

Consumer Medicine Information

HEPSERA[®] (adefovir dipivoxil 10 mg) Tablets

WHAT IS IN THIS LEAFLET

Read all of this leaflet carefully before you start taking this medicine.

This leaflet answers some of the common questions about HEPSERA. It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist about your medical condition or treatment. If you have further questions, please ask your doctor or your pharmacist.

Keep this leaflet with your HEPSERA medicine. You may need to read it again.

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

It is extremely important that you do not change or stop your medicine without first talking with your doctor or pharmacist (see **WHEN YOU ARE TAKING HEPSERA TABLETS** and **POSSIBLE SIDE EFFECTS**).

WHAT HEPSERA TABLETS ARE USED FOR

HEPSERA belongs to a group of medicines called antiviral medicines.

HEPSERA is used to treat chronic hepatitis B in patients 12 years of age or older.

Hepatitis B is caused by infection with the hepatitis B virus (HBV) which can damage the liver. HEPSERA reduces the amount of the virus in your body, by lowering the ability of the virus to multiply and infect new liver cells and can improve the inflammation and scar tissue caused by the hepatitis B virus in your liver. Lowering the amount of virus in your body may reduce the chance of developing cirrhosis, liver failure and liver cancer.

We do not know how long HEPSERA may help treat your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance.

BEFORE YOU TAKE HEPSERA

When you must not take it

- If you are hypersensitive (allergic) to adefovir, adefovir dipivoxil or to any of the other ingredients of HEPSERA tablets. Read the side effects section to find out symptoms of allergy. The ingredients of HEPSERA are listed in the product description section of this leaflet.
- Do not take HEPSERA if you are already taking VIREAD (tenofovir disoproxil fumarate), TRUVADA (tenofovir disoproxil fumarate/emtricitabine combination tablet), or ATRIPLA (tenofovir

disoproxil fumarate/
emtricitabine/efavirenz
combination tablet).

- Do not take HEPSERA if you are over the age of 65 before discussing this with your doctor. HEPSERA is not recommended for use in children less than 12 years of age.
- Do not take HEPSERA after the expiry or “use by” date (EXP) printed on the back of the pack. If you take it after the expiry date has passed, it may not work as well.
- Do not take HEPSERA if the packaging is torn or shows signs of tampering.
- If you are not sure whether you should be taking HEPSERA, talk to your doctor.

Before you start to take HEPSERA

You must tell your doctor if:

- You are allergic to foods, dyes, preservatives or any other medicines.
- You are pregnant, trying to become pregnant or breast-feeding. The safe use of HEPSERA in human pregnancy has not been demonstrated. For this reason, it is important that women of childbearing age receiving treatment with HEPSERA use an effective method of contraception to avoid becoming pregnant. It is not known whether the active substance (adefovir dipivoxil) in this medicine is

excreted in human breast milk. Consequently, nursing mothers should stop breast-feeding during treatment with HEPSERA.

- You have or have ever had kidney problems. If you have reduced function of your kidneys or are at risk of having reduced function then HEPSERA may damage your kidneys. While taking HEPSERA you will require regular tests of your kidney function and may require a smaller dose of HEPSERA than patients with normal kidney function.
- HEPSERA should not be taken if you have unrecognised or untreated HIV infection because HEPSERA may reduce the effectiveness of some drugs used to treat HIV. There is limited experience in treating individuals with both chronic hepatitis B infection and HIV. Your doctor should offer to test your blood to see if you have HIV infection before you start treatment with HEPSERA.

This medicine is only available from a pharmacist after it has been prescribed by a doctor who specialises in the treatment of chronic hepatitis B infection. If you wish to continue receiving treatment with HEPSERA it is important you remain under the care of a hospital or doctor who specialises in the treatment of chronic hepatitis B infection.

HEPSERA does not reduce the risk of passing HBV to others through sexual contact or blood contamination. Therefore, it is important to continue to take

appropriate precautions to prevent passing HBV to others.

Taking other medicines

Tell your doctor if:

- You are taking any other medicines, including medicines you buy without a prescription from a pharmacy, supermarket or health food shop.
- You are already taking VIREAD (tenofovir disoproxil fumarate).
- Some medicines may affect the way others work. Your doctor or pharmacist will be able to tell you what to do when taking HEPSERA with other medicines.

HOW TO TAKE HEPSERA

- Stay under a doctor's care when taking HEPSERA. Do not change your treatment or stop treatment without first talking with your doctor.
- Take HEPSERA exactly as your doctor prescribed it. Follow the directions from your doctor or pharmacist, exactly as written on the label. Set up a dosing schedule and follow it carefully.

Take one HEPSERA 10 mg tablet once daily with or without food. Food does not affect how HEPSERA works. If you have reduced function of your kidneys you may require a lower dose.

- Always take the dose recommended by your doctor to ensure that your medicine

is fully effective and to reduce the development of drug resistance.

- You may be prescribed another HBV medicine to take with HEPSERA. Check with your doctor or pharmacist if you have any questions.
- HEPSERA is absorbed rapidly. Do not take another HEPSERA dose if vomiting has occurred unless it occurs within 1 hour after taking HEPSERA.
- When your HEPSERA supply starts to run low, get more from your doctor or pharmacist. This is very important because the amount of virus in your blood may increase if the medicine is stopped for even a short time. The virus may develop resistance to HEPSERA, become harder to treat and may result in very severe hepatitis and serious liver problems (see POSSIBLE SIDE EFFECTS).

How much to take

Take one HEPSERA 10 mg tablet once daily or as advised by your doctor.

