

PATIENT INFORMATION

REZDIFFRA (rez di' frah)
(resmetirom)
tablets, for oral use

What is REZDIFFRA?

REZDIFFRA is a prescribed medicine used along with diet and exercise to treat adults with nonalcoholic steatohepatitis (NASH) with moderate to advanced liver scarring (fibrosis), but not with cirrhosis of the liver.

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

Before you take REZDIFFRA, tell your healthcare provider about all of your medical conditions, including if you:

- have any liver problems other than NASH.
- have gallbladder problems or have been told you have gallbladder problems, including gallstones.
- are pregnant or plan to become pregnant. It is not known if REZDIFFRA will harm your unborn baby.
 - **Pregnancy Safety Study.** There is a pregnancy safety study for women who are or become pregnant during treatment with REZDIFFRA. The purpose of this pregnancy safety study is to collect information about your health and your baby's health. You or your healthcare provider can report your pregnancy by visiting <https://pregnancyregistry.madrigalpharma.com/> or calling 1-800-905-0324.
- are breastfeeding or plan to breastfeed. It is not known if REZDIFFRA passes into your breast milk. Talk to your healthcare provider about the best way to feed your baby if you take REZDIFFRA.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements.

REZDIFFRA and other medicines may affect each other, causing side effects. REZDIFFRA may affect the way other medicines work, and other medicines may affect how REZDIFFRA works.

Especially tell your healthcare provider if you take medicines that contain gemfibrozil to help lower your triglycerides because REZDIFFRA is not recommended in patients taking these medicines.

Tell your healthcare provider if you are taking medicines such as clopidogrel to thin your blood or statin medicines to help lower your cholesterol.

Know the medicines you take. Keep a list of them to show your healthcare provider and pharmacist when you get a new medicine.

How should I take REZDIFFRA?

- Take REZDIFFRA exactly as your healthcare provider tells you to take it.
- Your dose of REZDIFFRA is based on your body weight.
- Take REZDIFFRA by mouth, 1 time a day with or without food.
- Swallow REZDIFFRA tablets whole. Do not split, crush, or chew tablets.
- If you miss a dose of REZDIFFRA, skip the missed dose and take your next dose at the regular time.

What are the possible side effects of REZDIFFRA?

REZDIFFRA may cause serious side effects, including:

- **liver injury (hepatotoxicity).** Stop taking REZDIFFRA and call your healthcare provider right away if you develop the following signs or symptoms of hepatotoxicity:
 - tiredness
 - nausea
 - vomiting
 - fever
 - rash
 - your skin or the white part of your eyes turns yellow (jaundice)
 - pain or tenderness in the upper middle or upper right area of your stomach (abdomen)
- **gallbladder problems.** Gallbladder problems such as gallstones, or inflammation of the gallbladder, or inflammation of the pancreas from gallstones can occur with NASH and may occur if you take REZDIFFRA. Call your healthcare provider right away if you develop any signs or symptoms of these conditions, including nausea, vomiting, fever, or pain in your stomach area (abdomen) that is severe and will not go away. The pain may be felt going from your abdomen to your back and the pain may happen with or without vomiting.

The most common side effects of REZDIFFRA include:

- diarrhea
- itching
- vomiting
- constipation
- nausea
- stomach (abdominal) pain
- dizziness

These are not all the possible side effects of REZDIFFRA. For more information, ask your healthcare provider or pharmacist.

Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

You may also report side effects to www.fda.gov/medwatch.

How should I store REZDIFFRA?

- Store REZDIFFRA at room temperature between 68°F to 77°F (20°C to 25°C).

Keep REZDIFFRA and all medicines out of the reach of children.**General information about the safe and effective use of REZDIFFRA.**

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use REZDIFFRA for a condition for which it was not prescribed. Do not give REZDIFFRA to other people, even if they have the same symptoms that you have. It may harm them.

You can ask your pharmacist or healthcare provider for information about REZDIFFRA that is written for health professionals.

What are the ingredients in REZDIFFRA?

Active ingredient: resmetirom

Inactive ingredients: colloidal silicon dioxide, croscarmellose sodium, magnesium stearate, mannitol, and microcrystalline cellulose. The film coating contains: polyethylene glycol, polyvinyl alcohol, talc, titanium dioxide, red iron oxide (100 mg tablets), and yellow iron oxide (80 mg and 100 mg tablets).

Manufactured for and Distributed by:

Madrigal Pharmaceuticals, Inc.

West Conshohocken, PA

This Patient Information has been approved by the U.S. Food and Drug Administration.

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