

TECAVIR 0.5 (Entecavir Tablets 0.5mg)

TECAVIR 1 (Entecavir Tablets 1mg)

Entecavir (0.5mg, 1mg)

What is in this leaflet

1. What TECAVIR is used for
2. How TECAVIR works
3. Before you use TECAVIR
4. How to use TECAVIR
5. While you using it
6. Side effects
7. Storage and Disposal of TECAVIR
8. Product Description
9. Manufacturer and Product Registration Holder
10. Date of revision
11. Serial Number

1. What TECAVIR is used for

Entecavir tablets is anti-viral medicines, used to treat chronic (long term) hepatitis B virus (HBV) infection in adults. Entecavir 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).

2. How TECAVIR works

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

3. Before you use TECAVIR

- When you must not use it

If you are allergic to entecavir or any of the other ingredients of this medicine

Pregnancy and lactation

Do not take TECAVIR if you are pregnant, trying to get pregnant or think you may be pregnant.

Do not take TECAVIR if you are breastfeeding. Ask your doctor or pharmacist for advice before taking any medicine.

- Before you start to use it

You should not take this medication if you are allergic to entecavir, or if you also have HIV (human immunodeficiency virus) that is not being treated.

If you have certain conditions, you may need a dose adjustment or special tests to safely take this medication. Before you take entecavir, tell your doctor if you are allergic to any drugs, or if you have:

- HIV or AIDS;
- kidney disease;
- liver disease; or
- if you have had a liver transplant.

Some people have developed a life-threatening condition called lactic acidosis (excess of lactic acid in your blood) while taking entecavir. 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. Your doctor will monitor you regularly while you are receiving entecavir.

- Taking other medicines

Tell your doctor if you are taking any other medicines, especially those that may affect the kidney. These medicines include any that you buy without a prescription from a pharmacy, supermarket or health food shop. Do not start using a new medication without telling your doctor.

4. How to use TECAVIR

- 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.

Not all patients need to take the same dose of TECAVIR.

The recommended dose is either 0.5 mg or 1 mg once daily orally (by mouth).

- When to use it

Use as directed by your doctor or pharmacist.

- How long to use it

Continue taking TECAVIR for as long as your doctor recommends.

- If you forget to use it

Consult your doctor or pharmacist on what you should do if you forget to use it.

Take the missed dose as soon as you remember. If it is almost time for your next dose, wait until then to take the medicine and skip the missed dose. Do not take a double dose to make up for the missed 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.

5. While you are using it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell all the doctors, dentists and pharmacists treating you that you are taking TECAVIR.

Tell your doctor immediately if you

TECAVIR 0.5 (Entecavir Tablets 0.5mg)

TECAVIR 1 (Entecavir Tablets 1mg)

Entecavir (0.5mg, 1mg)

become pregnant while taking this medication.

Take appropriate precautions to prevent others from becoming infected with HBV. Taking entecavir will not stop you from infecting other people with HBV through sexual contact or body fluids (including blood contamination). A vaccine is available to protect those at risk from becoming infected with HBV.

- Things you must not do

Do not stop taking the medicine unless advised by your doctor.

Do not take any new medicines without consulting your doctor.

6. Side effects

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

The following are side effects that have been reported:

Common: headache, insomnia (inability to sleep), fatigue (extreme tiredness), dizziness, somnolence (sleepiness), vomiting, diarrhoea, nausea, dyspepsia (indigestion), and increased blood levels of liver enzymes.

Uncommon: rash, alopecia (hair loss)

Rare: anaphylactoid reaction (life-threatening 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.

Visit your doctor or pharmacist immediately if you experience any side effects after taking this medicine.

You may report any side effects or

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

7. Storage and Disposal of TECAVIR

- Storage

Keep out of the reach and sight of children.

Store below 30°C and protect from light and moisture.

- 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.

8. Product Description

- What it looks like

TECAVIR 0.5 (Entecavir Tablets 0.5 mg)

White to off-white, triangle shaped, biconvex film-coated tablets debossed with 'J' on one side and '110' on other side.

TECAVIR 1 (Entecavir Tablets 1 mg)

Pink, triangle shaped, biconvex, filmcoated tablets, debossed with 'J' on one side and '111' on the other side.

Ingredients

- Active ingredient Entecavir monohydrate
- Inactive ingredients

TECAVIR 0.5 (Entecavir Tablets 0.5 mg)

Calcium Carbonate, Starch, (Pregelatinized), Carmellose sodium, Soy polysaccharides, Purified Water,

Citric acid monohydrate, Sodium stearyl fumarate, Opadry White 13B58802.

TECAVIR 1 (Entecavir Tablets 1 mg)

Calcium Carbonate, Starch, (Pregelatinized), Carmellose sodium, Soy polysaccharides, Purified Water, Citric acid monohydrate, Sodium stearyl fumarate, Opadry pink 03B84566.

- MAL number(s):

TECAVIR 0.5 (Entecavir Tablets 0.5 mg)

MAL18126105AZ

TECAVIR 1 (Entecavir Tablets 1 mg)

MAL18126104AZ

9. Manufacturer and Product Registration Holder

Manufacturer

Hetero Labs Limited,
Unit V,
Sy. No 439, 440, 441 & 458,
TSIC Formulation SEZ,
Polepally Village, Jadcherla
Mandal, Mahaboobnagar Dist.
Telangana, 509301, India.

Product Registration Holder

Camber Laboratories Sdn. Bhd.
Unit E-13A-02, Menara
SUEZCAP 2, No.2,
KL Gateway, Jalan Kerinchi,
Gerbang Kerinchi Lestari,
59200 Kuala Lumpur, Malaysia.

10. Date of revision

11/06/2025

11. Serial Number

NPRA(R2/2)240320/1232