

This medicine is dispensed with a doctor's prescription only

Entecavir Teva 0.5 mg Film-coated tablets

Entecavir Teva 1 mg Film-coated tablets

Composition:

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

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

For information on inactive ingredients, see section 6 - 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

This medicine has been prescribed to treat your illness. Do not pass it on to others. It may harm them, even if it seems to you that their illness is similar to yours.

This medicine is intended for adults.

1. What is this medicine intended for?

Entecavir Teva is an anti-viral medicine used to treat chronic hepatitis B virus (HBV) infection in adults with:

- Compensated liver disease and evidence of active viral replication, and persistently elevated serum alanine aminotransferase (ALT) levels.
- Decompensated liver disease.

Chronic hepatitis B virus (HBV) infection 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 this medicine if:

- You are sensitive (allergic) to the active ingredient (entecavir) or to any of the other ingredients in this medicine (see section 6 - 'Additional information').

Special warnings about using this medicine:

- Taking Entecavir Teva does not prevent you from infecting other people with hepatitis B virus (HBV) through sexual contact or body fluids (including blood contamination). For this reason, it is important to take appropriate precautions to prevent others from becoming infected with hepatitis B virus (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 Entecavir Teva.

Before using Entecavir Teva, tell your doctor if:

- You have ever had impaired kidney function. 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 the medicine without consulting your doctor since your hepatitis may worsen after stopping treatment. When treatment with Entecavir Teva is stopped, your doctor will continue to monitor you and take blood tests for several months.
- Check with your doctor about whether your liver functions properly and if not, what the possible effects on your Entecavir Teva treatment may be.
- You are a carrier of HIV (human immunodeficiency virus). 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. Entecavir Teva does not control your HIV infection.
- You have previously received treatment for chronic hepatitis B.

Children and adolescents

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

Drug interactions

If you are taking or have recently taken other medicines, including non-prescription medications and dietary supplements, tell your doctor or pharmacist.

Using this medicine and food

In most cases, you may take Entecavir Teva with or without food. However, if you have had a previous treatment with a medicine containing the active ingredient lamivudine, you should act as follows: If you were switched over to Entecavir Teva because the treatment with lamivudine was not successful, you should take Entecavir Teva on an empty stomach once daily.

If your liver disease is very advanced, your doctor will also instruct you to take Entecavir Teva on an empty stomach. Empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

Pregnancy, breastfeeding and fertility

Pregnancy

- Tell your doctor if you are pregnant or planning to become pregnant. It has not been demonstrated that Entecavir Teva is safe to use during pregnancy.
- Entecavir Teva must not be used during pregnancy unless specifically directed by your doctor.

Fertility

- It is important that women of childbearing age receiving treatment with Entecavir Teva use an effective method of contraception to avoid becoming pregnant.

Breastfeeding

- You should not breastfeed during treatment with Entecavir Teva. Tell your doctor if you are breastfeeding. It is not known whether entecavir, the active ingredient in Entecavir Teva, 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 operate machines.

If you have any concerns consult your doctor.

3. How to use this medicine?

Always use this medicine according to your doctor's instructions. Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

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

Only your doctor will determine your dose and how you should take this medicine. Check with your doctor if you are not sure.

For adults, the recommended dosage is usually 0.5 mg or 1 mg once daily orally.

The dose determined for you 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 of the medicine for you or instruct you to take it less often than once a day.
- The condition of your liver.

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. It is important not to skip any dose of the treatment.

Do not exceed the recommended dose.

Some patients must take Entecavir Teva on an empty stomach (see section 2 under 'Using this medicine and food'). If your doctor instructs you to take the medicine on an empty stomach, take the medicine at least 2 hours after a meal and at least 2 hours before your next meal.

Crushing/splitting/chewing

Entecavir Teva 0.5 mg - do not split the tablet if there is no score line. Entecavir Teva 1 mg - you may split the tablet on the score line. There is no information about crushing/chewing the tablets.

If you have taken an overdose or if a child has accidentally swallowed some medicine, immediately see a doctor or go to a hospital emergency room and bring the medicine package with you.

If you forget to take the medicine

It is important that you do not miss any doses. If you forget to take the medicine at the required time, take the missed dose as soon as you remember, and take the next dose at its regular time. If it is almost time for your next dose, do not take the missed dose and take the next dose at the regular time. Do not take a double dose to make up for the forgotten dose.

Adhere to the treatment as recommended by your doctor.

If you stop taking this medicine

Do not stop taking the medicine without consulting your doctor. Some people report very serious hepatitis symptoms when they stop taking Entecavir Teva. Tell your doctor immediately about any changes in symptoms that you notice after stopping treatment.

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

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. Side effects:

Like with all medicines, using Entecavir Teva may cause side effects in some users. Do not be alarmed by this list of side effects. You may not experience any of them.

Patients treated with Entecavir Teva have reported the following side effects:

Common side effects (affect at least 1 in 100 patients):

Headache, insomnia (inability to sleep), fatigue (extreme tiredness), dizziness, somnolence, vomiting, diarrhoea, nausea, dyspepsia, and increased blood levels of liver enzymes.

Uncommon side effects (affect at least 1 in 1,000 patients):

Rash, hair loss.

Rare side effects (affect at least 1 in 10,000 patients):

Severe allergic reaction.

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

Reporting side effects

You can report side effects to the Ministry of Health - by following the link 'Reporting Side Effects of Drug Treatment' on the Ministry of Health home page (www.health.gov.il) which links to an online form for reporting side effects. You can also use this link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Prevent poisoning! To prevent poisoning, keep this, and all other medicines, in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor!
- Do not use the medicine after the expiry date (exp. date) which is stated on the package. The expiry date refers to the last day of that month.
- Store in the original package, below 25°C.
- Shelf life after the first opening of the bottle pack: use within 100 days, but no later than the expiry date.
- Do not throw away medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines that you no longer use. These measures will help protect the environment.

6. Additional information

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

Entecavir Teva 0.5 mg:

Mannitol, cellulose, microcrystalline (Avicel PH 101), maize starch-Rx 1500 pregelatinized, crospovidone type A, magnesium stearate, poly(vinyl alcohol) partially hydrolysed (E1203), titanium dioxide (E171), macrogol (polyethylene glycol) MW3350, talc (E553b).

Entecavir Teva 1 mg:

Mannitol, cellulose, microcrystalline (Avicel PH 101), maize starch-Rx 1500 pregelatinized, crospovidone type a, magnesium stearate, poly(vinyl alcohol) partially hydrolyzed (E1203), titanium dioxide (E171), macrogol (polyethylene glycol) MW3350, talc (E553b), iron oxide red (E172).

What the medicine looks like and contents of the pack:

Entecavir Teva 0.5 mg:

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.

Entecavir Teva 1 mg:

Light pink to pink, round shaped tablet with deep score line, debossed with "1" on one side of the tablet and with "E/E" on the other side of the tablet.

A bottle pack contains 30 film-coated tablets and a desiccant.

A blister pack (tray) contains 7, 10 or 30 film-coated tablets.

Not all pack types and sizes may be marketed.

Manufacturer and registration holder's name and address:

Teva Israel Ltd.,
124 Dvora HaNevi'a St., Tel Aviv 6944020.

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

Entecavir Teva 0.5 mg - 154.78.34441
Entecavir Teva 1 mg - 154.79.34439