

PATIENT INFORMATION

HEPSERA (hep-SER-rah)
(adefovir dipivoxil)
tablets

Read this Patient Information before you start taking HEPSERA and each time you get a refill. There may be new information. This information does not take the place of talking with your doctor about your medical condition or your treatment.

What is the most important information I should know about HEPSERA?

HEPSERA can cause serious side effects, including:

- **Worsening of hepatitis B infection.** Your hepatitis B (HBV) infection may become worse (flare-up) if you take HEPSERA and then stop taking it. A “flare-up” is when your HBV infection suddenly returns in a worse way than before.
 - **Do not** run out of HEPSERA. Refill your prescription or talk to your doctor before your HEPSERA is all gone.
 - **Do not** stop taking HEPSERA without first talking with your doctor.
 - If you stop taking HEPSERA, your doctor will need to check your health often and do blood tests regularly to check your HBV infection for at least several months.
- **HEPSERA may cause severe kidney problems.** Severe kidney problems can happen in anyone who takes HEPSERA, but certain people may have a higher risk of severe kidney problems with HEPSERA, including:
 - people who already have kidney problems or are at an increased risk for kidney problems, **and**
 - people who take certain medicines that can cause kidney problems. Ask your doctor whether any of the medicines you currently take can cause kidney problems.

Your doctor should do blood tests to check your kidney function during treatment with HEPSERA.

If you have kidney problems before you start taking HEPSERA your doctor may change your dose of HEPSERA. If you develop kidney problems during treatment, your doctor may need to change your dose of HEPSERA or may stop your treatment.

- **HIV resistance.** Your doctor may test you for HIV-1 infection before you start HEPSERA. If you have both HBV and HIV-1 and you only take HEPSERA, the HIV-1 virus may develop resistance and become harder to treat.
- **Build-up of acid in your blood (lactic acidosis).** Lactic acidosis can happen in some people who take HEPSERA. Lactic acidosis is a serious medical emergency that can lead to death.

Call your doctor right away if you get any of the following symptoms which could be signs of lactic acidosis:

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

- **Severe liver problems.** In rare cases, severe liver problems can happen that lead to death. **Call your doctor right away if you get any of the following signs or symptoms of liver problems.**

- your skin or the white part of your eyes turns yellow (jaundice).
- dark or “tea-colored” urine
- light-colored stools (bowel movements)
- nausea
- loss of appetite for several days or longer
- pain, aching, or tenderness on the right side of your stomach-area

You may be more likely to get lactic acidosis or serious liver problems if you are female, are very overweight (obese), or have been taking nucleoside analog medicines for a long time.

What is HEPSERA?

HEPSERA is a medicine used to treat people 12 years of age and older with chronic (long-lasting) infections with active hepatitis B virus.

HEPSERA is not for use in children under 12 years of age.

- HEPSERA may lower the amount of hepatitis B virus (HBV) in your body.
- HEPSERA may improve the condition of your liver.

Who should not take HEPSERA?

Do not take HEPSERA if you are allergic to any of the ingredients in HEPSERA. See the end of this leaflet for a complete list of the ingredients in HEPSERA.

What should I tell my healthcare provider before taking HEPSETRA?

Before taking HEPSETRA, tell your doctor about all of your medical conditions, including if you:

- have or had kidney problems. Your dose and schedule of HEPSETRA may need to be changed.
- are pregnant or plan to become pregnant. It is not known if HEPSETRA will harm your unborn baby.
Pregnancy Registry: There is a pregnancy registry for women who take HEPSETRA during pregnancy. The purpose of this registry is to collect information about the health of you and your baby. Talk with your doctor about how you can take part in this registry.
- are breastfeeding. It is not known if HEPSETRA passes into your breast milk. Talk with your doctor about the best way to feed your baby during treatment with HEPSETRA.

Tell your doctor about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. Some medicines may affect how HEPSETRA works, especially medicines that affect how your kidneys work. HEPSETRA can affect how your other medicines work. Your dose of HEPSETRA and the other medicines may need to be changed. Do not start a new medicine without telling your doctor. Your doctor can tell you if it is safe to take HEPSETRA with other medicines.

Especially tell your doctor if you take a medicine that contains tenofovir disoproxil fumarate or tenofovir alafenamide.

How should I take HEPSETRA?

- Take HEPSETRA exactly as your doctor tells you to take it.
- Your doctor will tell you how much HEPSETRA to take, and when and how often to take it.
- **Do not** change your dose or stop HEPSETRA without talking to your doctor. Your hepatitis may get worse if you change doses or stop.
- Take HEPSETRA at the same time each day that your doctor tells you, to avoid missing doses.
- Take HEPSETRA with or without food.
- Stay under the care of your doctor during treatment with HEPSETRA.
- When your HEPSETRA supply gets low, call your doctor or pharmacy for a refill. **Do not** run out of HEPSETRA.
- If you take too much HEPSETRA, call your doctor or go to the nearest hospital emergency room right away.
- It is not known how long you should take HEPSETRA. You and your doctor will need to decide when it is best for you to stop taking HEPSETRA. Some people get worsening of their hepatitis B infection when they stop taking HEPSETRA.
See “What is the most important information I should know about HEPSETRA?”.

What are the possible side effects of HEPSETRA?

HEPSETRA can cause serious side effects. See **“What is the most important information I should know about HEPSETRA?”**

The most common side effects of HEPSETRA are weakness, headache, stomach pain, and nausea.

These are not all the possible side effects of HEPSETRA. For more information, ask your doctor or pharmacist.

Call your doctor for advice about side effects. You may report side effects to FDA at 1-800-FDA-1088

How should I store HEPSETRA?

- Store HEPSETRA at room temperature, between 68°F to 77°F (20°C to 25°C).
- Keep HEPSETRA in its original container.
- Do not use HEPSETRA if the seal over the bottle is broken or missing when you receive it.

Keep HEPSETRA and all medicines out of the reach of children.

General information about the safe and effective use of HEPSETRA.

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use HEPSETRA for a condition for which it was not prescribed. Do not give HEPSETRA to other people, even if they have the same symptoms that you have. It may harm them. If you would like more information, talk with your doctor. You can ask your doctor or pharmacist for information about HEPSETRA that is written for health professionals.

What are the ingredients in HEPSETRA?

Active Ingredient: adefovir dipivoxil

Inactive Ingredients: croscarmellose sodium, lactose monohydrate, magnesium stearate, pregelatinized starch, and talc

Manufactured for: Gilead Sciences, Inc. Foster City, CA 94404 HEPSETRA is a registered trademark of Gilead Sciences, Inc., or its related companies.

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For more information, go to www.Gilead.com or call 1-800-445-3235.

This Patient Information has been approved by the U.S. Food and Drug Administration.

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