

Hepacure®

Hepacure 1 mg
Hepacure 0.5 mg
film-coated tablets
(Entecavir)

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).

In this leaflet:

1. What **Hepacure** is and what it is used for
2. What you need to know before you take **Hepacure**
3. How to take **Hepacure**
4. Possible side effects
5. How to store **Hepacure**
6. Further information

1. What **Hepacure** is and what it is used for

Hepacure is an anti-viral medicine, used to treat chronic (long term) hepatitis B virus (HBV) infection in adults. **Hepacure** can be used in people whose liver is damaged but still functions properly (compensated liver disease) and in people whose liver is damaged and does not function properly (decompensated liver disease).

Infection by the hepatitis B virus can lead to damage to the liver.

Hepacure reduces the amount of virus in your body, and improves the condition of the liver.

2. Before you take **Hepacure**

Do not take **Hepacure**

- If you are hypersensitive to entecavir or any of the other ingredients of this medicine.

Warning and precautions

Talk to your doctor or pharmacist before taking **Hepacure**:

- If you have ever had problems with your kidneys, tell your doctor. This is important because **Hepacure** is eliminated from your body through the kidneys and your dose or dosing schedule may need to be adjusted.

- Do not stop taking **Hepacure** without your doctor's advice since your hepatitis may worsen after stopping treatment. When your treatment with **Hepacure** is stopped, your doctor will continue to monitor you and take blood tests for several months.

- Discuss with your doctor whether your liver functions properly and, if not, what the possible effects on your **Hepacure** treatment may be.

- If you are also infected with HIV (human immunodeficiency virus) be sure to tell your doctor. You should not take **Hepacure** to treat your hepatitis B infection unless you are taking medicines for HIV at the same time, as the effectiveness of future HIV treatment may be reduced.

Hepacure will not control your HIV infection.

- Taking **Hepacure** will not stop you from infecting other people with hepatitis B virus (HBV) through sexual contact or body fluids (including blood contamination).

So, it is important to take appropriate precautions to prevent others from becoming infected with HBV. A vaccine is available to protect those at risk from becoming infected with HBV.

- **Hepacure** belongs to a class of medicines that can cause lactic acidosis (excess of lactic acid in your blood) and enlargement of the liver.

Symptoms such as nausea, vomiting and stomach pain might indicate the development of lactic acidosis. This rare but serious side effect has occasionally been fatal. Lactic acidosis occurs more often in women, particularly if they are very overweight.

- If you have previously received treatment for chronic hepatitis B, please inform your doctor.

Children and adolescents

Hepacure should not be used for children below 2 years of age or weighing less than 10 kg.

Other medicines and **Hepacure**

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

Hepacure with food and drink

In most cases you may take **Hepacure** with or without food. However, if you have had a previous treatment with a medicine containing the active substance lamivudine you should consider the following:

If you were switched over to **Hepacure** because the treatment with lamivudine was not successful, you should take **Hepacure** on an empty stomach once daily. If your liver disease is very advanced, your doctor will also instruct you to take **Hepacure** on an empty stomach.

Empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant or planning to become pregnant. It has not been demonstrated that **Hepacure** is safe to use during pregnancy.

Hepacure must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with **Hepacure** to use an effective method of contraception to avoid becoming pregnant. You should not breast-feed during treatment with **Hepacure**. Tell your doctor if you are breast-feeding. It is not known whether entecavir, the active ingredient in **Hepacure**, is excreted in human breast milk.

Driving and using machines

Dizziness, tiredness (fatigue) and sleepiness (somnia) are common side effects which may impair your ability to drive and use machines.

If you have any concerns consult your doctor.

Hepacure tablets contain lactose.

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take **Hepacure**

Not all patients need to take the same dose of **Hepacure**.

For adults the recommended dose is either 0.5 mg or 1 mg once daily by mouth.

Your dose will depend on:

- Whether you have been treated for HBV infection before, and what medicine you received.

- Whether you have kidney problems. Your doctor may prescribe a lower dose for you or instruct you to take it less often than once a day.

- The condition of your liver.

For children and adolescents: Adolescents and children weighing at least 32.6 kg may take 0.5 mg tablet. All dosing will be taken once daily orally.

Take **Hepacure** as long as your doctor has told you. Your doctor will tell you if and when you should stop the treatment.

If you took more **Hepacure than you should**

Contact your doctor at once.

If you forget to take **Hepacure**

It is important that you do not miss any doses. If you miss a dose of **Hepacure**, take it as soon as possible, and then take your next scheduled dose at its regular time.

If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose.

Do not stop **Hepacure** without your doctor's advice

Some people get very serious hepatitis symptoms when they stop taking **Hepacure**. Tell your doctor immediately about any changes in symptoms that you notice after stopping treatment.

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.

- **Common** (at least 1 in 100 patients): headache, insomnia, fatigue, dizziness, somnolence (sleepiness), vomiting, diarrhoea, nausea, dyspepsia, and increased blood levels of liver enzymes.

- **Uncommon** (at least 1 in 1,000 patients): rash, hair loss.

- **Rare** (at least 1 in 10,000 patients): severe allergic reaction.

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

5. How to store **Hepacure**

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

- Do not store above 30°C. Store in the original pack.

- Do not use this medicine after the expiry date which is stated on the blister or pack.

- 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. Further Information

What **Hepacure** contains

- The active substance is entecavir. Each film-coated tablet contains 0.5 mg or 1 mg entecavir.

- The other ingredients are:

Microcrystalline cellulose, lactose, povidone, croscopolidone, magnesium stearate, hypromellose, polyethylene glycol, titanium dioxide, red iron oxide non irradiated, FD&C blue and indigo carmine aluminum lake.

What **Hepacure** looks like and contents of the pack

The 1 mg and 0.5 mg film-coated tablets are pink and round shaped, supplied in packs containing 3 blisters, each blister contains 10 film-coated tablets.

Marketing Authorization holder and manufacturer:

Azal Pharma

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Website: www.azalpharma.com

To report any Side effect

National Medicines and Poisons Board (NMPB)
Fax (+249)183522263
E-mail: info@nmpb.gov.sd
Website: www.nmpb.gov.sd

THIS IS A MEDICAMENT

- Medicament is a product which affects your health, and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of pharmacist who sold the medicament.
- The doctor and the pharmacist are experts in medicine, its benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consultation your doctor.
- Keep medicament out of reach of children.

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Khartoum - Sudan

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