PATIENT INFORMATION LEAFLET

BARAVIR 0.5 mg film coated tablet

It is taken orally.

- **Active Ingredient:** Each film-coated tablet contains 0.5325 mg entecavir monohydrate equivalent to 0.5 mg entecavir.
- **Excipient:** Lactose monohydrate (bovine sourced), microcrystalline cellulose 101, microcrystalline cellulose 102, PVP K-30, crospovidone, magnesium stearate and titanium dioxide

Please read the LEAFLET carefully before you start using this medication as it involves important information for you.

- *Keep this leaflet. You may need to read it again later.*
- *If you have further questions, please consult your doctor or pharmacist.*
- *This medication is prescribed specifically for you; please do not give it to others.*
- *While using this medication if you go to the doctor or hospital, tell your doctor that you are using this medication.*
- *Please follow what is written in this leaflet. Do not use **high or low** doses other than the recommended dose for you.*

In this leaflet,

Headlines are included.

1. What is BARAVIR and what is it used for?

BARAVIR belongs to a group of medicines called antivirals. BARAVIR is used in the treatment of hepatitis B virus (HBV) infection in adults.

BARAVIR 0.5 mg film-coated tablets each contain 0.5325 mg entecavir monohydrate equivalent to 0.5 mg entecavir as active ingredient.

BARAVIR 0.5 mg film-coated tablet is in the form of white triangular biconvex film-coated tablets. Each box contains 30 tablets. BARAVIR is used in the treatment of hepatitis B virus (HBV) infection in adults.

Infection caused by the hepatitis B virus can damage your liver. BARAVlR reduces the amount of viruses in your body and improves the condition of your liver.

2. **Special warnings and precautions for the use of BARAVIR**

DO NOT USE BARAVIR in the following situations.

Do not use if you are allergic to entecavir or other ingredients of BARAVIR.

USE BARAVIR CAREFULLY in the following situations.

• If you have an infection caused by (or caused by) human immunodeficiency virus (HIV),

• If you have kidney failure, the dose of the drug may need to be changed as BARAVIR is excreted from your body through the kidneys,

• If you have cirrhosis, consult your doctor about possible effects on your body.

• If you have had a liver transplant,

• If you have HIV, be sure to tell your doctor about this.

• Do not use BARAVIR unless you are using any medication to treat HIV concurrent with your hepatitis B infection, as this will reduce the effectiveness of future HIV treatment. BARAVIR will not control your HIV infection.

Please consult your doctor if these warnings are valid for you, even at any time in the past.

BARAVIR does not prevent you from transmitting HBV to other people. Therefore, take the necessary precautions to avoid transmitting HBV to other people. Vaccination will protect against the risk of HBV transmission. BARAVIR belongs to a group of drugs that can cause lactic acidosis (accumulation of lactic acid in the blood) and liver enlargement. Symptoms such as nausea, vomiting, and stomach pain may indicate lactic acidosis. These rare but serious side effects are rarely fatal. Lactic acidosis occurs more frequently, especially in overweight women. If you are using BARAVIR, your doctor will examine you regularly.

Using BARAVIR with food and beverage

BARAVIR can be taken on an empty or full stomach in many cases. If you have been treated with a drug containing lamivudine active ingredient before, but this treatment was unsuccessful and you have switched to BARAVIR treatment, take BARAVIR once a day on an empty stomach. If you have advanced liver disease, your doctor will recommend that you take BARAVIR on an empty stomach (2 hours before or 2 hours after a meal).

Pregnancy

Consult your doctor or pharmacist before using this medicine.

BARAVIR should not be used during pregnancy unless absolutely necessary. Your doctor will talk about the potential risks of using BARAVIR during pregnancy. Its use during pregnancy has not been proven to be safe. Both men and women using BARAVIR should be advised to use effective contraceptive methods throughout the treatment period.

If you notice that you are pregnant during your treatment, consult your doctor or pharmacist immediately.

Lactation

Consult your doctor or pharmacist before using this medicine.

If you are breastfeeding, do not use BARAVIR, because it is not known whether the active ingredient of the drug passes into your milk.

Use of vehicles and machines

BARAVIR is not expected to affect the ability to drive and use machines; however, side effects such as dizziness, weakness and drowsiness may affect your ability to drive and use machines. If you have any doubts, consult your doctor.

Important information about some of the excipients contained in BARAVIR

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking BARAVIR due to the lactose monohydrate (bovine sourced) it contains.

Using with other medicines

• Inform your doctor if you are taking medications that reduce your kidney function.

If you are currently using any prescription or non-prescription medication or have used it recently, please inform your doctor or pharmacist about this issue.

