

HEPSERA TABLET

Adefovir dipivoxil (10 mg)

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What Hepsera is used for

Hepsera is used to treat chronic hepatitis B, an infection with hepatitis B virus (HBV), in adults.

How Hepsera works

Hepsera belongs to a group of medicines called antiviral medicines.

Infection with the hepatitis B virus leads to damage to the liver. Hepsera reduces the amount of the virus in your body, and has been shown to reduce liver damage.

Before you use Hepsera

- When you must not use it

Do not take Hepsera

- If you are allergic to adefovir, adefovir dipivoxil or any of the other ingredients of this medicine
- Tell your doctor at once if you could be allergic to adefovir, adefovir dipivoxil or any of the other ingredients of Hepsera.

- Before you start to use it

Please inform your doctor if you have or have had the following medical condition:

- Kidney disease
- Liver disease
- HIV co-infection

If you are over 65 years of age your doctor may monitor your health more closely.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Tell your doctor immediately if you are pregnant or planning to become pregnant. It is not known whether Hepsera is safe to use during human pregnancy.

Use an effective method of contraception to avoid becoming pregnant if you are a woman of child-bearing age taking Hepsera.

Do not breast-feed while taking Hepsera. It is not known whether the active substance in this medicine passes into breast milk.

Do not use Hepsera in children or adolescents under 18 years of age.

- Taking other medicines

Do not take Hepsera if you are taking any medicines containing tenofovir.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines, including medicines and herbal products obtained without a prescription.

It is especially important to tell your doctor if you are taking or have recently taken any of the following medicines which may damage your kidneys, or interact with Hepsera:

- Ibuprofen (used for pain relief)
- Lamivudine (used to treat hepatitis B and HIV infection)
- Paracetamol (used for pain and fever)
- Trimethoprim (used for bacterial infection)
- Sulphamethoxazole (used for bacterial infection)

How to use Hepsera

- How much to use

Always take this medicine exactly as your doctor has told you. This is to make sure that your medicine is fully effective and to reduce the development of resistance to the treatment. Check with your doctor or pharmacist if you are not sure.

The recommended dose is one 10 mg tablet each day, taken with or without food. A different dose may be given to patients with kidney problems.

- When to use it

Always take this medicine exactly as your doctor has told you. Hepsera can be taken with or without food.

- How long to use it

Do not stop taking Hepsera without your doctor's advice. If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- If you forget to use it

It is important not to miss a dose.

- If you do miss a dose of Hepsera, take it as soon as you can, and then take your next scheduled dose at its regular time.

- If it is nearly time for your next dose, skip the missed dose. Wait and take the next dose at the regular time. Do not take a double dose (two doses close together).
- If you are sick (vomit) less than 1 hour after taking Hepsera take another tablet. You do not need to take another tablet if you are sick more than 1 hour after taking Hepsera.

- *If you use too much (overdose)*

If you accidentally take too many Hepsera tablets, contact your doctor or nearest hospital immediately.

While you are using it

- *Things you must do*

After stopping Hepsera tell your doctor immediately about any new, unusual or worsening symptoms that you notice after stopping treatment. Some patients have had symptoms or blood tests indicating that their hepatitis has worsened after stopping treatment with Hepsera. It's best for your doctor to monitor your health after stopping treatment with Hepsera. You may need blood tests for several months after treatment.

- *Things you must not do*

Do not stop taking Hepsera without your doctor's advice.

This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

- *Things to be careful of*

- Once you start taking Hepsera
 - look out for possible signs of lactic acidosis which include:
 - deep, rapid, difficult breathing
 - drowsiness
 - numbness or weakness in the limbs
 - feeling sick (nausea), being sick (vomiting)
 - stomach pain
- Take care not to infect other people. Hepsera does not reduce the risk of passing on HBV to others through sexual contact or blood contamination. You must continue to take precautions to avoid this. A vaccine is available to protect those at risk from becoming infected with HBV.
- If you are HIV positive this medicine will not control your HIV infection.

Side Effects

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

Common side effects

(These can affect 1 to 10 in every 100 people taking Hepsera)

- Headache
- Feeling sick (nausea)
- Diarrhoea
- Digestive problems including wind or discomfort after eating meals
- Stomach pain
- Kidney problems, as shown by blood tests

Tell a doctor or pharmacist if you are worried about any of these.

Very common side effects

(These can affect more than 10 in every 100 people taking Hepsera)

- Weakness
- Tell a doctor or pharmacist if you are worried about this.

Side effects before or after having a liver transplant

Some patients have experienced:

- Rash and itching – common
- Feeling sick (nausea) or being sick (vomiting) – common
- Kidney failure – common
- Kidney problems – very common

Tell a doctor or pharmacist if you are worried about any of these.

- Also tests may show decreases in phosphate (common) or increases in creatinine (very common) in the blood.

Other possible side effects

Some patients may also experience:

- Kidney failure
- Damage to kidney tubule cells
- Kidney problems may lead to softening of the bones (which causes bone pain and sometimes leads to fractures) and muscle pain or weakness.
- Inflammation of the pancreas (pancreatitis)

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list. Ask your doctor or pharmacist if you do not understand anything in this list.

You may report any side effects of adverse drug reactions directly to the National Centre

for Adverse Drug Reaction Monitoring by calling Tel: 03-78835550, or visiting the website npra.moh.gov.my (Public → Reporting Medicinal Problems / Side Effects / AEFI / Vaccine Safety).

Storage and Disposal of Hespera

- Storage

Keep this medicine out of the sight and reach of children. Do not use this medicine after the expiry date which is stated on the bottle and carton after {EXP}. The expiry date refers to the last day of that month. Do not store above 30°C (86°F). Store in the original package in order to protect from moisture. Keep the bottle tightly closed. Return any leftover tablets to your pharmacist. Only keep them if your doctor tells you to.

- Disposal

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

Product Description

- What it looks like

Hespera tablets, 10 mg are white to off-white, round, flat-faced tablets with a bevelled edge and debossed with “GSK KNU” on one side, and blank on the other side.

Hespera tablets are supplied in high density polyethylene (HDPE) bottles with a child-resistant closure. Each bottle contains 30 tablets and silica gel desiccant.

- Ingredients

- Active ingredient(s)
10 mg adefovir dipivoxil

- Inactive ingredient(s)
Pregelatinised starch (gluten free); croscarmellose sodium; lactose monohydrate; talc and magnesium stearate.

- MAL number

MAL20040907ARZ

Manufacturer

GlaxoSmithKline (Tianjin) Co. Ltd.
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Product Registration Holder

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