

## Package leaflet: Information for the user

### Entecavir Teva 0.5 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 Teva is and what it is used for
2. What you need to know before you take Entecavir Teva
3. How to take Entecavir Teva
4. Possible side effects
5. How to store Entecavir Teva
6. Contents of the pack and other information

#### 1. What Entecavir Teva is and what it is used for

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

##### Do not take Entecavir Teva

- **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 Teva

- **if you have ever had problems with your kidneys**, tell your doctor. This is important because Entecavir Teva is eliminated from your body through the kidneys and your dose or dosing schedule may need to be adjusted.
- **do not stop taking Entecavir Teva without your doctor's advice** since your hepatitis may worsen after stopping treatment. When your treatment with this medicine 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 Teva treatment may be.
- **if you are also infected with HIV** (human immunodeficiency virus) be sure to tell your doctor. You should not take Entecavir Teva 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. This medicine will not control your HIV infection.
- **taking Entecavir Teva 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 Teva 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 this medicine.
- **if you have previously received treatment for chronic hepatitis B**, please inform your doctor.

### **Children and adolescents**

Entecavir Teva should not be used for children below 2 years of age or weighing less than 32.6 kg.

### **Other medicines and Entecavir Teva**

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

### **Entecavir Teva with food and drink**

In most cases you may take this medicine 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 this medicine because the treatment with lamivudine was not successful, you should take this medicine on an empty stomach once daily. If your liver disease is very advanced, your doctor will also instruct you to take this medicine 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 this medicine 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 Teva is safe to use during pregnancy. This medicine must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with this medicine use an effective method of contraception to avoid becoming pregnant.

You should not breast-feed during treatment with Entecavir Teva. Tell your doctor if you are breast-feeding. It is not known whether entecavir, the active substance in this medicine, 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.

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

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

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.

**Use in children and adolescents**

**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.

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

Contact your doctor at once.

**If you forget to take Entecavir Teva**

It is important that you do not miss any doses. If you miss a dose of this medicine, 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 Teva**

Do not stop Entecavir Teva without your doctor's advice. Some people get very serious hepatitis symptoms when they stop taking this medicine. 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 Teva have reported the following side effects:

common (may affect up to 1 in 10 people):

- headache
- inability to sleep (insomnia)
- extreme tiredness (fatigue)

- dizziness
- sleepiness (somnolence)
- vomiting
- diarrhoea
- nausea
- indigestion (dyspepsia)
- 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

### **Reporting of side effects**

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: [www.hpra.ie](http://www.hpra.ie); E-mail: [medsafety@hpra.ie](mailto:medsafety@hpra.ie). By reporting side effects you can help provide more information on the safety of this medicine.

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

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. The expiry date refers to the last day of that month.

This medicine 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 Teva contains**

- The active substance is entecavir.
- Each film-coated tablet contains 0.5 mg entecavir.
- The other ingredients are:  
Tablet Core: mannitol (E421), cellulose microcrystalline (E460), maize starch pregelatinized, crospovidone type A (E1202), magnesium stearate.  
Tablet Coating: poly(vinyl alcohol) partially hydrolyzed (E1203), titanium dioxide (E171), macrogol 3350 (polyethylene glycol), talc (E553b).

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

White to off white, round shaped tablet, debossed with "05" on one side of the tablet and with "E" on the other side of the tablet with diameter of approximately 5.96 - 6.26 mm.

The film-coated tablets are supplied in:

- PVC/PVdC – Aluminium blisters in cartons containing 10, 30, 60 or 90 tablets.

- PVC/PVdC – Aluminium unit-dose blisters in cartons containing 30x1tablets.
- Aluminium/OPA/PVC – Aluminium blisters in cartons containing 10, 30, 60 or 90 tablets.
- Aluminium/OPA/PVC – Aluminium unit-dose blisters in cartons containing 30x1tablets.
- HDPE bottles with polypropylene child resistant caps in cartons containing 30 or 100 tablets.
- HDPE bottles with polypropylene child resistant caps and silica gel desiccants in cartons containing 30 or 100 tablets.

Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Teva B.V.  
Swensweg 5  
2031GA Haarlem  
Netherlands

### **Manufacturers**

Teva Operations Poland Sp. z.o.o  
ul. Mogilska 80.  
Kraków  
31-546  
Poland

Merckle GmbH  
Ludwig-Merckle-Strasse 3, Blaubeuren  
Baden-Wuerttemberg  
89143  
Germany

PLIVA Hrvatska d.o.o. (PLIVA Croatia Ltd.)  
Prilaz baruna Filipovića 25  
Zagreb  
10000  
Croatia

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

Austria	Entecavir ratiopharm 0,5mg Filmtabletten
Croatia	Entekavir Pliva 0,5 mg filmom obložene tablete
Denmark	Entecavir Teva
France	Entecavir Teva 0.5mg, comprimé pelliculé
Hungary	Entecavir Teva 0,5 mg filmtabletta
Ireland	Entecavir Teva 0.5 mg Film-coated Tablets
Netherlands	Entecavir Teva 0,5 mg, filmomhulde tabletten
Norway	Entecavir Teva
Poland	Entecavir Teva
Portugal	Entecavir Teva
Slovenia	Entekavir Teva 0,5 mg filmsko obložene tablete
Spain	Entecavir Teva 0,5 mg comprimidos recubiertos con película EFG
Sweden	Entecavir Teva

**This leaflet was last revised in May 2017.**