3. How is BARAVIR used?

Instructions for appropriate use and dose / frequency of administration:
Always use BARAVIR as directed by your doctor. If you are not sure, you should definitely consult your doctor or pharmacist. The usual dose of BARAVIR is 0.5 mg or 1 mg once a day. Depending on whether you have previously received HBV treatment and the medication you have taken or your kidney problems; your doctor may decide that you need to take lower doses or take BARAVIR less than a day. The dose to be given to you will also be determined according to the condition of your liver. Your doctor will tell you the appropriate dose for you. Always take the dose recommended by your doctor to get the full effect of your medication and to reduce the development of resistance to treatment.

Take BARAVIR for the duration recommended by your doctor.

Your doctor will tell you when to stop treatment.

Application route and method:

Take the tablets with a sufficient amount of water (e.g. a glass). If you have been treated with a drug containing lamivudine active ingredient before, but this treatment was unsuccessful and you have switched to BARAVIR treatment, take BARAVIR once a day on an empty stomach. If you have advanced liver disease, your doctor will recommend that you take BARAVIR on an empty stomach (2 hours before or 2 hours after a meal).

Different age groups

Use in children:

The safety and efficacy of BARAVIR in patients younger than 16 years is unknown.

It is not recommended for use in patients younger than 16 years.

Use in the elderly:

The dose of BARAV1R does not need to be adjusted according to age.

Special use cases:

Kidney/Liver Failure:

The dose of BARAVIR may need to be changed in patients with renal failure.

There is no need to adjust the dose of BARAVIR in patients with liver failure.

If you have the impression that the effect of BARAVIR is too strong or too weak, talk to your doctor or pharmacist.

If you have used more BARAVIR than you should

If you have used more BARAVIR than you should, talk to a doctor or a pharmacist.

If you forget to use the BARAVIR

It is important to remember to take any dose. If you forget to take a dose of BARAVIR, take it as soon as you realize that you have forgotten. If it is time for your next dose, do not take the missed dose and take your next dose at the usual time.

Do not take a double dose to make up for forgotten doses.

Effects that may occur when treatment with BARAVIR is terminated

Some people may experience very serious liver inflammation symptoms when BARAVIR treatment is discontinued. If you notice any change in symptoms after stopping treatment, tell your doctor immediately. Do not stop BARAVIR treatment unless recommended by your doctor; your liver inflammation may get worse when you stop treatment. When your treatment with BARAVIR is terminated, your doctor will continue to monitor you and perform blood tests for several months.

If you have any further questions on the use of this medicine, consult your doctor or pharmacist.

4. What are the possible side effects?

Like all medicines, there may be side effects in people sensitive to the ingredients of BARAVIR.

If any of the following occur, stop using BARAVIR and IMMEDIATELY inform your doctor or go to the nearest emergency department.

• Sudden hypersensitivity response

• Rash,

• Itching

• Skin redness

These are all very serious side effects. If you have one of these, you have a serious allergy to BARAVIR. You may need urgent medical attention or hospitalization.

All of these very serious side effects are very rare.

If you notice any of the following, tell your doctor.

Side effects are listed below according to their frequency.

Very common: It can be seen in at least 1 of 10 patients.

Common: less than one in 10 patients, but more than one in 100 patients.

Uncommon: less than one in 100 patients, but more than one in 1,000 patients.

Rare: less than one in 1,000 patients, but more than one in 10,000 patients.

Very rare: May be seen less than one in 10,000 patients.

Unknown: It cannot be estimated from the available data.

Common:

•Headache

• Insomnia

• Tiredness

• Dizziness

• Drowsiness

• Nausea

• Diarrhea

• Indigestion

• Vomiting

• Increase in liver enzymes

Uncommon:

• Rash

• Hair loss

Rare:

• Severe allergic reactions

If you encounter any side effects not mentioned in these leaflet, inform your doctor or pharmacist.

5. How to store BARAVIR?

Keep BARAVIR out of the reach and sight of children and in its package. Store at room temperature below 25 ° C. Use in accordance with the expiry date.

Do not use BARAVIR after the expiry date on the label or package.

"Expiry Date" is the last day of the specified month.

Do not use BARAVIR if you notice any damage to the product and / or package.

Marketing Authorization Holder

Drogsan İlaçları San. ve Tic. A.Ş.

Oğuzlar Mah. 1371. Sokak No:7/3

06520 Balgat/ ANKARA

Production Facility:

Farma-Tek İlaç Sanayi ve Ticaret A.Ş.

Merkez/ Kırklareli

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