

HEPSERA® Tablets

10 mg adefovir dipivoxil

Consumer Medicine Information

What is in this leaflet

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.

What HEPSERA tablets are used for

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.

How HEPSERA works

HEPSERA belongs to a group of medicines called antiviral medicines.

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.

Use in children

HEPSERA is not recommended for use in children under 12 years of age as its safety and effectiveness in that age group have not been established.

Before you take HEPSERA

Who must not take it

Do not take HEPSERA if you are allergic to:

- adefovir dipivoxil or
- any of the other ingredients of HEPSERA.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- rash, itching or hives on the skin
- swelling of the face, lips, tongue or other parts of the body

The ingredient of HEPSERA is listed in the product description section of this leaflet.

Do not take HEPSERA, if you are already taking any other medicines that contain similar antiretroviral ingredients such as:

- VIREAD
- TRUVADA
- ATRIPLA
- STRIBILD

- EVIPLERA
- GENVOYA

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 date printed on the pack or if the packaging is torn or shows signs of tampering.

If it has expired or is damaged, return it to your pharmacist for disposal.

If you are not sure whether you should start taking HEPSERA, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Tell your doctor if 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.

Tell your doctor if 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.

Your doctor can discuss with you the benefits and risks of taking HEPSERA.

Taking other medicines

Tell your doctor or pharmacist if you are taking any other medicines including any

that you buy without a prescription from your pharmacy, supermarket or health food shop.

Tell your doctor or pharmacist if you are already taking VIREAD (tenofovir disoproxil fumarate).

These medicines may be affected by HEPSERA or may affect how well it works. You may need different amounts of the medicine, or you may need to take different medicines. Your doctor or pharmacist will advise you.

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 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 it

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 it

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

If it is almost time for your next dose, skip the dose you missed and take the next dose when you are meant to.

Otherwise, take it as soon as you remember, then go back to taking it as you would normally.

Do not take a double dose to make up for the dose that you have missed.

This may increase the chance of you getting an unwanted side effect.

If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering to use your medicine, ask your pharmacist for some hints.

If you take too much (overdose)

Immediately telephone your doctor, pharmacist or Poisons Information Centre 13 11 26 (Australia) and 0800 764 766 (New Zealand) or go to Accident and Emergency at your nearest hospital if you think that you or anyone else may have taken too much HEPSERA. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

While you are taking HEPSERA

Things you must do

Tell all doctors and pharmacists who are treating you that you are taking HEPSERA.

If you feel that HEPSERA is not helping your condition, tell your doctor or pharmacist.

Tell your doctor if, for any reason, you have not used HEPSERA exactly as prescribed.

Otherwise, your doctor may think that it was not effective and change your treatment unnecessarily.

Tell your doctor as soon as possible if there is any worsening of your condition.

Things you must not do

Do not give HEPSERA to anyone else, even if they have the same condition as you.

Do not stop taking HEPSERA or change the dose without checking with your doctor.

It is important not to suddenly stop taking your HEPSERA tablets, unless advised to do so by your doctor, since your condition may worsen.

Things to be careful of

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

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 patient's 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.

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

Storage

Keep your HEPSERA tablets in the bottle with the cap tightly closed until you take 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 where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

Disposal

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

Product description

What it looks 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.

Ingredients

Each HEPSERA tablet contains 10 mg of adefovir dipivoxil.

Each HEPSERA tablet also contains the following ingredients:

- Croscarmellose sodium
- Lactose monohydrate
- Magnesium stearate
- Pregelatinized maize starch
- Talc

Sponsor

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