

PATIENT INFORMATION

Adefovir Dipivoxil Tablets (a def' oh vir dye" piv ox' il)

Read this Patient Information before you start taking adefovir dipivoxil tablets 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 adefovir dipivoxil tablets?

Adefovir dipivoxil tablets can cause serious side effects, including:

- **Worsening of hepatitis B infection.** Your hepatitis B (HBV) infection may become worse (flare-up) if you take adefovir dipivoxil tablets 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 adefovir dipivoxil tablets. Refill your prescription or talk to your doctor before your adefovir dipivoxil tablets is all gone.
 - Do not stop taking adefovir dipivoxil tablets without first talking with your doctor.
 - If you stop taking adefovir dipivoxil tablets, your doctor will need to check your health often and do blood tests regularly to check your HBV infection for at least several months.
- **Adefovir dipivoxil tablets may cause severe kidney problem.** Severe kidney problems can happen in anyone who takes adefovir dipivoxil tablets, but certain people may have a higher risk of severe kidney problems with adefovir dipivoxil tablets, 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 adefovir dipivoxil tablets.

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

- **HIV resistance.** Your doctor may test you for HIV-1 infection before you start adefovir dipivoxil tablets. If you have both HBV and HIV-1 and you only take adefovir dipivoxil tablets, 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 adefovir dipivoxil tablets. 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 are adefovir dipivoxil tablets?

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

Adefovir dipivoxil tablets is not for use in children under 12 years of age.

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

Who should not take adefovir dipivoxil tablets?

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

What should I tell my healthcare provide before taking adefovir dipivoxil tablets?

Before taking adefovir dipivoxil tablets, tell your doctor about all of your medical conditions, including if you:

- have or had kidney problems. Your dose and schedule of adefovir dipivoxil tablets may need to be changed.
- are pregnant or plan to become pregnant. It is not known if adefovir dipivoxil tablets will harm your unborn baby. **Pregnancy Registry:** There is a pregnancy registry for women who take adefovir dipivoxil tablets 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 adefovir dipivoxil tablets passes into your breast

milk. Talk with your doctor about the best way to feed your baby during treatment with adefovir dipivoxil tablets.

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 adefovir dipivoxil tablets works, especially medicines that affect how your kidneys work. adefovir dipivoxil tablets can affect how your other medicines work. Your dose of adefovir dipivoxil tablets 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 adefovir dipivoxil tablets with other medicines.

How should I take adefovir dipivoxil tablets?

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

What are the possible side effects of adefovir dipivoxil tablets?

Adefovir dipivoxil tablets can cause serious side effects. See “**What is the most important information I should know about adefovir dipivoxil tablets?**”)

The most common side effects of adefovir dipivoxil tablets are weakness, headache, stomach pain, and nausea.

These are not all the possible side effects of adefovir dipivoxil tablets. 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 adefovir dipivoxil tablets?

- Adefovir dipivoxil tablets should be stored at 20°C to 25°C (68°F to 77°F).
- Keep adefovir dipivoxil tablets in its original container.
- Do not use adefovir dipivoxil tablets if the seal over the bottle is broken or missing

when you receive it.

Keep adefovir dipivoxil tablets and all medicines out of the reach of children.

General information about the safe and effective use of adefovir dipivoxil tablets:

Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use HEPSERA for a condition for which it was not prescribed. Do not give HEPSERA 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 HEPSERA that is written for health professionals.

What are the Ingredients of adefovir dipivoxil tablets?

Active Ingredient: adefovir dipivoxil

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

All registered trademarks in this document are the property of their respective owners.

APOTEX INC.

Adefovir Dipivoxil Tablets

10 mg

Manufactured By:
Apotex Inc.
Toronto, Ontario
Canada M9L 1T9

Manufactured For:
Apotex Corp.
Weston, Florida
USA 33326

Revised: January 2019

Rev. 3