

## Package leaflet: Information for the patient

**Entecavir Rowex 0.5 mg Film-coated tablets**

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

#### **1. What Entecavir Rowex is and what it is used for**

**Entecavir Rowex tablets are anti-viral medicines, used to treat chronic (long term) hepatitis B virus (HBV) infection in adults.** Entecavir Rowex 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 Rowex tablets are also used to treat chronic (long term) HBV infection in children and adolescents aged 2 years to less than 18 years.** Entecavir Rowex 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 Rowex 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 Rowex**

##### **Do not take Entecavir Rowex**

- **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 Rowex if you have ever had problems with your kidneys, tell your doctor. This is important because Entecavir Rowex is eliminated from your body through the kidneys and your dose or dosing schedule may need to be**

adjusted.

- **do not stop taking Entecavir Rowex without your doctor's advice** since your hepatitis may worsen after stopping treatment. When your treatment with Entecavir Rowex 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 Rowex treatment may be.
- **if you are also infected with HIV** (human immunodeficiency virus) be sure to tell your doctor. You should not take Entecavir Rowex 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 Rowex will not control your HIV infection.
- **taking Entecavir Rowex 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 Rowex 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 Rowex**.
- **if you have previously received treatment for chronic hepatitis B**, please inform your doctor.

#### **Children and adolescents**

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

#### **Other medicines and Entecavir Rowex**

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

#### **Entecavir Rowex with food and drink**

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

#### **Entecavir Rowex 0.5 mg Film-coated tablets**

Children and adolescents (from 2 to less than 18 years of age) can take Entecavir Rowex 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 Rowex must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with Entecavir Rowex use an effective method of contraception to avoid becoming pregnant.

You should not breast-feed during treatment with Entecavir Rowex. Tell your doctor if you are breast-feeding. It is not known whether entecavir, the active ingredient in Entecavir Rowex, 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 Rowex contains lactose**

This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

## **3. How to take Entecavir Rowex**

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

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.

### **Entecavir Rowex 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. 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 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 Rowex 1 mg Film-coated tablets without a functional score line**

**For children and adolescents** (from 2 to less than 18 years of age), Entecavir Rowex 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.

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

Contact your doctor at once.

#### **If you forget to take Entecavir Rowex**

It is important that you do not miss any doses. If you miss a dose of Entecavir Rowex, 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 Rowex**

Do not stop Entecavir Rowex 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 (may affect up to 1 in 10 people): headache, insomnia (inability to sleep), fatigue (extreme tiredness), dizziness, somnolence (sleepiness), vomiting, diarrhoea, nausea, dyspepsia (indigestion), and increased blood levels of liver enzymes.

uncommon (may affect up to 1 in 100 people): rash, hair loss.

rare (may affect up to 1 in 1,000 people): 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. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system:

HPRA Pharmacovigilance; website: [www.hpra.ie](http://www.hpra.ie). By reporting side effects, you can help provide more information on the safety of this medicine.

## **5. How to store Entecavir Rowex**

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, carton box and blister after “EXP”. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening of the bottle, please use within 6 months.

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 Rowex contains**

- The active substance is entecavir.

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

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

- The other ingredients are:

*Tablet core:* lactose monohydrate, microcrystalline cellulose, crospovidone (Type A), magnesium stearate.

*Tablet coating:* hypromellose 2910, macrogol 6000, titanium dioxide (E171), talc.

Entecavir Rowex 1 mg Film-coated tablets additionally contain iron oxide red (E172) and iron oxide yellow (E172).

### **What Entecavir Rowex looks like and contents of the pack**

#### Entecavir Rowex 0.5 mg Film-coated tablets

White, round, film-coated tablet with debossment on both sides, “SZ” on one side and “108” on the other side with diameter approximately 8.0 mm.

#### Entecavir Rowex 1 mg Film-coated tablets

Pink, round, film-coated tablet with debossment on both sides, “SZ” on one side and “109” on the other side with diameter approximately 10.0 mm.

The film-coated tablets are packed in OPA/Aluminium/PVC-Aluminium blisters or are packed in a HDPE bottle with polypropylene child resistant screw cap and inserted in a carton.

Pack sizes:

Blister: 10, 30 and 90 film-coated tablets

Bottle: 30 film-coated tablets

Not all pack sizes may be marketed.

### **Marketing Authorisation Holder and Manufacturer**

**Marketing Authorisation Holder**

Rowex Ltd., Bantry, Co. Cork, Ireland.

**Manufacturer**

Lek Pharmaceuticals d.d., Verovškova ulica 57, 1526 Ljubljana, Slovenia.

**This medicinal product is authorised in the Member States of the EEA under the following names:**

Belgium	Entecavir Sandoz 0,5 mg filmomhulde Tabletten Entecavir Sandoz 1 mg filmomhulde Tabletten
Czech Republic	Entecavir Sandoz
France	ENTECAVIR SANDOZ 0,5 mg, comprimé pelliculé ENTECAVIR SANDOZ 1 mg, comprimé pelliculé
Greece	Entecavir/Sandoz 0,5 mg δισκία επικαλυμμένα με λεπτό υμένιο
Ireland	Entecavir Rowex 0.5 mg Film-coated tablets Entecavir Rowex 1 mg Film-coated tablets
Latvia	Entecavir Sandoz 0,5 mg apvalkotās tabletes Entecavir Sandoz 1 mg apvalkotās tabletes
Lithuania	Entecavir Sandoz 0,5 mg plėvele dengtos tabletės Entecavir Sandoz 1 mg plėvele dengtos tabletės
The Netherlands	Entecavir Sandoz 0,5 mg, filmomhulde tabletten Entecavir Sandoz 1 mg, filmomhulde tabletten
Slovenia	Entekavir Sandoz 0,5 mg filmsko obložene tablete Entekavir Sandoz 1 mg filmsko obložene tablete

**This leaflet was last revised in 09/2020.**