

PATIENT INFORMATION LEAFLET

AVIRAVIR 1 mg film coated tablets

For oral use.

Active ingredient : Each film-coated tablet contains 1.065 mg entecavir monohydrate as active ingredient equivalent to 1 mg entecavir.

Excipient(s) : Lactose monohydrate (sourced from cow's milk), microcrystalline cellulose, pH101, crospovidone, povidone, microcrystalline cellulose PH 102, magnesium stearate, hypromellose, titanium dioxide, macrogol, red iron oxide.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- *Keep this leaflet. You may need to read it again*
- *If you have any further questions, ask your doctor, pharmacist or nurse*
- *This medicine has been prescribed for you only. Do not pass it on to others.*
- *During the use of this drug, tell that you are using this medication when you go to the doctor or hospital.*
- *Follow exactly what is written in this leaflet. Do not use **lower or higher** dose except recommended dose for you.*

What is in this leaflet:

1. *What AVIRAVIR is and what it is used for,*
2. *What you need to know before you take AVIRAVIR,*
3. *How to take AVIRAVIR,*
4. *Possible side effects,*
5. *How to store AVIRAVIR.*

1. What AVIRAVIR is and what it is used for

AVIRAVIR is included in a group of drugs called antivirals. AVIRAVIR is used to treat hepatitis B virus (HBV) infection in adults.

Each AVIRAVIR 1 mg film-coated tablets contains 1 mg entecavir as active ingredient.

AVIRAVIR 1 mg film-coated tablets are pink and triangular-shaped film-coated tablets. There are 30 tablets per boxes.

AVIRAVIR is used to treat hepatitis B virus (HBV) infection in adults.

Infection by the hepatitis B virus can lead to damage to the liver. AVIRAVIR reduces the amount of virus in your body, and improves the condition of the liver.

2. What you need to know before you take AVIRAVIR

Don't take AVIRAVIR in the following situations:

Do not take if you are allergic (hypersensitive) to entecavir or any of the other ingredients of AVIRAVIR.

Use AVIRAVIR cautiously in the following

If,

- You have an infection that generated (or caused) by human immunodeficiency virus (HIV's),
- If you have kidney failure - may need to change the dose of the drug because AVIRAVIR is eliminated from your body through the kidneys.
- Consult your doctor about whether you have cirrhosis, if, possible effects on your body.
- If you had liver transplantation,
- If you are infected with HIV (human immunodeficiency virus) be sure to tell your doctor. You should not take AVIRAVIR 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. AVIRAVIR will not control your HIV infection.

If these warnings are included in any period in the past, though true for you, please consult your doctor.

Taking AVIRAVIR 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.

AVIRAVIR 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 AVIRAVIR.

AVIRAVIR with food and drink

In most cases you may take AVIRAVIR with or without food. However, if you have had a previous treatment with a medicine containing the active substance lamivudine you should consider the following. If you were switched over to AVIRAVIR because the treatment with lamivudine was not successful, you should take AVIRAVIR on an empty stomach once daily. If your liver disease is very advanced, your doctor will also instruct you to take AVIRAVIR on an empty stomach (at least 2 hours after a meal and at least 2 hours before your next meal).

Pregnancy

Ask your doctor or pharmacist for advice before taking this medicine.

AVIRAVIR should not be used during pregnancy unless clearly necessary. Your doctor will talk about the potential risks of AVIRAVIR during pregnancy. It has not been proven to be safe during pregnancy. It should be advised to use an effective method of contraception to both of women and men treatment with AVIRAVIR to avoid becoming pregnant during the treatment period.

Consult your doctor or pharmacist if you notice that you are pregnant during treatment.

Breast-feeding

Ask your doctor or pharmacist for advice before taking this medicine.

Do not use AVIRAVIR if you are breast-feeding. Because it is not known whether entecavir, the active ingredient in AVIRAVIR, is excreted in human breast milk.

Driving and using machines

Not expected to affect the ability to drive and use machines. But dizziness, fatigue and somnolence are common side effects which may impair the ability to drive and use machines.

Important informations about some excipients of AVIRAVIR

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

Other medicines and AVIRAVIR

If you are taking medications that reduce renal function, please inform your doctor.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines with or without prescription.

3. How to take AVIRAVIR**Instructions for proper use:**

Always use AVIRAVIR as prescribed by your doctor. If you are not sure, you should always consult your doctor or pharmacist.

