B. PACKAGE LEAFLET

Package leaflet: Information for the user

Entecavir 0.5 mg film-coated tablets
Entecavir 1 mg film-coated tablets
entecavir

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

1. What Entecavir is and what it is used for

Entecavir tablets are 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).

Entecavir tablets are also used to treat chronic (long term) HBV infection in children and adolescents aged 2 years to less than 18 years. Entecavir 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 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

Do not take Entecavir
- **if you are allergic (hypersensitive)** to entecavir or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions
Talk to your doctor or pharmacist before taking Entecavir
- **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.

- **do not stop taking Entecavir without your doctor's advice** since your hepatitis may worsen after stopping treatment. When your treatment with Entecavir 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 treatment may be.

- **if you are also infected with HIV** (human immunodeficiency virus) be sure to tell your doctor. You should not take Entecavir 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 will not control your HIV infection.

- **taking Entecavir 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 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.

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

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

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

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

<u>0,5 mg film-coated tablets</u>
Children and adolescents (from 2 to less than 18 years of age) can take entecavir 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 is safe to use during pregnancy. Entecavir must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with Entecavir use an effective method of contraception to avoid becoming pregnant.

You should not breast-feed during treatment with Entecavir. Tell your doctor if you are breast-feeding. It is not known whether entecavir, the active ingredient in Entecavir, 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 contains soya polysaccharides
This medicinal product contains soya polysaccharides. If you are allergic to peanut or soya, do not use this medicinal product.

Entecavir contains Sodium

This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

Entecavir contains soy polysaccharides
This medicine contains soy polysaccharides. If you are allergic to soya, do not use this medicine.

3. How to take Entecavir

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

Always take this medicine exactly as your doctor 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.

0,5 mg film-coated tablets
For children and adolescents (from 2 to less than 18 years of age), your child's doctor will decide the right dose based on your child's weight. The entecavir oral solution is recommended for patients weighing from 10 kg to 32.5 kg.Children weighing at least 32.6 kg may take the oral solution or the 0.5 mg tablet. All dosing will be taken once daily orally (by mouth). There are no recommendations for entecavir in children less than 2 years of age or weighing less than 10 kg.

1 mg film-coated tablets
For children and adolescents (from 2 to less than 18 years of age), entecavir oral solution or entecavir 0.5 mg tablets are available

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 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 on an empty stomach (see **Entecavir with food and drink** in **Section 2**). If your doctor instructs you to take Entecavir 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 than you should
Contact your doctor at once.

If you forget to take Entecavir
It is important that you do not miss any doses. If you miss a dose of Entecavir, 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.

Do not stop Entecavir without your doctor's advice
Some people get very serious hepatitis symptoms when they stop taking Entecavir. Tell your doctor immediately about any changes in symptoms that you notice after stopping treatment.

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 have reported the following side effects:

Adults
Common (at least 1 in 100 patients):
- headache,
- insomnia (inability to sleep),
- fatigue (extreme tiredness),
- dizziness,
- somnolence (sleepiness),
- vomiting,
- diarrhoea,
- nausea,
- dyspepsia (indigestion),
- increased blood levels of liver enzymes.

Uncommon (at least 1 in 1,000 patients):
- rash,
- hair loss.

Rare (at least 1 in 10,000 patients):
- severe allergic reaction.

Children and adolescents
The side effects experienced in children and adolescents are similar to those experienced in adults as described above with the following difference:
Very common (at least 1 in 10 patients): low levels of neutrophils (one type of white blood cells, which are important in fighting infection).

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

5. How to store Entecavir

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

Do not use this medicine after the expiry date which is stated on the bottle, blister or carton after EXP. That expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

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

6. Contents of the pack and other information

What Entecavir contains

The active substance is Entecavir.

Entecavir 0.5 mg film-coated tablets
Each film-coated tablet contains 0.5 mg entecavir (as monohydrate).

Entecavir 1 mg film-coated tablets
Each film-coated tablet contains 1 mg entecavir (as monohydrate).

The other ingredients are:
Tablet core: Calcium carbonate, Starch, Pregelatinized, Carmellose sodium, Soy polysaccharides, Citric acid monohydrate, Sodium stearyl fumarate.

Tablet coating:
Entecavir 0.5 mg film-coated tablets
Hypromellose 6cP, Titanium dioxide (E171), Macrogol 400, Polysorbate 80

Entecavir 1 mg film-coated tablets
Hypromellose 6cP, Titanium dioxide (E171), Macrogol 400, Iron oxide red (E172)

What Entecavir looks like and contents of the pack
Entecavir 0.5 mg film-coated tablets: White to off white, triangle shaped, biconvex film- coated tablets debossed with 'J' on one side and '110' on other side.

Entecavir 1 mg film-coated tablets: Pink, triangle shaped, biconvex film - coated tablets debossed with 'J' on one side and '111' on other side.

Entecavir are available in blister packs containing 7, 10, 14, 20, 28, 30, 50, 56, 60, 80, 84, 90, 100, 112, 120, 200 or 500 film-coated tablets and in unit-dose blister packs containing 7 x 1, 10 x 1, 14 x 1, 20 x 1, 28 x 1, 30 x 1, 50 x 1, 56 x 1, 60 x 1, 80 x 1, 84 x 1, 90 x 1, 100 x 1, 112 x 1, 120 x 1, 200 x 1 or 500 x 1 film-coated tablets.

[Product Name] are available in HDPE bottles with child resistant closure containing 30 or 90 film-coated tablets.

Entecavir are available in bottles containing 30 or 90 film-coated tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder:
Amarox Limited
Congress House, 14 Lyon Road
Harrow, Middlesex HA1 2EN
United Kingdom

Manufacturer:
Pharmadox Healthcare Limited
KW20A Kordin Industrial Park
Paola, PLA 3000
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This leaflet was last revised in 06/2026.