

Package leaflet: Information for the user

Entecavir 0.5 mg film-coated tablets

Entecavir 1 mg film-coated tablets

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.

What is in this leaflet

1. What Entecavir Tablets are and what it is used for
2. What you need to know before you take Entecavir Tablets
3. How to take Entecavir Tablets
4. Possible side effects
5. How to store Entecavir Tablets
6. Contents of the pack and other information

1. What Entecavir Tablets are and what it is used for

Entecavir Tablets contains the active substance entecavir and belongs to a group of medicines called anti-viral. It is used to treat chronic (long term) hepatitis B virus (HBV) infection in adults. Entecavir Tablets 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).

Entecavir Tablets are also used to treat chronic (long term) HBV infection in children and adolescents. Entecavir Tablets can be used in children whose liver is damaged but still functions properly (compensated liver disease).

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

2. What you need to know before you take Entecavir Tablets

Do not take Entecavir Tablets

- if you are allergic to entecavir or any of the other ingredients of this medicine (listed in section 6)

Warnings and precautions

Talk to your doctor or pharmacist before taking Entecavir Tablets

- if you have ever had problems with your kidneys, tell your doctor. This is important because entecavir is eliminated from your body through the kidneys and your dose or dosing schedule may need to be adjusted.
- discuss with your doctor whether your liver functions properly and, if not, what the possible effects on your entecavir treatment may be.
- if you are also infected with HIV (human immunodeficiency virus) be sure to tell your doctor. You should not take Entecavir Tablets 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 Tablets will not control your HIV infection.

- Entecavir Tablets 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 Tablets.
- if you have previously received treatment for chronic hepatitis B, please inform your doctor.
- taking Entecavir Tablets 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.

Children and adolescents

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

Other medicines and Entecavir Tablets

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

Entecavir Tablets with food and drink

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

Children and adolescents (from 2 to less than 18 years of age) can take Entecavir Tablets with or without food.

Pregnancy, breast feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

It has not been demonstrated that Entecavir Tablets are safe to use during pregnancy. Entecavir Tablets must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with Entecavir Tablets use an effective method of contraception to avoid becoming pregnant.

You should not breast-feed during treatment with Entecavir Tablets. It is not known whether entecavir, the active ingredient in Entecavir Tablets, is excreted in human breast milk.

Driving and using machines

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.

Entecavir Tablets contain 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 Entecavir Tablets

Not all patients need to take the same dose of Entecavir Tablets.

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

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 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 (from 2 to less than 18 years of age), Entecavir 0.5 mg tablets are available or an entecavir oral solution may be available. Your child's doctor will decide the right dose based on your child's weight. Children weighing at least 32.6 kg may take the 0.5 mg tablet or an entecavir oral solution may be available. For patients weighing from 10 kg to 32.5 kg, an entecavir oral solution is recommended. All dosing will be taken once daily orally (by mouth). There are no recommendations for Entecavir Tablets in children less than 2 years of age or weighing less than 10 kg.

Your child's doctor will decide the right dose based on your child's weight.

Entecavir Tablets should not be used for children weighing less than 32.6 kg and if you or your child are unable to swallow tablets. In such cases you may check with your doctor for the availability of entecavir oral solution.

Your doctor will advise you on the dose that is right for you. Always take the dose recommended by your doctor to ensure that your medicine is fully effective and to reduce the development of resistance to treatment. Take Entecavir Tablets as long as your doctor has told you. Your doctor will tell you if and when you should stop the treatment.

Some patients must take Entecavir Tablets on an empty stomach (see Entecavir Tablets with food and drink in Section 2). If your doctor instructs you to take Entecavir Tablets on an empty stomach, empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

If you take more Entecavir Tablets than you should

Contact your doctor at once.

If you forget to take Entecavir Tablets

It is important that you do not miss any doses. If you miss a dose of Entecavir Tablets, 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 stop taking Entecavir Tablets

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

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

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.

Patients treated with Entecavir Tablets have reported the following side effects:

Tell your doctor immediately and stop taking Entecavir Tablets if you experience:

Rare (may affect up to 1 in 1,000 people)

- severe allergic reaction

Other side effects include

Common (may affect up to 1 in 10 people)

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

Uncommon (may affect up to 1 in 100 people)

- rash
- hair loss

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Entecavir Tablets

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

This medicinal product does not require any special storage conditions

Do not use this medicine after the expiry date which is stated on the carton and label after “EXP”. The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicine you no longer required. These measures will help to protect the environment.

6. Contents of the pack and other information

What Entecavir Tablets contain

- The active substance is entecavir.

Entecavir 0.5 mg film-coated tablets
Each film-coated tablet contains 0.5 mg of entecavir

Entecavir 1 mg film-coated tablets
Each film-coated tablet contains 1 mg of entecavir

- The other ingredients are

Tablet core: Lactose monohydrate, microcrystalline cellulose (E460), crospovidone (E1202), hydroxyl propyl cellulose (E463), magnesium stearate (E470b).

Film-coat:

Hypromellose (E464), titanium dioxide (E171), macrogol (E1521).

Entecavir 1 mg film-coated tablets additionally contains iron oxide red (E172).

What Entecavir Tablets looks like and contents of the pack

The Entecavir 1 mg film-coated tablets are pink coloured, triangular shaped, biconvex, film coated tablets, debossed with “E” on one side and “1” on the other side. Length 11.00 mm ± 0.20 mm and breadth 10.60 mm ± 0.20 mm.

The Entecavir 0.5 mg film-coated tablets are white to off-white, triangular shaped biconvex, film coated tablet, debossed with “E” on one side and plain on other side. Length 8.70 mm ± 0.20 mm and breadth 8.40 mm ± 0.20 mm.

Each carton contains either:

- 30 x 1 film-coated tablet; 3 blister cards of 10 x 1 film-coated tablet each in Alu/Alu blisters,
- or
- 90 x 1 film-coated tablet; 9 blister cards of 10 x 1 film-coated tablet each in Alu/Alu blisters.

Not all pack sizes and container types may be marketed.

Marketing Authorisation Holder

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