

APO-Adefovir Tablets

Consumer Medicine Information (CMI) summary

The [full CMI](#) on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using APO-Adefovir Tablets?

APO-Adefovir Tablets contains the active ingredient adefovir dipivoxil. APO-Adefovir Tablets is used to treat chronic hepatitis B in patients 12 years of age or older.

For more information, see Section [1. Why am I using APO-Adefovir Tablets?](#) in the full CMI.

2. What should I know before I use APO-Adefovir Tablets?

Do not use if you have ever had an allergic reaction to adefovir dipivoxil or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section [2. What should I know before I use APO-Adefovir Tablets?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with APO-Adefovir Tablets and affect how it works.

A list of these medicines is in Section [3. What if I am taking other medicines?](#) in the full CMI.

4. How do I use APO-Adefovir Tablets?

- The recommended dose is one 10mg tablet taken once daily. Doses greater than 10mg daily should not be taken.
- Swallow tablet with water.

More instructions can be found in Section [4. How do I use APO-Adefovir Tablets?](#) in the full CMI.

5. What should I know while using APO-Adefovir Tablets?

Things you should do	Remind any doctor, dentist or pharmacist you visit that <ul style="list-style-type: none">• you are using APO-Adefovir Tablets.• you are pregnant or are planning to become pregnant• you are breastfeeding or are planning to breast-feed• you are about to have any blood tests• you are going to have surgery or an anesthetic or are going into hospital
Things you should not do	<ul style="list-style-type: none">• Do not stop using this medicine suddenly without first checking with your doctor.• Do not give this medicine to anyone else, even if their symptoms seem similar to yours.• Do not take your medicine to treat any other condition unless your doctor tells you to.
Driving or using machines	<ul style="list-style-type: none">• Be careful when driving or operating machinery until you know how this medicine affects you.•
Drinking alcohol	<ul style="list-style-type: none">• Tell your doctor if you drink alcohol
Looking after your medicine	<ul style="list-style-type: none">• Keep your medicine in its original packaging until it is time to take it.• Keep your medicine in a cool dry place where the temperature will stay below 25°C.• Keep this medicine where children cannot reach it.

For more information, see Section [5. What should I know while using APO-Adefovir Tablets?](#) in the full CMI.

6. Are there any 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. All medicines can have side effects. Sometimes they are serious but most of the time they are not. If you experience any side effects, stop taking your medicine and contact your doctor immediately or go to the Accident and Emergency department at your nearest hospital.

For more information, including what to do if you have any side effects, see Section [6. Are there any side effects?](#) in the full CMI.

APO-Adefovir Tablets

Active ingredient: *Adefovir dipivoxil*

Consumer Medicine Information (CMI)

This leaflet provides important information about using APO-Adefovir Tablets. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using APO-Adefovir Tablets.**

Where to find information in this leaflet:

- [1. Why am I using APO-Adefovir Tablets?](#)
- [2. What should I know before I use APO-Adefovir Tablets?](#)
- [3. What if I am taking other medicines?](#)
- [4. How do I use APO-Adefovir Tablets?](#)
- [5. What should I know while using APO-Adefovir Tablets?](#)
- [6. Are there any side effects?](#)
- [7. Product details](#)

1. Why am I using APO-Adefovir Tablets?

APO-Adefovir Tablets contains the active ingredient adefovir dipivoxil. APO-Adefovir Tablets belongs to a group of medicines called antiviral medicines.

APO-Adefovir Tablets 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. Adefovir 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 adefovir may help treat your hepatitis. Sometimes viruses change in your body and medicines no longer work. This is called drug resistance. There is no evidence that this medicine is addictive.

2. What should I know before I use APO-Adefovir Tablets?

Warnings

Do not use APO-Adefovir Tablets if:

- you are hypersensitive to, or have had an allergic reaction to adefovir dipivoxil or any of the ingredients listed at the end of this leaflet.
- Always check the ingredients to make sure you can use this medicine.

- These medicines should not be administered with adefovir:
 - VIREAD (tenofovir disoproxil fumarate)
 - TRUVADA (tenofovir disoproxil fumarate/emtricitabine combination tablet),
 - ATRIPLA (tenofovir disoproxil fumarate/emtricitabine/efavirenz combination tablet)
 - STRIBILD (tenofovir disoproxil fumarate/emtricitabine/elvitegravir/cobicistat)
 - EVIPLERA (tenofovir disoproxil fumarate/emtricitabine/ rilpivirine combination tablet).
 - tenofovir alafenamide tabletIf you are taking this, you may need a different dose or you may need to take different medicines.
- Other medicines not listed above may also interact with adefovir.

Check with your doctor if you:

- have allergies to:
 - any other medicines
 - any other substances, such as foods, preservatives or dyes.
 - You have or have had any medical conditions, especially the following:
 - kidney problemsIf 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.
 - unrecognised or untreated HIV infection.
- Adefovir 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 this medicine.
- **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.
- You are over the age of 65.
- You are planning to have surgery or an anaesthetic.

