

PATIENT PACKAGE INSERT IN ACCORDANCE WITH THE PHARMACISTS' REGULATIONS (PREPARATIONS) - 1986

The medicine is dispensed with a doctor's prescription only

Entecavir Teva

0.5 mg

Film-coated tablets

The active ingredient and its quantity:

Each film-coated tablet contains:
Entecavir (as monohydrate) 0.5 mg

Entecavir Teva

1 mg

Film-coated tablets

The active ingredient and its quantity:

Each film-coated tablet contains:
Entecavir (as monohydrate) 1 mg

For information on inactive ingredients, see section 6 – "Further information".

Read this leaflet carefully in its entirety before using the medicine. This leaflet contains concise information about the medicine. If you have further questions, refer to the doctor or pharmacist.

This medicine has been prescribed for the treatment of your ailment. Do not pass it on to others. It may harm them even if it seems to you that their ailment is similar. This medicine is intended for adults.

1. WHAT IS THE MEDICINE INTENDED FOR?

Entecavir Teva is an antiviral medicine used to treat chronic hepatitis in adults, caused by hepatitis B virus (HBV) infection.

Entecavir Teva can be given:

- in patients with a damaged but still properly functioning liver (compensated liver disease).
- in patients with a damaged liver that does not function properly (decompensated liver disease).

Chronic infection with hepatitis B virus (HBV) may cause liver damage. Entecavir Teva reduces the level of the virus in your body, thereby improving the condition of the liver.

Therapeutic group:

Nucleosides and nucleotides of the reverse-transcriptase enzyme inhibitor group.

2. BEFORE USING THE MEDICINE

Do not use the medicine if:

- You are sensitive (allergic) to the active ingredient (entecavir) or any of the additional ingredients contained in the medicine (see section 6 "Further Information").

Special warnings regarding use of the medicine:

- Taking the medicine does not prevent infection of others via sexual contact or body fluids (e.g., contaminated blood). It is important to take appropriate precautionary measures to prevent infecting others with hepatitis B.
- There is a vaccine against hepatitis B, which may help protect people who are in close contact with you and who are at high risk of becoming infected.
- Patients with advanced liver disease or with liver cirrhosis may be at higher risk of liver failure due to exacerbation of hepatitis, and therefore, should be closely monitored during the course of the medicinal treatment.

Entecavir Teva belongs to a class of medicines that can cause lactic acidosis (excess of lactic acid in the blood) and enlargement of the liver. Symptoms of development of lactic acidosis include: nausea, vomiting and stomach pain. This rare but serious side effect has occasionally been fatal. Lactic acidosis occurs more often in women, particularly if they are extremely overweight. Your doctor will monitor your medical condition regularly during the course of treatment with Entecavir Teva.

Before beginning treatment with Entecavir Teva, tell the doctor if:

- You suffered in the past from impaired kidney function. This is important since Entecavir Teva is cleared from your body through the kidneys and it may be necessary to change the dosage or the dosing schedule of the medicine.
- You suffer from impaired liver function, as it may have an effect on the Entecavir Teva treatment.
- You are an HIV carrier. In this case, do not take Entecavir Teva to treat hepatitis B unless you are concomitantly taking medicines to treat HIV, since the efficacy of future treatment for HIV may be reduced. Entecavir Teva is not a preparation for treating HIV.
- You have previously received treatment against chronic hepatitis B.

Children and adolescents

Entecavir Teva is not intended for use in children and adolescents under 18 years of age.

Drug interactions:

If you are taking, or have recently taken, other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist. Since Entecavir is primarily eliminated by the kidneys, taking this medicine together with medical preparations that reduce the function of the kidneys or other preparations that compete for active elimination via the kidneys may increase the concentration of each of these medical preparations in the blood.

Use of the medicine and food:

In most cases, Entecavir Teva can be taken with or without food.

If you have previously taken a medicine containing the active ingredient lamivudine, act in the following manner:

If you were switched to treatment with Entecavir Teva after the treatment with lamivudine was unsuccessful, take Entecavir Teva once a day, on an empty stomach (at least two hours after a meal and at least two hours before the next meal).

If your liver disease is very advanced, the doctor will recommend that you take Entecavir Teva once a day on an empty stomach (at least two hours after a meal and at least two hours before the next meal).

Pregnancy and breastfeeding:

Inform the doctor if you are pregnant or are planning to become pregnant. It has not yet been established if Entecavir Teva is safe for use during pregnancy.

Do not take Entecavir Teva during pregnancy unless the doctor has explicitly instructed otherwise.

It is important that women of child-bearing age use effective contraceptives during the course of treatment with Entecavir Teva, to avoid becoming pregnant.

Do not breastfeed during the course of treatment with the medicine. Inform the doctor if you are breastfeeding. It is not known whether the active ingredient of Entecavir Teva is excreted into breast milk.

Driving and operating machinery:

Use of this medicine may cause dizziness, tiredness and drowsiness and therefore requires that caution be exercised when driving a car, operating dangerous machinery and when engaging in any activity that requires alertness.

If you have any concerns, consult the attending doctor.

3. HOW SHOULD YOU USE THE MEDICINE?

Always use the preparation according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the preparation dosage or treatment regimen.

Not all patients have to take the same dosage of Entecavir Teva.

