

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986

This medicine is dispensed with a doctor's prescription only

**Entecavir Sandoz®
0.5 mg
Film-coated tablets**

Composition:
Each tablet contains:
entecavir (as monohydrate)
0.5 mg

**Entecavir Sandoz®
1 mg
Film-coated tablets**

Composition:
Each tablet contains:
entecavir (as monohydrate)
1 mg

Inactive ingredients and allergens: See section 6 under 'Additional information' and 'Important information about some of this medicine's ingredients' in section 2.

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 Sandoz 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 can lead to damage to the liver. Entecavir Sandoz reduces the level of virus in your body and improves the condition of the liver.

Therapeutic group:

Nucleosides and nucleotides of the reverse transcriptase enzyme inhibitor group.

2. Before using this medicine

Do not use this medicine if:

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

Special warnings about using this medicine:

- Taking Entecavir Sandoz 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 Sandoz 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 during treatment with Entecavir Sandoz.

Before treatment with Entecavir Sandoz, tell your doctor if:

- You have ever had impaired kidney function. This is important because Entecavir Sandoz 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 your treatment with Entecavir Sandoz 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. If not, find out what the effect of impaired liver function on your Entecavir Sandoz treatment may be.
- You are a carrier of HIV (human immunodeficiency virus). You should not take Entecavir Sandoz to treat your hepatitis B infection unless you are taking medicines to treat HIV at the same time, as the effectiveness of future HIV treatment may be reduced. Entecavir Sandoz will not control your HIV infection.
- You have previously received treatment for chronic hepatitis B.

Children and adolescents

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

Pregnancy, breast-feeding and fertility

Pregnancy

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

Fertility

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

Breast-feeding

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

Important information about some of this medicine's ingredients

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.

Each 0.5 mg tablet contains 120 mg of lactose monohydrate.

Each 1 mg tablet contains 241 mg of lactose monohydrate.

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 Sandoz.

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 dose 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 medicines 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 Sandoz 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 Sandoz 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

Do not split the tablet as there is no score line. There is no information about crushing/chewing the tablets.

If you have taken a higher dose 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 not to forget to take any dose.

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 the medicine. Tell your doctor immediately about any change in symptoms that you notice after stopping treatment.

Do not take medicines in the dark! Check the label and the 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 Sandoz 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 Sandoz have reported the following side effects:

Common side effects (appear in 1-10 in 100 users):

- headache
- insomnia (inability to sleep)
- fatigue (extreme tiredness)
- dizziness
- sleepiness
- vomiting
- diarrhoea
- nausea
- dyspepsia (indigestion)
- increased blood levels of liver enzymes

Uncommon side effects (appear in 1-10 in 1,000 users):

- rash
- hair loss

Rare side effects (appear in 1-10 in 10,000 users):

- 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.

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) appearing on the package. The expiry date refers to the last day of that month.

Storage conditions:

Do not store above 30°C.

Do not throw away any medicine via wastewater or household waste. Ask the pharmacist how to throw away medicines that you no longer use. These measures will help to protect the environment.

6. Additional information

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

Entecavir Sandoz 0.5 mg:

Tablet core: lactose monohydrate, microcrystalline cellulose, crospovidone (Type A), magnesium stearate
Tablet coating: hypromellose 2910, macrogol 6000, titanium dioxide (E 171), talc

Entecavir Sandoz 1 mg:

Tablet core: lactose monohydrate, microcrystalline cellulose, crospovidone (Type A), magnesium stearate
Tablet coating: hypromellose 2910, macrogol 6000, titanium dioxide (E 171), talc, iron oxide red (E 172), iron oxide yellow (E 172)

What the medicine looks like and content of the pack:

Entecavir Sandoz 0.5 mg: White, round, film-coated tablet debossed with "SZ" on one side and "108" on the other side.

Entecavir Sandoz 1 mg: Pink, round, film-coated tablet debossed with "SZ" on one side and "109" on the other side.

A blister pack (tray) contains 10, 30 or 90 film-coated tablets.

Not all pack sizes may be marketed.

Registration holder and importer's name and address:

Novartis Israel Ltd., P.O.Box 7126, Tel Aviv.

Revised in March 2022 according to MOH guidelines.

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

Entecavir Sandoz 0.5 mg film-coated tablets: 169-26-36055-00

Entecavir Sandoz 1 mg film-coated tablets: 169-27-36056-00