

ENTECAVIR STELLA 0.5MG FILM-COATED TABLETS

Entecavir 0.5 mg as entecavir monohydrate

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What Entecavir STELLA 0.5 mg is used for

Entecavir STELLA 0.5 mg is indicated for the treatment of long term (chronic) hepatitis B virus infection in adults. Entecavir STELLA 0.5 mg 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).

How Entecavir STELLA 0.5 mg works

Infection by the hepatitis B virus can lead to damage to the liver. Entecavir STELLA 0.5 mg reduces the amount of virus in your body, and improves the conditions of the liver.

Before you use Entecavir STELLA 0.5 mg

- When you must not use it

Do not take Entecavir STELLA 0.5 mg if you have hypersensitivity to entecavir or any component of Entecavir STELLA 0.5 mg.

- Before you start use it

Talk to your doctor or pharmacist before taking Entecavir STELLA 0.5 mg:

- if you have ever had problems with your kidneys, tell your doctor. This is important because Entecavir STELLA 0.5 mg is eliminated from your body through the kidneys and your dose or dosing schedule may need to be adjusted.
- do not stop taking Entecavir STELLA 0.5 mg without your doctor's advice since your hepatitis may worsen after

stopping treatment. When your treatment with Entecavir STELLA 0.5 mg 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 Entecavir STELLA 0.5 mg treatment may be.
- if you are also infected with HIV (human immunodeficiency virus) be sure to tell your doctor. You should not take Entecavir STELLA 0.5 mg 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. Entecavir STELLA 0.5 mg will not control your HIV infection.
- taking Entecavir STELLA 0.5 mg 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.
- Entecavir STELLA 0.5 mg 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. Your doctor will monitor you regularly while you are receiving Entecavir STELLA 0.5 mg.
- if you have previously received treatment for chronic hepatitis B, please inform your doctor.

- Taking other medicines

Tell your doctor if you are taking any other medicines, including any that you buy without a prescription from a pharmacy, supermarket or health food shop. Your doctor or pharmacist will advise whether you should take Entecavir STELLA 0.5 mg together with any other medicines.

How to use Entecavir STELLA 0.5 mg

- How much to use

Not all patients need to take the same dose of Entecavir STELLA 0.5 mg. Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure. Your doctor will decide on the dose that suits you base on your condition. *For adults* the recommended dose is either 0.5 mg or 1 mg once daily orally (by mouth).

Your dose will depend on:

- Whether you have been treated for HBV infection before, and what medicines 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

Your doctor will advise you on the dose that is right for you. Always take the dose recommend by your doctor to ensure that your medicine is fully effective and to reduce the development of resistance to treatment.

Some patients must take Entecavir STELLA 0.5 mg on an empty stomach. If your doctor instructs you to take Entecavir STELLA 0.5 mg on an empty stomach, empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

- How long to use it

Take Entecavir STELLA 0.5 mg as long as your doctor has told you. Your doctor will tell you if and when you should stop the treatment.

- If you forget to use it

It is important that you do not miss any doses. If you miss a dose of Entecavir STELLA 0.5 mg, 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.

- If you use too much (overdose)

If overdose occurs, contact your doctor immediately or go to the Emergency

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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 it

- Things you must do

Take your medicine exactly as your doctor has told you.

Tell your doctor if you are pregnant or planning to become pregnant. It has not been demonstrated that Entecavir STELLA 0.5 mg is safe to use during pregnancy. Entecavir STELLA 0.5 mg must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with Entecavir STELLA 0.5 mg use an effective method of contraception to avoid becoming pregnant.

- Things you must not do

You should not breast-feed during treatment with Entecavir STELLA 0.5 mg. Tell your doctor if you are breast-feeding. It is not known whether entecavir, the active ingredient in Entecavir STELLA 0.5 mg, is excreted in human breast milk.

Do not take any new medicines without consulting your doctor.

- Things to be careful of

In most cases you may take Entecavir STELLA 0.5 mg 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 Entecavir STELLA 0.5mg because the treatment with lamivudine was not successful, you should take Entecavir STELLA 0.5 mg on an empty stomach once daily. If your liver disease is very advanced, your doctor will also instruct you to take Entecavir STELLA 0.5 mg on an empty stomach. Empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

Dizziness, tiredness (fatigue) and sleepiness (somnolence) are common side effects which may impair your ability to drive and use machines. If you have any concerns consult your doctor.

Side effects

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

Patients treated with Entecavir STELLA 0.5 mg have reported the following side effects:

- insomnia (inability to sleep)
- headache
- dizziness
- somnolence (sleepiness)
- vomiting
- diarrhea
- nausea
- dyspepsia (indigestion)
- fatigue (extreme tiredness)
- increased transaminases (increased blood levels of the liver enzymes)

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

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)].

Storage and Disposal of Entecavir STELLA 0.5 mg

- Storage

- The expiry date of this pack is printed on the box. Do not use this pack after this date.
- Do not store above 30°C.
- Keep out of reach of children.

- 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

White, triangle-shaped, film-coated tablet, engraved with “0.5” on one side and “E” on the other side.

- Ingredients

- Active ingredient:

Each tablet contains 0.5 mg of entecavir (as entecavir monohydrate).

- Inactive ingredients:

- pregelatinized starch
- soy polysaccharides
- anhydrous citric acid
- sodium stearyl fumarate
- carmellose sodium
- calcium carbonate
- opadry complete film coating system 13B58802 white.

MAL number

MAL20046119AZ

Manufacturer and Product Registration Holder

Manufacturer

STELLAPHARM J.V. CO., LTD. –
BRANCH 1 (A Joint Venture Company of Auxilto GmbH, Germany)

No. 40 Tu Do Avenue, Vietnam -
Singapore Industrial Park, An Phu Ward,
Thuan An Town, Binh Duong Province,
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Product Registration Holder

Stadpharm Sdn. Bhd.

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No. 2, Jalan PJU 1A/7A, 47301 Petaling
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Date of revision

04/05/2020