APO-ADEFOVIR Tablets
Contains the active ingredient adefovir (as adefovir dipivoxil)

Consumer Medicine Information
For a copy of a large print leaflet, Ph: 1800 195 055

What is in this leaflet
Read this leaflet carefully before taking your medicine.
This leaflet answers some common questions about adefovir. It does not contain all the available information. It does not take the place of talking to your doctor or pharmacist.
The information in this leaflet was last updated on the date listed on the last page. More recent information on this medicine may be available.

Ask your doctor or pharmacist:
• if there is anything you do not understand in this leaflet,
• if you are worried about taking your medicine, or
• to obtain the most up-to-date information.
You can also download the most up-to-date leaflet from www.apotex.com.au.

All medicines have risks and benefits. Your doctor has weighed the risks of you using this medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

The expiry date (EXP) printed on the pack has passed.

The packaging is torn, shows signs of tampering or it does not look quite right.

Before you start taking it
Before you start taking this medicine, tell your doctor if:
1. You have allergies to:
   - any other medicines
   - any other substances, such as foods, preservatives or dyes.
2. You have or have had any medical conditions, especially the following:
   - kidney problems
   If you have reduced function of your kidneys or are at risk of having reduced function then adefovir may damage your kidneys. While taking this medicine you will require regular tests of your kidney function and may require a smaller dose of this medicine than patients with normal kidney function.
   - untreated HIV infection.

Before you start this medicine, your doctor will have discussed the risks and benefits of taking adefovir. It does not take the place of talking to your doctor or pharmacist.

Use in children
This medicine should not be used in children under 12 years of age.

What this medicine is used for
The name of your medicine is APO-Adefovir tablets. It contains the active ingredient adefovir dipivoxil.

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

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

How to take it
Adefovir belongs to a group of medicines called antiviral medicines.

Hepatitis B is caused by infection with the hepatitis B virus (HBV) which can damage the liver. Adefovir reduces the amount of the virus in the body, by lowering the ability of the virus to affect the body; rash, itching or hives on the skin; fainting; or hay fever-like symptoms.

If you think you are having an allergic reaction, do not take any more of the medicine and contact your doctor immediately or go to the Accident and Emergency department at the nearest hospital.

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**Hepatic flares**
It is extremely important that you do not stop taking this medicine without your doctor's advice. Some patients with hepatitis B infection may have a "flare-up" of Hepatitis B if they stop taking this medicine, 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 this medicine, tell your doctor immediately about any new, unusual, or worsening symptoms that you notice after stopping treatment.

After you stop taking this medicine, your doctor will still need to check your health and take blood tests to check your liver for several months.

**Possible side effects**
Tell your doctor as soon as possible if you do not feel well while you are taking adefovir or if you have any questions or concerns.

Do not be alarmed by the following lists of side effects. You may not experience any of them. All medicines can have side effects. Sometimes they are serious but most of the time they are not.

Tell your doctor if you notice any of the following:
- Weakness
- Headache
- Nausea
- Flatulence
- Diarrhoea
- Problems with digestion
- Stomach pain

**If you experience any of the following, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.**

These are very serious side effects and you may need urgent medical attention or hospitalisation:

- **Serious Liver Problems (hepatotoxicity)**
  - Your skin or the white part of your eyes turn 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**
  - 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.

**Allergic reactions**
If you think you are having an allergic reaction to adefovir, do not take any more of this medicine and tell your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

Symptoms of an allergic reaction may include some or all of the following:
- cough, shortness of breath, wheezing or difficulty breathing
- swelling of the face, lips, tongue, throat or other parts of the body
- rash, itching or hives on the skin
- fainting
- hay fever-like symptoms.

**Storage and disposal**

**Storage**
Keep your medicine in its original packaging until it is time to take it.

If you take your medicine out of its original packaging it may not keep well.

Keep your medicine in a cool dry place where the temperature will stay below 25°C.

Do not store your medicine, or any other medicine, in the bathroom or near a sink. Do not leave it on a window sill or in the car. Heat and dampness can destroy some medicines.

Keep this medicine where 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 it has passed its expiry date, your pharmacist can dispose of the remaining medicine safely.

**Product description**

**What APO-Adefovir tablets looks like**

**10mg Tablets:**
White to off-white, round, flat-faced bevelled edge tablet. Engraved "APO" on one side, "A10" on the other side.

Available in bottles (white, round HDPE bottle with white PP "Lift N Peel" child-resistant cap and desiccant) of 30 tablets.

**Ingredients**
Each tablet contains 10mg of adefovir as the active ingredient.

It also contains the following inactive ingredients:
- Anhydrous lactose
- Starch pregelatinized
- Croscarmellose sodium
- Magnesium stearate
- Talc

This medicine is gluten-free, sucrose-free, tartrazine-free and free of other azo dyes.

**Australian Registration Numbers**

APO-Adefovir 10mg Tablet: AUST R 212048.

**Sponsor**

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Australia

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