Package leaflet: Information for the patient

Rezdiffra 60 mg film-coated tablets
Rezdiffra 80 mg film-coated tablets
Rezdiffra 100 mg film-coated tablets
resmetirom

▼This medicine is subject to additional monitoring. This will allow quick identification of new safety information. You can help by reporting any side effects you may get. See the end of section 4 for how to report side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist or nurse.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Rezdiffra is and what it is used for

Rezdiffra contains the active substance resmetirom.

Rezdiffra is a medicine used in adults to treat metabolic dysfunction-associated steatohepatitis (MASH). MASH is a liver disease where fat builds up in the liver, which can result in inflammation and damage to the liver cells. Rezdiffra is used in adults who have experienced inflammation and cell damage, resulting in moderate scarring (consistent with stage 2 fibrosis) or significant scarring (consistent with stage 3 fibrosis).

The active substance in Rezdiffra, resmetirom, works by binding to and activating a protein called thyroid hormone receptor beta (THR-β) in a type of liver cell called hepatocytes. In patients with MASH, THR-β is working less. By activating THR-β in the liver, resmetirom increases fat breakdown. This reduces the amount of fat stored in the liver which can help reduce inflammation, fibrosis and improve its function.

2. What you need to know before you take Rezdiffra

Do not take Rezdiffra

- if you are allergic to resmetirom or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Rezdiffra.

In particular tell your doctor if you:
- have liver problems other than MASH, such as a liver infection including viral hepatitis (inflammation of the liver caused by a viral infection) or any liver disease involving the immune system (the body's natural defences). This includes autoimmune hepatitis (inflammation of the liver caused by the immune system attacking the body's own cells) and primary biliary cholangitis (liver damage caused when the immune system attacks the bile ducts, tubes which carry bile from the liver)
- drink alcoholic beverages or have liver damage due to drinking alcohol
- have gallbladder problems, including gallstones (small stones, usually made of cholesterol, that form in the gallbladder)

Children and adolescents

Do not give this medicine to children and adolescents under 18 years of age. It is not known if Rezdiffra is safe and effective for them.

Other medicines and Rezdiffra

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Tell your doctor or pharmacist if you take any of the following medicines because these medicines may increase the level of Rezdiffra in your body which may increase your risk of side effects with Rezdiffra:
- *clopidogrel* (to reduce clotting of the blood)
- *deferasirox* (to remove excess iron from the body)
- *gemfibrozil* (to lower blood fats)
- *teriflunomide* (to treat multiple sclerosis)

Tell your doctor or pharmacist if you take any of the following medicines because Rezdiffra may increase the levels of these medicines in your body which may increase your risk of side effects with these medicines:
- *atorvastatin, pravastatin, rosuvastatin, simvastatin* (a group of medicines called statins, to lower cholesterol levels)
- *pioglitazone* (or other so-called CYP2C8 substrates, a particular class of medicine to treat diabetes)

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Rezdiffra has not been studied in pregnant women. Rezdiffra is not recommended for use during pregnancy.

It is not known if Rezdiffra can pass into breast milk and affect the baby. Your doctor will help you to decide whether to stop breast-feeding or avoid Rezdiffra treatment, considering the benefit of breast-feeding to the baby and Rezdiffra to the mother.

Driving and using machines

This medicine has no or negligible influence on your ability to drive or use machines.

Rezdiffra contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Rezdiffra

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much to take

Rezdiffra is available as a tablet taken by mouth, which can be taken with or without food. The dose of Rezdiffra is based on your body weight. For patients weighing:
- less than 100 kg, the recommended dose is 80 mg taken once daily.
- 100 kg or more, the recommended dose is 100 mg taken once daily.

Your doctor may adjust your dose depending on your liver function and if you take certain medicines (see section "Other medicines and Rezdiffra").

If you take more Rezdiffra than you should

Tell your doctor if you have or think you have taken too much Rezdiffra.

If you forget to take Rezdiffra

Do not take a double dose to make up for a forgotten dose. Take the next dose at the usual time.

If you stop taking Rezdiffra

Do not stop taking Rezdiffra without first discussing with your doctor.

If you have any further questions on the use of this medicine, ask your doctor, pharmacist or nurse.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

You may experience nausea and diarrhoea when you start taking Rezdiffra. These side effects are generally mild and often stop on their own in less than 3 weeks. If these problems are not resolved within 3 weeks or if they become worse, contact your doctor.

Very common (may affect more than 1 in 10 people):
- diarrhoea
- feeling sick (nausea)

Common (may affect up to 1 in 10 people):
- itching (pruritus)

Uncommon (may affect up to 1 in 100 people):
- vomiting
- belly (abdominal) pain
- constipation
- rash
- dizziness

Rare (may affect up to 1 in 1,000 people):
- inflammation of the pancreas due to a blockage (obstructive pancreatitis)
- gallstones (cholelithiasis)
- inflammation of the gallbladder (cholecystitis) or problems with the pancreas or bile duct
- itchy rash (urticaria)

Not known (frequency cannot be estimated from the available data):
- Abnormal liver function tests (hepatoxicity)

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Rezdiffra

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton and blister after EXP. The expiry date refers to the last day of that month.

Store below 30 °C.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Rezdiffra contains

- The active substance is resmetirom.
  Each film-coated tablet contains:
  - Rezdiffra 60 mg: 60 mg of resmetirom.
  - Rezdiffra 80 mg: 80 mg of resmetirom.
  - Rezdiffra 100 mg: 100 mg of resmetirom.

- The other ingredients are:
  - *Tablet core*: Microcrystalline cellulose, mannitol, croscarmellose sodium (see section 2 "Rezdiffra contains sodium"), colloidal anhydrous silica, magnesium stearate.
  - *Tablet film-coating*: Poly(vinyl alcohol), titanium dioxide (E171), macrogol, talc.
    - Rezdiffra 80 mg film-coated tablets also contain yellow iron oxide (E172).

- Rezdiffra 100 mg film-coated tablets also contain yellow iron oxide (E172) and red iron oxide (E172).

What Rezdiffra looks like and contents of the pack

Rezdiffra 60 mg film-coated tablets are white, 6.4 mm x 12.2 mm oval film-coated tablets with “P60” on one side and plain on the other side.

Rezdiffra 80 mg film-coated tablets are yellow, 7.1 mm x 13.5 mm oval film-coated tablets with “P80” on one side and plain on the other side.

Rezdiffra 100 mg film-coated tablets are beige to pinkish, 7.6 mm x 14.6 mm oval film-coated tablets with “P100” on one side and plain on the other side.

Rezdiffra film-coated tablets are packed in PVC/PCTFE blisters with aluminium foil lidding.

Pack size

28 film-coated tablets.

Marketing Authorisation Holder

Madrigal Pharmaceuticals EU Limited
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Manufacturer

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This leaflet was last revised in 03/2026

This medicine has been given ‘conditional approval’. This means that there is more evidence to come about this medicine. The Medicines and Healthcare products Regulatory Agency will review new information on this medicine at least every year and this leaflet will be updated as necessary.

Other sources of information

Detailed information on this medicine is available on the Medicines and Healthcare products Regulatory Agency web site: https://www.gov.uk/government/organisations/medicines-and-healthcare-products-regulatory-agency.