



Information for the patient

Odxibat 200 micrograms hard capsules

Odxibat 1200 micrograms hard capsules

Odevixibat

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 or pharmacist.
- 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 or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Odxibat is and what it is used for
2. What you need to know before you take Odxibat
3. How to take Odxibat
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1. What Odxibat is and what it is used for

Odxibat contains the active substance odevixibat. Odevixibat is a medicine which increases the removal of substances called bile acids from the body. Bile acids are components of the digestive fluid called bile, which is produced by the liver and secreted into the intestines. Odevixibat blocks the mechanism that normally reabsorbs them from the intestines after they have done their job. This allows them to pass out of the body in the stool.

Odxibat is used to treat progressive familial intrahepatic cholestasis (PFIC) in patients aged 6 months or older. PFIC is a liver disease caused by build-up of bile acids (cholestasis) that gets worse over time and is often accompanied with severe itching.

2. What you need to know before you take Odxibat

Do not take Odxibat

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Odxibat if you have:

- been diagnosed with a complete absence or lack of function of bile salt export pump protein
- severely reduced liver function
- reduced stomach or bowel motility, or reduced circulation of bile acids between liver, bile and small intestine due to medicines,

surgical procedures or diseases other than PFIC since these may reduce the effect of odevixibat

Talk to your doctor if you develop diarrhoea while taking Odxibat. Drinking sufficient liquid is recommended in patients with diarrhoea to prevent dehydration.

Increased levels in liver function tests can occur in some patients receiving Odxibat. Assessment of liver function is recommended for all patients prior to Odxibat treatment. Your doctor may recommend more frequent monitoring if you have elevated liver function test results.

Your doctor may recommend assessment of Vitamin A, D and E blood levels and the blood clotting value called INR prior to and during Odxibat treatment.

Children

Odxibat is not recommended for babies under 6 months because it is not known if the medicine is safe and effective in this age group.

Other medicines and Odxibat

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

Treatment with odevixibat may affect the absorption of fat-soluble vitamins such as Vitamin A, D and E, and some medicines, including oral contraceptives.

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.

Odxibat is not recommended during pregnancy and in women of childbearing potential not using contraception. Use of a barrier contraceptive method is recommended since the uptake of lipophilic oral contraceptives may be affected by odevixibat.

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

Driving and using machines

Odxibat has no or negligible influence on the ability to drive or capacity to use machinery.

3. How to take Odxibat

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

Treatment must be started and supervised by a doctor experienced in the management of progressive liver disease with reduced bile flow.

The dose of Odxibat is based on your weight. Your doctor will work out the right number and strength of capsules for you to take.

The recommended dose is

- 40 micrograms odevixibat per kilogram body weight once daily
- If the medicine is not working well enough after 3 months, your doctor may increase the dose to 120 micrograms odevixibat

per kilogram body weight (up to a maximum of 7200 micrograms once daily).
No dose differences are recommended for adults.

Method of use

Take the capsules once daily in the morning with or without food.

All capsules can be either swallowed whole with a glass of water or opened and sprinkled on food.

The larger 200 micrograms capsules are intended to be opened and sprinkled on food but may be swallowed whole.

The smaller 1200 micrograms capsules are intended to be swallowed whole but may be opened and sprinkled on food.

If the medicine does not improve your condition after 6 months of continuous daily treatment, your doctor will recommend an alternative treatment.

If you take more Odxibat than you should

Tell your doctor if you think you have taken too much Odxibat.

Possible overdose symptoms are diarrhoea, stomach and bowel problems.

If you forget to take Odxibat

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 Odxibat

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

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

4. Possible side effects

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

Side effects may occur with the following frequency:

common (may affect up to 1 in 10 people)

- diarrhoea, including diarrhoea with bloody stool, soft stools
- abdominal (belly) pain
- enlarged liver

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. By reporting side effects, you can help provide more information on the safety of this medicine.

5. How to store Odxibat

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 bottle after EXP. The expiry date refers to the last day of that month.

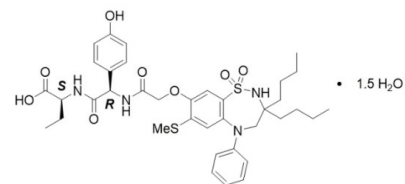
Store in the original package to protect from light. Do not store above 25 °C.

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 Odxibat contains

- The active substance is odeixibat. is (2S)-2-((2R)-2-(2-((3,3-dibutyl-7-(methylsulfonyl)-1,1-dioxo-5-phenyl-2,3,4,5-tetrahydro-1H-1,6,2,5-benzothiadiazepin-8yl)oxy)acetamido)-2-(4-hydroxyphenyl)acetyl)amino}butanoic acid, which is formulated as the sesquihydrate having the following chemical structure:



Each Odxibat 200 micrograms hard capsule contains 200 micrograms odeixibat (as sesquihydrate).

Each Odxibat 1 200 micrograms hard capsule contains 1 200 micrograms odeixibat (as sesquihydrate).

- Other ingredients are:

Capsule content: Microcrystalline cellulose, Hypromellose

Capsule shell: Hypromellose Titanium dioxide

What Odxibat looks like and contents of the pack

Odxibat 200 micrograms hard capsules: Size 0 capsules white

Odxibat 1 200 micrograms hard capsules: Size 3 capsules white

Odxibat hard capsules are packed in a plastic bottle with a tamper evident, child resistant polypropylene closure. Pack size: 30 hard capsules.

Manufacturer

Tongmeng(Lao) Pharmaceutical and Food Co., Ltd

Rd13 South,31km,Ban Naphasuk,Saithany District. Vientiane. Lao PDR



TLPH