

HOVID ENTECAVIR TABLETS

Entecavir tablets 0.5mg (0.5mg), Entecavir tablets 1.0mg (1 mg)

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What Hovid Entecavir is used for

Hovid Entecavir is indicated for the treatment of chronic hepatitis B (HBV) infection in adult:

- whose liver is damaged but still functions properly (compensated liver disease)
- whose liver is damaged and does not function properly (decompensated liver disease).

How Hovid Entecavir works

Infection by the hepatitis B virus can lead to damage to the liver. Hovid Entecavir reduces the amount of virus in your body, and improves the condition of the liver.

Before you use Hovid Entecavir

- When you must not use it

Do not take this medicine if:

- you are allergic (hypersensitive) to entecavir or any of the other ingredients of this medicine
- you are HIV/HBV co-infected patient and also not receiving highly active antiretroviral therapy (HAART).
- you are pregnant or planning to become pregnant, unless considered essential by the physician. It has not been demonstrated that Hovid Entecavir is safe to use during pregnancy
- you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether entecavir, the active ingredient in Hovid Entecavir, is excreted in human breast milk.

Hovid Entecavir is not recommended for children below the age of 16 years.

- Before you start to use it

Inform and discuss with your doctor or pharmacist if:

- you have ever had problems with your kidneys
- you have a transplanted liver
- your liver does not function properly (decompensated liver disease)
- you have any other allergies or health problem
- you have previously received treatment for chronic hepatitis B

Your doctor will decide whether Hovid Entecavir tablet is suitable for you or not.

- Taking other medicines

Talk to your doctor or pharmacist if you are taking any other medicines in any form including any that you buy or obtained without a prescription as interactions with Entecavir may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use Hovid Entecavir

- How much to use

Follow all directions given to you by your doctor and pharmacist carefully. They may differ from the information contained in this leaflet. If you do not understand the instructions on the label, ask your doctor or pharmacist for help. Your doctor will decide on the dose that suits you based on your condition.

Hovid Entecavir is for oral administration only.

The recommended dose is either 0.5 mg or 1 mg tablet once daily. The dose depends 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.

- When to use it

Use as directed by your doctor or pharmacist. Hovid Entecavir should be taken on empty stomach unless otherwise advised by your doctor or pharmacist.

- How long to use it

Continue taking Hovid Entecavir for as long as your doctor recommends.

- If you forget to use it

Take the missed dose as soon as you remember, 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.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using Hovid Entecavir

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell your doctor immediately if you experience any allergy reaction / adverse effects while taking this medicine.
- Tell your doctor immediately if you become pregnant while taking this medication.

- Things you must not do

- Do not take Hovid Entecavir with food unless advised by your doctor or pharmacist.
- Do not give your medicine to anyone else even if they have the same condition as you.

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- Do not take any new medicines without consulting your doctor or pharmacist.
- Do not take this medicine to treat other health problems unless told by your doctor or pharmacist.
- Do not stop taking the medicine unless advised by your doctor.

-Disposal

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

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- Things to be careful of

Therapy with Hovid Entecavir has not been proven to reduce the risk of transmission of HBV and, therefore, appropriate precautions should still be taken.

Side effects

Tell your doctor immediately if you think you are experiencing any of the following possible unwanted side effects while taking the medicine such as:

- Sleeping difficulty
- Headache
- Dizziness
- Extreme sleepiness
- Nausea
- Diarrhea
- Indigestion
- Vomiting
- Fatigue
- Worsening of liver inflammation
- Liver not functioning properly
- Hair loss
- Rash

Other unwanted side effects not listed may occur. Tell your doctor immediately.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npa.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Hovid Entecavir

-Storage

Keep out of reach of children.
Store below 30°C.

Product description

-What it looks like

Hovid Entecavir Tablets 0.5 mg

White triangular shaped film-coated tablets debossed 'A' on one side and '88' on the other side.

Hovid Entecavir Tablets 1 mg

Pink triangular shaped film-coated tablets debossed 'A' on one side and '89' on other side.

-Ingredients

-Active ingredients

Each Hovid Entecavir Tablets 0.5 mg contains: Entecavir 0.5 mg

Each Hovid Entecavir Tablets 1 mg contains: Entecavir 1 mg

-Inactive ingredients

Lactose monohydrate
Microcrystalline cellulose
Crospovidone
Hypromellose
Magnesium stearate

-MAL Number(s):

MAL20016149ACZ

Manufacturer

Cohance Lifesciences Limited
Plot No. A-19/C, A-23A, A-23B,
Road No.18, IDA, Nacharam,
Medchal-Malkajgiri District,
Telangana, 500 076, India.

Product Registration Holder

Hovid Bhd.
121, Jalan Tunku Abdul Rahman
(Jalan Kuala Kangsar),
30010 Ipoh, Perak, Malaysia.

Date of revision

0407/2023