Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986
This medicine is dispensed with a doctor's prescription only

Enteavenir 0.5 mg
film-coated tablets

Enteavenir 1 mg
film-coated tablets

Composition:
Each film-coated tablet of Enteavenir 0.5 mg contains:
entecavir (as monohydrate) 0.5 mg

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

For information on inactive ingredients, see chapter 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?
Enteavenir is an anti-viral medicine used to treat chronic hepatitis caused by 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. Enteavenir reduces the virus levels in your body and thus 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 to any of the other ingredients in this medicine (see chapter 6 - 'Additional information').

Special warnings about using this medicine:
- Taking Enteavenir will not stop you from infecting other people with hepatitis B virus (HBV) through sexual contact or body fluids (including blood contamination). Therefore, it is important to take appropriate precautions to prevent others from becoming infected with viral hepatitis B (HBV). A vaccine is available for hepatitis B to protect people at high risk from becoming infected with hepatitis B virus (HBV).
- Enteavenir 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 extremely overweight. Your doctor will monitor your medical condition regularly while you are being treated with Enteavenir.

Before using Enteavenir, tell your doctor if:
- You have ever had impaired kidney function. This is important because Enteavenir 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 Enteavenir is stopped, your doctor will continue to monitor your condition and take blood tests for several months.
- Check with your doctor on whether your liver functions normally. If not, check what the effect of treatment with Enteavenir on it will be.
- If you are a carrier of HIV (human immunodeficiency virus). You should not take Enteavenir to treat your hepatitis B viral infection unless you are taking medicines to treat HIV at the same time, as the effectiveness of future HIV treatment may be reduced. Enteavenir does not control your HIV infection.
- You have previously received treatment for chronic hepatitis B, please inform your doctor.

Children and adolescents
Enteavenir is not intended for use in children and adolescents under the age of 18 years.

Drug interactions
If you are taking or have recently taken other medicines, including nonprescription medications and dietary supplements, tell your doctor or pharmacist.

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

Pregnancy, breastfeeding and fertility
Pregnancy
- Inform your doctor if you are pregnant or are planning to become pregnant. It has not been demonstrated yet that Enteavenir is safe to use during pregnancy.
- Enteavenir must not be used during pregnancy unless specifically directed otherwise by your doctor.

Fertility
It is important that women of childbearing age receiving treatment with Enteavenir use effective methods of contraception to avoid becoming pregnant.

Breastfeeding
You should not breastfeed during treatment with Enteavenir. Inform your doctor if you are breastfeeding. It is not known whether entecavir, the active ingredient in Enteavenir, is excreted in breast milk.

Driving and using machines
Dizziness, tiredness (fatigue) and sleepiness (somnolence) are common side effects when using this medicine, which may impair your ability to drive or operate machines.
If you have any concerns consult your doctor.

Important information about some of this medicine's ingredients
This medicine contains less than 1 millimole (23 mg) sodium per dose, that is to say essentially 'sodium-free'.

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 Enteavenir.

Only your doctor will determine your dose and how you should take this medicine. Check with your doctor or pharmacist 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 hepatitis B virus 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.

The medicine should be taken according to the prescribed dose and dosing schedule by your doctor to ensure that your medicine is fully effective and to reduce the development of resistance to treatment. Take Enteavenir as long as your doctor has told you. Your doctor will tell you if and when you can stop the treatment. It is important not to skip any dose of the treatment.

Do not exceed the recommended dose.

Some patients must take Enteavenir on an empty stomach (see chapter 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.

There is no information about splitting/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 this medicine
It is important that you do not miss any doses.
If you forget to take the medicine at the scheduled 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 patients report very serious hepatitis symptoms when they stop treatment with Enteavenir. 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 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 Enteavenir 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 Enteavenir 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, 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.
- **Storage conditions:** Store below 25°C
- Shelf life after the first opening of the bottle pack: Use within 90 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:
Tablet core:
Calcium carbonate, starch pregelatinized, soy polysaccharides, citric acid monohydrate, sodium stearyl fumarate, carmellose sodium.

Tablet coating:
Enteavenir 0.5 mg:
Hypromellose 6cP, titanium dioxide, macrogol 400, polysorbate 80.
Enteavenir 1 mg:
Hypromellose 6cP, titanium dioxide, macrogol 400, iron oxide red (E172).

What the medicine looks like and contents of the pack:
Enteavenir 0.5 mg:
White to off white, triangle shaped, biconvex film-coated tablet debossed with 'J' on one side and '110' on the other side.

Enteavenir 1 mg:
Pink, triangle shaped, biconvex film-coated tablet debossed with 'J' on one side and '111' on the other side.

A bottle pack contains 30 film-coated tablets.
A blister pack (tray) contains 30 or 90 film-coated tablets.
Not all pack types and sizes may be marketed.

Registration holder's name and address: BioAvenir Ltd., 1 David Hamelech Street, Herzliya Pituach, 4666101.

Manufacturer's name and address:
Hetero Labs Limited
Unit V, Tsiic Formulation Sez, Survey Nos 439, 440,441 & 458 Polepally Village, Jadcherla Mandal, Mahaboob Nagar District, Telangana State, India

This leaflet was revised in April 2021 according to MOH guidelines.

Registration number of the medicine in the Ministry of Health's National Drug Registry:
Enteavenir 0.5 mg - 166-96-36713-99
Enteavenir 1 mg - 166-97-36714-99