

ENCAVID TABLETS 0.5MG

Entecavir Tablets (0.5mg)

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What Encavid Tablets 0.5mg is used for

Encavid Tablets 0.5mg is indicated for the treatment of chronic hepatitis B (HBV) infection in adult with evidence of active viral replication.

How Encavid Tablets 0.5mg works

Infection by the hepatitis B virus can lead to damage to the liver. Encavid Tablets 0.5mg reduces the amount of virus in your body, and improves the condition of the liver.

Before you use Encavid Tablets 0.5mg

- 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).

Do not take Encavid Tablets 0.5mg if you are pregnant or planning to become pregnant, unless considered essential by the physician. It has not been demonstrated that Encavid Tablets 0.5mg is safe to use during pregnancy.

Do not take Encavid Tablets 0.5mg if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine. It is not known whether entecavir, the active ingredient in

Encavid Tablets 0.5mg is excreted in human breast milk.

Encavid Tablets 0.5mg 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, please inform your doctor.

Your doctor will decide whether Encavid Tablets 0.5mg 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.

Interactions may occur. Talk to your doctor or pharmacist if you have any other concerns.

How to use Encavid Tablets 0.5mg

- 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.

Adults:

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

- When to use it

Use as directed by your doctor or pharmacist. Encavid Tablets 0.5mg should be taken on empty stomach unless otherwise advised by your doctor or pharmacist.

- How long to use it

Continue taking Encavid Tablets 0.5mg 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 Encavid Tablets 0.5mg

- Things you must do

- Take your medicine exactly as your doctor has told you.
- Tell your doctor immediately if you become pregnant while taking this medication.

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-Things you must not do

Do not:

- take Encavid Tablets 0.5mg with food unless advised by your doctor or pharmacist.
- give your medicine to anyone else even if they have the same condition as you
- take any new medicines without consulting your doctor or pharmacist
- stop taking the medicine unless advised by your doctor

- Things to be careful of

Therapy with Encavid Tablets 0.5mg 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.

- 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 nptra.gov.my [Consumers→ Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)]

Storage and Disposal of Encavid Tablets 0.5mg

-Storage

Keep out of reach of children.
Store below 30°C. Protect from light.

-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.

Product description

-What it looks like

Encavid Tablets 0.5mg

White colored, circular, biconvex, film coated tablets, plain on both sides.

-Ingredients

-Active ingredients

Each Encavid Tablets 0.5mg contains:
Entecavir monohydrate 0.54mg eq to
Entecavir 0.5 mg

-Inactive ingredients

Lactose monohydrate
Maize starch
Pregelatinised starch
Croscarmellose sodium
Colloidal anhydrous silica
Sodium starch glycolate
Magnesium stearate
Instacoat sol white IC-S-6578

-MAL Number(s):

MAL23046008ACZ

Manufacturer

RV Lifesciences Limited
Plot No. H-19, MIDC Waluj,
Aurangabad (MS) 431133, India.

Product Registration Holder

Hovid Pharmacy Sdn. Bhd.
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