The normal dose of AVIRAVIR is 0.5 mg or 1 mg once daily.

Depending on whether you have been treated for HBV before and the medicine you are taking or if you have kidney problems;

your doctor may decide that you should take lower doses or that you should take AVIRAVIR less often than once a day. The dose you will be given will also be determined by the condition of your liver.

Your doctor will tell you the dose that is right for you. Always take the dose recommended by your doctor to get the full effect of your medicine and to reduce the development of resistance to treatment. Take AVIRAVIR for the duration recommended by your doctor. Your doctor will tell you when to stop treatment.

Way and method of administration:

Take tablets in sufficient quantity (e.g., a cup) with water.

AVIRAVIR can be taken with or without food in many cases.

- If you have previously received treatment with a medicine containing lamivudine, however this treatment has failed and after you start to take AVIRAVIR, take AVIRAVIR once a day without food.
- If you have advanced liver disease, your doctor will advise you to take AVIRAVIR on an empty stomach (more than 2 hours before and more than 2 hours after a meal).

Different age groups:**Use in children:**

The safety and efficacy of AVIRAVIR aren't known in patients under the age of 16. In children it is not recommended for use in patients under the age of 16.

Use in elderly:

No dosage adjustment based on age is required.

Cases of special use:**Renal/Hepatic impairment:**

Dosage adjustment may require in patients with renal impairment. No dosage adjustment is required in patients with hepatic impairment.

If you have an impression about effect of AVIRAVIR that it is strong or weak, tell your doctor or pharmacist.

If you take more AVIRAVIR than you should:

If you use AVIRAVIR more than you need, talk to your doctor and pharmacist.

If you forget to take AVIRAVIR

It is important that you do not miss any doses. If you miss a dose of AVIRAVIR, take it as soon as possible, and then take your next scheduled dose at its regular time. If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time.

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

If you stop taking AVIRAVIR

Some people get very serious hepatitis symptoms when they stop taking AVIRAVIR. Tell your doctor immediately about any changes in symptoms that you notice after stopping treatment.

Do not stop AVIRAVIR treatment unless your doctor advise. If you stop taking AVIRAVIR, your liver inflammation may worsen. When your treatment is ended, your doctor will continue to monitor you and make blood tests for several months.

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

4. Possible side effects

Like all medicines, AVIRAVIR can cause side effects, although not everybody gets them.

If you notice any of the following, inform your doctor or refer to the nearest hospital emergency department:

- Immediate hypersensitivity reactions,
- Rash,
- Itching,
- Redness of the skin.

These are all serious side effects. If you have one of them, then you have a serious allergy to AVIRAVIR. You may need emergency medical attention or hospitalization.

These serious side effects are very rare.

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

- Common (affects 1 to 10 users in 100): Headache, insomnia, fatigue, dizziness, somnolence, nausea, diarrhea, indigestion, vomiting, elevated liver enzymes

- Uncommon (affects 1 to 10 users in 1,000): Rash, hair loss
- Rare (affects 1 to 10 users in 10,000): Severe allergic reactions

Reporting of side effects

If you experience any side effects that may or may not be listed in this leaflet, talk to your doctor, pharmacist or nurse. In addition, report the side effects you experience to the Turkish Pharmacovigilance Center (TÜFAM) by clicking on the "Drug Side Effect Reporting" icon on www.titck.gov.tr or by calling the side effect reporting line at 0 800 314 00 08. By reporting side effects, you will contribute to obtaining more information about the safety of the medicine you are using.

If you experience any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. How to store AVIRAVIR?

Keep this medicine out of the sight and reach of children and store in the original package.

Store at room temperature below 25 °C.

Use in accordance with the expiry date.

Do not use AVIRAVIR after the expiry date on the package.

Do not use AVIRAVIR if you notice any defects in the product and/or its packaging. Remaining and consult your pharmacist for unused medicines.

Marketing Authorisation Holder:

Humanis Saglik A.S.

Mahmutbey Mahallesi, Tasocagi Yolu Caddesi, Solen Residence Apt. No:19/1/11

Bagcilar/Istanbul/TURKEY

Manufacturer:

Humanis Saglik A.S.

Karaagac Mah., Fatih Blv., No:32 COSB – Kapakli/Tekirdag

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