

ENTECAVIR APO

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 ENTECAVIR APO?

ENTECAVIR APO contains the active ingredient entecavir (as monohydrate). ENTECAVIR APO is used to treat chronic hepatitis B virus infection in adults 16 years or older.

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

2. What should I know before I use ENTECAVIR APO?

Do not use if you have ever had an allergic reaction to ENTECAVIR APO 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 ENTECAVIR APO?](#) in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with ENTECAVIR APO 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 ENTECAVIR APO?

Follow all directions given to you by your doctor or pharmacist carefully. They may differ from the information contained in this leaflet.

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

5. What should I know while using ENTECAVIR APO?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using ENTECAVIR APO.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine suddenly or lower the dosage without first checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">Be careful before you drive or use any machines or tools until you know how ENTECAVIR APO affects you. ENTECAVIR APO may cause dizziness or light-headedness in some people. If this occurs, do not drive or operate machinery
Looking after your medicine	<ul style="list-style-type: none">Keep your medicine in a cool dry place where the temperature stays 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.Keep this medicine where children cannot reach it.

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

6. Are there any side effects?

Tell your doctor and pharmacist as soon as possible if you do not feel well while you are taking ENTECAVIR APO.

This medicine helps most people but may cause unwanted side effects in some people. All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical attention if you get some side effects.

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.

ENTECAVIR APO

Active ingredient: *entecavir(as monohydrate)*

Consumer Medicine Information (CMI)

This leaflet provides important information about using ENTECAVIR APO. **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 ENTECAVIR APO.**

Where to find information in this leaflet:

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

1. Why am I using ENTECAVIR APO?

ENTECAVIR APO contains the active ingredient **entecavir (as monohydrate)**. ENTECAVIR APO belongs to a group of medicines called antiviral medicines.

ENTECAVIR APO is used to treat adults infected with **hepatitis B virus**. ENTECAVIR APO is not recommended for use in children under 16 years, as there have been no studies of its effects in children.

Infection by the hepatitis B virus can lead to damage to the liver. ENTECAVIR APO reduces the amount of virus in your body, and has been shown to improve the condition of the liver. It is not known how safe ENTECAVIR APO is when taken for long periods.

Your doctor may have prescribed ENTECAVIR APO for another reason. Ask your doctor if you have any questions about why ENTECAVIR APO has been prescribed for you. ENTECAVIR APO is not addictive. This medicine is available only with a doctor's prescription.

2. What should I know before I use ENTECAVIR APO?

Warnings

Do not use ENTECAVIR APO if:

- you are allergic to entecavir (as monohydrate) or any of the ingredients listed at the end of this leaflet.

Symptoms of an allergic reaction may include: 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; or hay fever-like symptoms.

- Always check the ingredients to make sure you can use this medicine.

Do not take this medicine 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.

It is important to remain under the care of your doctor during ENTECAVIR APO therapy and after stopping ENTECAVIR APO.

You should report any new symptoms, medications or any other aspects affecting your health to your doctor. Your hepatitis B virus infection may get worse if you stop taking ENTECAVIR APO. If your doctor advises you to stop ENTECAVIR APO, they will monitor your health and perform regular blood tests to monitor your liver.

Check with your doctor if you:

- have allergies to any other medicines or substances such as foods, preservatives or dyes.
- have any other medical conditions, especially the following:
 - problems with your kidneys,
 - Hepatitis C or D,
 - advanced liver disease,
 - you have received a liver transplant,
 - you have HIV and you are not currently on HIV treatment. ENTECAVIR APO may affect your HIV which could impact on future treatment options for HIV
- are lactose intolerant. ENTECAVIR APO tablets contain lactose,
- planning to have surgery or anaesthetic,
- 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.

Experience is limited with the use of ENTECAVIR APO in pregnant women. Therefore, it should not be used during pregnancy unless it is clearly needed. It is important that women of childbearing age receiving treatment with ENTECAVIR APO use an effective method of contraception

to avoid becoming pregnant. If there is an urgent need to consider ENTECAVIR APO during pregnancy, your doctor will discuss with you the benefits and risks of taking it.

Talk to your doctor if you are breastfeeding or intend to breastfeed. It is not known whether ENTECAVIR APO passes into breast milk. Therefore to avoid possible side effects in the nursing infant, mothers should stop breastfeeding if they are taking ENTECAVIR APO.

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.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect ENTECAVIR APO.

4. How do I use ENTECAVIR APO?

How much to take / use

The usual dose of ENTECAVIR APO RBX is 0.5 mg or 1 mg once a day.

Your doctor will tell you what dose to take and how often you should take your ENTECAVIR APO tablets.

Please talk to your doctor or pharmacist for more information.

How to take it

Swallow the tablets whole with a glass of water. The dose of ENTECAVIR APO should be taken on an empty stomach (at least 2 hours after a meal and 2 hours before the next meal).

When to take ENTECAVIR APO

Take this medicine 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.

Talk to your doctor or pharmacist to work out when it is best for you to take your dose of ENTECAVIR APO.

How to long to take ENTECAVIR APO

Entecavir helps control your condition but does not cure it. Therefore you must continue taking entecavir for as long as your doctor tells you to.

Your doctor has prescribed ENTECAVIR APO to prevent hepatitis B virus from further damaging your liver.

Entecavir is a very important treatment that can improve the inflammation and scar tissue caused by the hepatitis B virus in your liver and may reduce the chance of developing cirrhosis, liver failure and liver cancer.

