What is in this leaflet
1. What Entecavir is and what it is used for

Entecavir tablets are anti-viral medicines, used to treat chronic (long term) hepatitis B (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). Infected 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 to entecavir or any of the other ingredients of the medicine (listed in section 6).

Warnings 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 your kidneys and your dose or dosing schedule may need to be adjusted.
- do not take Entecavir without your doctor’s advice since your liver may worsen when 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 not taking medications 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 affect your ability to become infected with other hepatitis B virus (HBV) through sexual contact or body fluids (including blood-contaminated semen). It is important to take appropriate precautions to prevent others from becoming infected with HBV. A vaccine is available to prevent you from contracting hepatitis B from 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 jaundice might indicate the development of fatty liver. This rare but serious side effect of Entecavir occurs more often in women, particularly if they are very overweight. Your doctor will monitor you regularly if 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 before 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
It is important that you 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. Children and adolescents (from 2 to less than 18 years) can take Entecavir with or without food.

Pregnancy, breast-feeding and fertility
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. Consult your doctor about contraception.

Your doctor has taken into account that Entecavir will not stop you from infecting other people with Hepatitis B. Infected by the hepatitis B virus (HBV). Entecavir film-coated tablets are white and oval-shaped with a break line on both sides. The active substance is entecavir. Each film-coated tablet contains entecavir monohydrate corresponding to 0.5 mg (halve a tablet of 1 mg), Entecavir 0.5 mg tablets are also available.

- this medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.


- 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 symptoms are the same as yours.
- if you get any side effects with this medicine or other medicines, tell your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

Some people get very serious hepatitis symptoms when they stop taking Entecavir. Tell your doctor immediately.

- **If you forget doses**
  - Do not take a double dose to make up for a forgotten dose.
  - Wait and take the next dose at the regular time.

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 the next dose at the regular time.
- Continue with your regular dosing schedule. Do not take extra doses.

**Dividing tablets**

- The 1 mg tablet can be divided into equal doses.

Entecavir tablets contain:

- Entecavir 0.5 mg: The active substance is entecavir. Each film-coated tablet contains entecavir monohydrate corresponding to 0.5 mg entecavir.
  - Tablet core: lactose monohydrate, microcrystalline cellulose, magnesium stearate (Type A), magnesium lauryl sulphate, white iron oxide (E172).
  - Tablet coating: hypromellose (E464), macrogol 400 (E1521), polysorbate 80 (E433), titanium dioxide (E171), carnauba wax, stearic acid.

Entecavir 1 mg: The active substance is entecavir. Each film-coated tablet contains entecavir monohydrate corresponding to 1 mg entecavir.

- Tablet core: lactose monohydrate, microcrystalline cellulose, magnesium stearate (Type A), magnesium lauryl sulphate, white iron oxide (E172), white iron oxide (E171).
- Tablet coating: hypromellose (E464), macrogol 400 (E1521), polysorbate 80 (E433), titanium dioxide (E171), carnauba wax, stearic acid.

Entecavir 0.5 mg tablets are also available.

Entecavir tablets are supplied in cartons containing 10 (± 1), 30 (± 1), 40 (± 1) or 90 ± 1 film-coated tablets in blister packs.

Net of pack sizes may be marketed.

**Marketing Authorisation Holder**

Dr. Reddy’s Laboratories (UK) Ltd., A Riverview Road, Beverley, East Yorkshire, HU17 0LD, United Kingdom

**Manufacturer**

Nabsa International s.a., c/lobel zoled Bulakus, Prienjosefska 961 16, 74723 Bela, Czech Republic

This leaflet was last revised in 04/2017.