authorisation valid throughout the EU on 18 August 2025.

Further information on Rezdiffra can be found on the Agency's website: ema.europa.eu/medicines/human/EPAR/rezdiffra.

This overview was last updated in 07-2025.