- You are currently receiving or are planning to receive dental treatment.
- You are taking or are planning to take any other medicines. This includes vitamins and supplements that are available from your pharmacy, supermarket or health food shop.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section [6. Are there any side effects?](#)

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

The safe use of adefovir in human pregnancy has not been demonstrated. For this reason, it is important that women of childbearing age receiving treatment with adefovir use an effective method of contraception to avoid becoming pregnant. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

It is not known whether adefovir is excreted in human breast milk. Consequently, nursing mothers should stop breastfeeding during treatment with this medicine.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with APO-Adefovir Tablets and affect how it works.

These medicines should not be administered with adefovir:

- VIREAD (tenofovir disoproxil fumarate)
- TRUVADA (tenofovir disoproxil fumarate/emtricitabine combination tablet),
- ATRIPLA (tenofovir disoproxil fumarate/emtricitabine/efavirenz combination tablet)
- STRIBILD (tenofovir disoproxil fumarate/emtricitabine/elvitegravir/cobicistat)
- EVIPLERA (tenofovir disoproxil fumarate/emtricitabine/ rilpivirine combination tablet).
- tenofovir alafenamide tablet

If you are taking this, you may need a different dose or you may need to take different medicines.

Other medicines not listed above may also interact with adefovir.

4. How do I use APO-Adefovir Tablets?

How much to take / use

- The recommended dose is one 10mg tablet taken once daily. Doses greater than 10mg daily should not be taken.
- Follow the instructions provided and use APO-Adefovir Tablets until your doctor tells you to stop.
- If you have reduced function of your kidneys, you may require a lower dose. You may be prescribed another HBV medicine to take with this medicine. Check with your doctor if you have any questions.
- This medicine is absorbed rapidly. Do not take another dose of this medicine if vomiting has occurred unless advised to do so by your doctor.

When to take / use APO-Adefovir Tablets

- APO-Adefovir Tablets should be used at the same time each day. Taking it at the same time each day will have the best effect and will also help you remember when to take it.
- It does not matter if you take it with or without food. Food does not affect how this medicine works.

How long take Apo-Adefovir Tablet

- This medicine helps to control your condition, but does not cure it, you will need to take this medicine every day. Continue taking your medicine for as long as your doctor tells you.
- It is very important to continue taking this medicine because the amount of virus in your blood may increase if the medicine is stopped for even a short period of time. The virus may develop resistance to adefovir, become harder to treat and may result in very severe hepatitis and serious liver problems.
- Make sure you have enough to last over weekends and holidays

If you forget to use APO-Adefovir Tablets

APO-Adefovir Tablets should be used regularly at the same time each day.

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

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

This may increase the chance of you experiencing side effects.

If you have trouble remembering to take your medicine, ask your pharmacist for some hints to help you remember.

If you use too much APO-Adefovir Tablets

If you think that you have used too much APO-Adefovir Tablets, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or

- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using APO-Adefovir Tablets?

Things you should do

Call your doctor straight away if you:

- you are about to be started on any new medicine
- you are pregnant or are planning to become pregnant
- you are breastfeeding or are planning to breast-feed
- you are about to have any blood tests
- you are going to have surgery or an anesthetic or are going into hospital

Remind any doctor, dentist or pharmacist you visit that you are using APO-Adefovir Tablets

Things you should not do

- Do not stop using this medicine suddenly or change the dose without first checking with your doctor.
- Give this medicine to anyone else, even if their symptoms seem similar to yours.
- Take your medicine to treat any other condition unless your doctor tells you to.

Things to be careful of

- This medicine 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.
- 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.
- Renal impairment

Long-term treatment with adefovir dipivoxil may increase the risk of renal impairment. While the overall risk of renal impairment in patients with adequate renal function is low, this is of special importance in patients both at risk of or having underlying renal dysfunction, and also in patients receiving medicinal products that may affect renal function.

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.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how APO-Adefovir Tablets affects you.

Drinking alcohol

Tell your doctor if you drink alcohol.

Looking after your medicine

Follow the instructions in the carton on how to take care of your medicine properly.

Store it in a cool dry place away from moisture, heat or sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills. Heat and dampness can destroy some medicines.
- 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.

Keep it where young children cannot reach it.

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

Getting rid of any unwanted medicine

If you no longer need to use this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not use this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
<ul style="list-style-type: none"> • Weakness • Headache • Nausea • Flatulence • Diarrhoea • Problems with digestion • Stomach pain 	<p>Speak to your doctor if you have any of these less serious side effects and they worry you.</p>

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none"> • [Serious Liver Problems (hepatotoxicity)] 	<p>Call your doctor straight away,</p>

<ul style="list-style-type: none"> • 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 • 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 arms 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. 	<p>or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.</p>
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<p>Other ingredients (inactive ingredients)</p>	<p>Lactose monohydrate pregelatinized maize starch Croscarmellose sodium Magnesium stearate Purified talc</p>
<p>Potential allergens</p>	<p>Lactose</p>

Do not take this medicine if you are allergic to any of these ingredients.

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

What APO-Adefovir Tablets looks like

APO-Adefovir 10mg Tablet

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. AUST R 212048.

Who distributes APO-Adefovir Tablets

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel St,

Cremorne VIC 3121

<http://arrotex.com.au>

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Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What APO-Adefovir Tablet contains

<p>Active ingredient</p>	<p>adefovir dipivoxil</p>
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