The dosage and treatment regimen will be determined by the doctor only. Check with the doctor or pharmacist if you are uncertain.

The recommended dosage for **adults** is generally 0.5 mg or 1 mg, once a day, for oral ingestion.

The dosage that will be determined for you depends on:

- whether you have been treated for HBV infection in the past, and which medicines you have received.
- whether you have kidney problems. The doctor may prescribe a lower dosage of the medicine for you or instruct you to take it less often than once a day.
- the condition of your liver.

Take the medicine according to the dosage and dosing schedule determined by the doctor, to ensure that the medicine will be fully effective and to reduce the development of resistance to the treatment. Continue taking Entecavir Teva for as long as the doctor tells you to. The doctor will tell you if you can stop the treatment and when. It is important not to miss any dose of the treatment.

Do not exceed the recommended dose.

Some patients must take Entecavir Teva on an empty stomach (see section 2, in the "Use of the medicine and food" subsection). If the doctor instructs you to take the medicine on an empty stomach, take it at least two hours after a meal and at least two hours before the next meal.

Tests and follow-up:

When taking Entecavir Teva periodic blood tests should be performed.

Crushing/halving/chewing

Do not halve in the absence of a score line.

There is no information regarding crushing/chewing.

If you took an overdose, or if a child has accidentally swallowed the medicine, refer immediately to a doctor or proceed to a hospital emergency room and bring the package of the medicine with you.

If you forget to take this medicine

It is important not to forget to take any dose. If you forgot to take the medicine at the required time, take a dose as soon as you remember and take the next dose at the regular time. If the time to take the next dose is close, do not take the forgotten dose; rather, take the next dose at the regular time. Do not take a double dose instead of the forgotten dose.

Adhere to the treatment regimen as recommended by the doctor.

If you stop taking the medicine

Even if there is an improvement in your health, do not stop treatment without consulting with the doctor, since the hepatitis may worsen after stopping the treatment. When treatment with Entecavir Teva is discontinued, the doctor will continue to monitor you and will perform blood tests for several months. Inform the doctor immediately of any exacerbation after stopping the treatment.

- **Do not take medicines in the dark! Check the label and dose each time you take medicine. Wear glasses if you need them.**

If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. SIDE EFFECTS:

As with any medicine, use of Entecavir Teva may cause side effects in some users. Do not be alarmed by the list of side effects. You may not suffer from any of them.

Patients taking Entecavir Teva reported the following side effects:

Common side effects (effects that occur in 1 to 10 patients out of 100): Headache, insomnia (inability to fall asleep), tiredness (extreme fatigue), dizziness, sleepiness, vomiting, diarrhea, nausea, indigestion, increased liver enzyme levels in the blood.

Uncommon side effects (effects that occur in at least 1 patient out of 1,000): Rash, hair loss.

Rare side effects (effects that occur in at least 1 patient out of 10,000): Severe allergic reaction.

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect not mentioned in this leaflet, consult with the doctor.

Reporting side effects

Side effects can be reported to the Ministry of Health by clicking on the link "Report side effects of drug treatment" on the homepage of the Ministry of Health website (www.health.gov.il), which directs you to an online form for reporting side effects, or via the following link: <https://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.gov.il>

5. HOW SHOULD THE MEDICINE BE STORED?

- **Avoid poisoning!** This medicine, and any other medicine, must be kept in a safe place out of the reach and sight of children and/or infants in order to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor!
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- **Store below 25°C, in the original package.**
- **After first opening, use within 60 days, but no later than the expiry date.**
- Do not discard medicines in the wastewater or waste bin. Ask the pharmacist how to dispose of medicines that are not in use. These measures will help protect the environment.

6. FURTHER INFORMATION

In addition to the active ingredient, the medicine also contains:

Entecavir Teva 0.5 mg:

Mannitol, microcrystalline cellulose (avical PH 101), pregelatinized starch, crospovidone, magnesium stearate, polyvinyl alcohol, titanium dioxide, macrogol/PEG (polyethylene glycol 3350), talc

Entecavir Teva 1 mg:

Mannitol, microcrystalline cellulose (avical PH 101), pregelatinized starch, crospovidone, magnesium stearate, polyvinyl alcohol, titanium dioxide, macrogol/PEG (polyethylene glycol 3350), talc, FD&C Red #40/Allura Red AC aluminum lake, FD&C Blue #2/Indigo carmine aluminum lake, iron oxide yellow

What the medicine looks like and the contents of the package:

Entecavir Teva 0.5 mg:

White to off-white, round-shaped tablet, debossed with "TEVA" on one side of the tablet and with "5786" on the other side of the tablet.

Entecavir Teva 1 mg:

Light pink to pink, round-shaped tablet, debossed with "TEVA" on one side of the tablet and with "5787" on the other side of the tablet.

The package contains 30 film-coated tablets.

Name of Manufacturer and License Holder and its Address:

Teva Pharmaceutical Industries Ltd., P.O.B. 3190, Petach Tikva.

This leaflet was checked and approved by the Ministry of Health in November 2015 and was updated in April 2018 in accordance with the Ministry of Health guidelines.

Registration number of the medicine in the National Drug Registry of the Ministry of Health:

Entecavir Teva 0.5 mg – 154.78.34441
Entecavir Teva 1 mg – 154.79.34439