It is extremely important that you do not stop taking entecavir without discussing it with your doctor. If entecavir is stopped suddenly, the hepatitis B virus can become very active again and lead to sudden development of severe liver failure. There is a high risk of dying if liver failure develops and liver transplantation may be necessary to save your life.

It is important to take ENTECAVIR APO every day or as directed by your doctor, to not miss medicine doses, and to make sure you have enough to last over weekends and holidays, or until you next see your doctor.

If you forget to use ENTECAVIR APO

If it is almost time to take your next dose, skip the missed dose and take your next dose at the usual time. Otherwise, take it as soon as you remember and then go back to taking your medicine as you would normally.

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

This may increase the chance of you experiencing side effects. It is very important not to miss your doses of entecavir.

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

If you use too much ENTECAVIR APO

If you think that you have used too much ENTECAVIR APO, 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 ENTECAVIR APO?

Things you should do

Tell your doctor if you are taking this medicine if:

- 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 anaesthetic or are going into hospital.

Go to your doctor regularly for a check-up. Your doctor may want to do tests to make sure the medicine is working and to prevent side effects.

When your treatment with entecavir is stopped, your doctor will continue to monitor you and take blood tests for several months.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you. Dizziness, fatigue and sleepiness are common side effects which may impair your ability to drive and use machines. If you have any concerns consult your doctor.

There is no evidence that entecavir reduces the risk of infecting others with hepatitis B through sexual contact or body fluids (including blood contamination).

Therefore it is important to take appropriate precautions to prevent others being infected with hepatitis B. Talk to your doctor about safe sexual practices that protect your partner. Never share needles. Do not share personal items that can have blood or bodily fluids on them, like toothbrushes and razor blades. A vaccine is available to protect those at risk of becoming infected with hepatitis B.

Things you should not do

- Do not give this medicine to anyone else, even if they have the same condition as you.
- Do not take your medicine to treat any other complaint unless your doctor tells you to.
- Do not stop taking your medicine or change the dosage without first checking with your doctor.

Driving or using machines

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

ENTECAVIR APO generally does not affect your ability to drive a car or operate machinery. However, this medicine may cause dizziness in some people. Make sure you know how you react to this medicine before you drive a car or operate machinery.

Looking after your medicine

Storage

Store ENTECAVIR APO tablets in a cool dry place where the temperature stays below 25°C.

Keep your tablets in the blister pack until it is time to take one. If you take the tablets out of the pack they may not keep as well.

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 window sills.

Keep it where young children cannot reach it.

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">• diarrhoea• indigestion• upper abdominal pain• tiredness• headache	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
<ul style="list-style-type: none">• signs of a sudden life-threatening allergic reaction: 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; or hay fever-like symptoms.• Some people who have taken entecavir or medicines like entecavir have developed a serious condition called lactic acidosis. Lactic acidosis is a serious medical emergency that can cause death. Lactic acidosis must be treated in the hospital. Reports of lactic acidosis with entecavir generally involved patients who were seriously ill due to their liver disease or other medical condition. Tell your doctor as soon as possible if you notice any of the following signs or symptoms of lactic acidosis:<ul style="list-style-type: none">• feeling very weak or tired• unusual muscle pain• trouble breathing• stomach pain with nausea and vomiting• feeling cold (especially in your arms and legs)• feeling dizzy or light-headed• fast or irregular heartbeat.	Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.

<ul style="list-style-type: none"> • signs or symptoms of liver problems: <ul style="list-style-type: none"> • your skin or the white part of your eyes turns yellow (jaundice) • urine turns dark • bowel movements (stools) turn light in colour • you don't feel like eating food for several days or longer • nausea • vomiting • lower stomach pain • signs of lower-than-normal blood cell numbers: <ul style="list-style-type: none"> • fever, chills, fatigue, mouth sores, sore throat, and unusual bleeding or bruising. 	
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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 ENTECAVIR APO contains

Active ingredient (main ingredient)	Each tablet contains 0.5 mg and 1.0 mg of entecavir (as monohydrate) as the active ingredient.
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Other ingredients (inactive ingredients)	<ul style="list-style-type: none"> • lactose monohydrate • povidone • crospovidone • microcrystalline cellulose • magnesium stearate • OPADRY complete film coating system 13B58802 White (which contains hypromellose, titanium dioxide, macrogol 400 and polysorbate 80) – 0.5 mg tablet • OPADRY complete film coating system 13B84610 Pink (which contains hypromellose, titanium dioxide, macrogol 400, polysorbate 80 and iron oxide red) – 1.0 mg tablet.
Potential allergens	Contains sugars as lactose

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 ENTECAVIR APO looks like

ENTECAVIR APO 0.5 mg Tablets

0.5 mg film-coated tablet is white to off-white, triangular shaped film coated tablets, debossed with 'RL1' on one side and plain on other side.

Blister packs of 30 tablets: AUST R 256432.

ENTECAVIR APO 1.0 mg Tablets

1.0 mg film-coated tablet is light pink to pink, triangular shaped film coated tablets, debossed with 'RL2' on one side and plain on other side

Blister packs of xx tablets: AUST R 256492.

*Not all strengths, pack types and/or pack sizes may be available.

Who distributes ENTECAVIR APO

Arrotex Pharmaceuticals Pty Ltd

15-17 Chapel Street

Cremorne VIC 3121

Australia

www.arrotex.com.au

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