

Entecavir APO

Contains the active ingredient entecavir (as monohydrate)

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 entecavir. 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:

- 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 against the benefits they expect it will have for you.

Pharmaceutical companies cannot give you medical advice or an individual diagnosis.

Keep this leaflet with your medicine. You may want to read it again.

What this medicine is used for

The name of your medicine is Entecavir APO tablets. It contains the active ingredient entecavir and belongs to a group of medicines called antiviral medicines.

It is used to treat chronic hepatitis B virus infection in adults 16 years or older.

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

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

How it works

Infection by the hepatitis B virus can lead to damage to the liver. Entecavir 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 is when taken for long periods.

There is no evidence that this medicine is addictive.

Use in children

This medicine should not be used in children under 16 years as safety and effectiveness have not been established.

Before you take this medicine

When you must not take it

Do not take this medicine if:

- **You are hypersensitive to, or have had an allergic reaction to, entecavir 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.

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.

- **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 to take 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:
 - problems with your kidneys
 - hepatitis C or D
 - you have received a liver transplant
 - you have HIV and you are not currently receiving HIV treatment. Entecavir may affect your HIV which could impact on future treatment options for HIV.
 3. You are currently pregnant or you plan to become pregnant. Experience is limited with the use of entecavir in pregnant women. Do not take this medicine whilst pregnant until you and your doctor have discussed the risks and benefits involved.
 4. You are currently breastfeeding or you plan to breast-feed. It is not known whether entecavir passes into breast milk. Do not take this medicine whilst breastfeeding.
 5. You are lactose intolerant. Entecavir tablets contain lactose.
 6. You are planning to have surgery or an anaesthetic.
 7. You are currently receiving or are planning to receive dental treatment.
 8. 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.

Medicines excreted by the kidney or which affect kidney function may interact with entecavir. Patients should be monitored closely for adverse events when entecavir is taken with such medicines.

If you are taking any of these medicines you may need a different dose or you may need to take different medicines.

Other medicines not stated above may also interact with entecavir.

How to take this medicine

Follow carefully all directions given to you by your doctor. Their instructions may be different to the information in this leaflet.

How much to take

Your doctor will tell you how much of this medicine you should take. This will depend on your condition and whether you are taking any other medicines.

The usual dose of entecavir is 0.5mg or 1mg once a day.

Do not stop taking your medicine or change your dosage without first checking with your doctor.

How to take it

Swallow the tablet whole with a glass of water.

When to take it

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.

Entecavir should be taken on an empty stomach (at least 2 hours after a meal and 2 hours before the next meal).

How long to take it for

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.

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.

Make sure you have enough to last over weekends and holidays, or until you next see your doctor.

If you forget to take it

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 take too much (overdose)

If you think that you or anyone else may have taken too much of this medicine, immediately telephone your doctor or the Poisons Information Centre (Tel: 13 11 26 in Australia) for advice. Alternatively, go to the Accident and Emergency department at your nearest hospital.

Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are taking this medicine

Things you must do

Tell your doctor that 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.

Tell any other doctors, dentists and pharmacists who are treating you that you take this medicine.

Things you must not do

Do not:

- 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.
- Stop taking your medicine, or change the dosage, without first checking with your doctor.

Things to be careful of

Be careful when driving or operating machinery until you know how this medicine affects you.

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.

Possible side effects

Tell your doctor as soon as possible if you do not feel well while you are taking entecavir 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:

- diarrhoea
- indigestion
- tiredness
- headache.

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:

- 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.

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 signs or symptoms of liver problems and you may need urgent medical attention or hospitalisation:

- 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
- lower stomach pain.

Other side effects not listed above may occur in some patients.

Allergic reactions

If you think you are having an allergic reaction to entecavir, 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 Entecavir APO tablets looks like

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.

It is available in blister pack of 30 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

It is available in blister pack of 30 tablets.

* Not all strengths may be available.

Ingredients

Each tablet contains 0.5 mg and 1.0mg of entecavir (as monohydrate) as the active ingredient.

It also contains the following inactive ingredients:

- 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.

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

Australian Registration Numbers

Entecavir APO 0.5mg tablet (blister pack): AUST R 256432.

Entecavir APO 1.0mg tablet (blister pack): AUST R 256492.

Sponsor

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