If you are not sure how much HEPSERA you should take, check with your doctor or pharmacist. Do not change the amount of HEPSERA you take unless told to do so by your doctor.

Your doctor will tell you how much HEPSERA to take and how often to take it. You will also find this information on the

label of your medicine container.

How long to take HEPSERA

Because your medicine helps to control your condition, but does not cure it, you will need to take HEPSERA every day. Do not stop taking HEPSERA without first talking to your doctor.

If you forget to take HEPSERA

It is important to take the prescribed daily dose in order to get the maximum benefit of treatment.

If you forget to take your daily dose of HEPSERA take it as soon as you remember. Do not take a double dose to make up for the forgotten dose. Do not take more than one dose of HEPSERA in a day.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (telephone 131126), or in New Zealand the Poisons Centre (telephone 0800 764 766), or go to the accident and emergency department at your nearest hospital if you think you or anyone else may have taken too many HEPSERA tablets. Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

WHEN YOU ARE TAKING HEPSERA TABLETS

Things you must do

- Tell your doctor or pharmacist that you are taking HEPSERA if you are about to be started on any other medicines.
- Tell your doctor if you become pregnant or are trying to become pregnant.
- Tell your doctor if for any reason you have not taken your medicine exactly as prescribed.

Things you must not do

- Do not stop taking HEPSERA or change the dose without first checking with your doctor.
- Do not give this medicine to anyone else even if their symptoms seem similar to yours.
- Do not use HEPSERA to treat any other complaints unless your doctor says so.

Things to be careful of

Be careful driving or operating machinery until you know how HEPSERA medicine affects you.

POSSIBLE SIDE EFFECTS

Like all medicines, HEPSERA can have side effects. Some may be serious and need medical attention.

Check with your doctor as soon as possible if you have any problems while taking HEPSERA, even if you do not think the problems are connected with the medicine or are not listed in this leaflet.

Tell your doctor or pharmacist if you notice any of the following:

- Weakness
- Headache
- Nausea
- Flatulence
- Diarrhoea
- Problems with digestion
- Stomach pain

Hepatic Flares

It is extremely important that you do not stop taking HEPSERA without your doctor's advice. Some patients with hepatitis B infection may have a "flare-up" of Hepatitis B if they stop taking HEPSERA, where the disease suddenly returns in a worse way than before. This flare-up may lead to liver failure and possibly liver transplantation or death.

After stopping HEPSERA, tell your doctor IMMEDIATELY about any new, unusual, or worsening symptoms that you notice after stopping treatment. After you stop taking HEPSERA, your doctor will still need to check your health and take blood tests to check your liver for several months.

Allergy

Some people are allergic to medicines. If you have any of the following symptoms soon after taking your medicine, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital:

- Skin troubles such as lumpy skin rash or "hives"
- Swelling of the face, lips, mouth or throat which may

- cause difficulty in swallowing or breathing
- Wheezing, chest pain or tightness
- Fainting

These are very serious effects. If you have them, you may have a serious allergic reaction. You may need urgent medical attention or hospitalisation. All these side effects are very rare.

Serious Liver Problems (hepatotoxicity)

If you have any of the following symptoms after taking your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- Your skin or the white part of your eyes turns yellow (jaundice)
- Your urine turns dark
- Your bowel movements (stools) turn light in colour
- Nausea
- Stomach pains

These side effects may be due to a condition called hepatotoxicity with liver enlargement and fat deposits in the liver (steatosis) which sometimes occurs in patients taking antiviral medicines.

Lactic Acidosis

If you have any of the following symptoms after taking your medication, tell your doctor IMMEDIATELY or go to the accident and emergency department at your nearest hospital.

- You feel very weak or tired.

- You have unusual (not normal) muscle pain.
- You have trouble breathing.
- You have stomach pain with nausea and vomiting.
- You feel cold, especially in your arm and legs.
- You feel dizzy or lightheaded.
- You have a fast or irregular heartbeat.

These side effects may be due to a condition called lactic acidosis (build up of an acid in the blood). Lactic acidosis can be a medical emergency and may need to be treated in the hospital.

Other side effects

This list of side effects is not complete. There have been other side effects in patients taking HEPSERA. In addition to the side effects listed above, some patients who are waiting for liver transplantation or who have undergone liver transplantation have also experienced an adverse effect on their kidneys, including a change in the amount of creatinine in their blood and failure of the kidneys. 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 don't understand anything in this list.

Do not be alarmed by this list of possible side-effects. Most of them are very rare and you may not experience any of them.

AFTER TAKING HEPSERA

Storing HEPSERA

Keep HEPSERA tablets where children cannot reach them. A locked cupboard at least one-and-a half metres above the ground is a good place to store them.

Keep HEPSERA tablets in a cool, dry place where it stays below 25 °C.

Do not store HEPSERA or any other medicine in a bathroom or near a sink.

Do not leave it in the car or on a windowsill – heat and dampness can destroy some medicines.

Keep your HEPSERA tablets in the bottle with the cap tightly closed until you take them. If you take HEPSERA tablets out of their pack they may not keep well.

Disposal

If your doctor tells you to stop taking HEPSERA, or the medicine has passed their expiry date, ask your pharmacist what to do with any tablets left over.

PRODUCT DESCRIPTION

What HEPSERA tablets look like

HEPSERA tablets are white, with “10” and “GILEAD” on one side and a picture of a liver on the other side. Each bottle contains 30 tablets.

HEPSERA Tablet Ingredients

Each HEPSERA tablet contains 10 mg of adefovir dipivoxil.

Other ingredients are:

Croscarmellose sodium
Lactose monohydrate
Magnesium stearate
Pregelatinized maize starch
Talc

AUST R 96916

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