

New Zealand Consumer Medicine Information

Entecavir 0.5 mg film coated tablet Entecavir 1 mg film coated tablet

What is in this leaflet

The information enclosed answers several general questions about Entecavir tablets. It is important to read this information thoroughly before starting your treatment.

This leaflet does not include all the accessible information on Entecavir tablets.

All medication has benefits and risks. Your doctor will have considered the risks of you using Entecavir tablets against the benefits expected.

This leaflet does not take preference over talking to a professional, therefore please discuss with your doctor or pharmacist any concerns you may have.

Keep this information with your medicine and refer to this leaflet if you have any queries.

What Entecavir is used for

Entecavir belongs to the antiviral medicines group and is used for the treatment of adults infected with the hepatitis B virus.

How Entecavir Works

Infection by the hepatitis B virus can result in liver damage.

Entecavir decreases the amount of hepatitis B virus in your body and helps to improve the condition of your liver.

There is no information on whether entecavir is safe to be taken for long periods of time.

Your doctor may have prescribed entecavir for a different reason. If you have any concerns about why this medicine has been prescribed, please discuss with your doctor.

Entecavir is not addictive.

Entecavir tablets are only accessible with a prescription from your doctor.

Entecavir should not be given to children under 16 years of age as there are no studies of its effects in adolescents.

Before you use Entecavir tablets

IMPORTANT: Read all information below before taking this medicine.

When you must not use Entecavir tablets

Do not use this medicine if you are allergic to entecavir or any of the other ingredients in Entecavir tablets (listed at the back of this leaflet).

Seek immediate medical attention if you experience any of the following side effects, as you may be allergic to this medicine:

- **Itching, rash, or reddened skin**
- **Fever or chills**
- **Increased heartbeat**
- **Swelling of the tongue, face, or other areas of the body**
- **Flushing or sweating**
- **Increase in wheezing, coughing and/or shortness of breath**

- **Feeling faint or dizzy**

Do not use after the expiry date. The expiry date can be found on the blister and printed on the carton. If Entecavir tablets are taken after the expiry has lapsed, it may not work as well as it should.

If the packaging of the Entecavir carton or blister displays signs of damage or tampering, do not use.

If you have any concerns about using Entecavir tablets, ask your doctor or pharmacist.

Before you start using this medicine

Tell your doctor **before** using Entecavir tablets if you:

1. Have an allergy to:
 - any other medication you have been prescribed or purchased
 - any dyes, preservatives or foods
2. Are pregnant or planning to become pregnant.

Information on the use of entecavir in pregnant women is limited. Therefore, do not use during pregnancy only if it is absolutely required. Your doctor will discuss the risks and benefits with you if it is urgent to consider taking entecavir during pregnancy.

3. Are breastfeeding or planning to breastfeed.

Women should discontinue breastfeeding when using Entecavir tablets to avoid any potential side effects in your infant as it is unknown whether entecavir transfers into breast milk.

4. Have any current or previous medical conditions (especially with your kidneys).
5. Have HIV and are not taking any HIV treatment.

This medicine is not recommended in people who have HIV and Hepatitis B together, and who are not presently taking anti-HIV treatment. Entecavir tablets could impact your HIV virus which may affect any potential HIV treatment options.

6. Are intolerant to lactose. Entecavir tablets contain lactose and must be used carefully in lactose intolerant patients.

Discuss with your doctor any concerns you may have.

During and after your entecavir therapy, it is essential to remain in your doctor's care.

Please inform your doctor of any new symptoms, or anything other affecting your health.

Do not stop taking this medication, as your hepatitis B virus infection may get worse. If your doctor informs you to stop entecavir treatment, they will carefully monitor your health and take routine blood tests to monitor your liver.

Using other medicines

Please inform your doctor if you are taking or have recently taken any other medicines, herbal preparations or vitamins, including any medicines obtained without a prescription from your pharmacy, health store or supermarket.

For additional information on medicines and what to avoid, discuss with your doctor or pharmacist.

How to use this medicine

Only take Entecavir tablets when they have been prescribed to you by your doctor.

Follow all instructions provided by your doctor carefully as they may be different from this leaflet.

How much Entecavir to take

The standard dose is 0.5 mg or 1 mg, once daily.

If you have a medical condition involving your kidneys, your doctor may adjust how often you take this medicine.

Please discuss with your doctor or pharmacist if you require further information.

How to take Entecavir

Swallow the Entecavir tablet whole with a large glass of water on an empty stomach.

When to take Entecavir

This medicine can be consumed at any time of the day providing it is taken on an empty stomach. An empty stomach implies at least two hours following a meal and at least two hours prior to your next meal.

Discuss with your doctor or pharmacist when it may be best for you to take your tablet.

How long to take Entecavir

Entecavir is an extremely important hepatitis B virus treatment that helps to improve scar tissue and inflammation in your liver. It may also decrease the possibility of developing liver failure, cirrhosis, and liver cancer. This medicine helps to control the virus but does not cure it.

Entecavir has been prescribed to prevent hepatitis B virus damaging your liver further.

Therefore, it is imperative that you take your Entecavir medication every day, as instructed by your doctor and continue to take for as long as required.

DO NOT STOP TAKING YOUR ENTECAVIR MEDICATION WITHOUT PRIOR APPROVAL FROM YOUR DOCTOR.

In the event that this medication is stopped quickly, the hepatitis B virus has the potential to become extremely active with a sudden consequence of severe failure of the liver.

If liver failure occurs, a liver transplantation might be required as there is an increased risk of death.

It is extremely important to take your tablets each day or as instructed by your doctor, to make sure you always have sufficient supply of your medication and to not miss any doses.

Do not discontinue taking this medicine or modify the dosage unless requested to do so by your doctor, even if you are feeling an improvement, as it is life threatening.

If you forget to take Entecavir tablets

If you have forgotten to take your normal dose at the correct time, take your next dose as soon as you remember. However, if you forget to take Entecavir close to the time of the next dose (for example, within two to three hours) then simply miss out the dose you have forgotten.

Do not take a double dose of Entecavir tablets at any given time if you have missed a dose. The probability of having an unwanted side effect may increase. If you are unsure, discuss with your doctor or pharmacist.

If you have difficulty remembering when your next dose of Entecavir is due, talk to your pharmacist for advice and notify your doctor that you have missed a dose.

It is extremely important to not miss any doses.

In case of an overdose

If you have received more Entecavir tablets than you should (overdose):

If you or someone else takes too much Entecavir, immediately phone the National Poisons Centre on 0800 POISON (0800 764 766) or go to your nearest Accident and Emergency Department even if you do not feel unwell or there are no signs of overdose symptoms.

Keep this phone number and information in an easily accessible place.

While you are using this medicine

Things you must do

- Abide by all instructions given by your doctor carefully as they may be different from the information provided in this leaflet.
- Tell your doctor without delay if you become pregnant while taking this medicine.
- If you are considering taking any other medicine while you are using Entecavir, tell your doctor, pharmacist and dentist. Entecavir can interfere with other medications you are taking.
- Make sure that all doctors, pharmacists and dentists who are working with you know that you are taking Entecavir tablets, especially if you are due to undergo surgery.

Things you must not do

- This medicine has been prescribed for you personally. Do not give it to anyone else even if their symptoms are the same as yours, as it may harm them.
- Entecavir should not be used to treat any other health condition, except if your doctor advises you to.
- Do not suddenly stop taking this medicine or reduce the dosage before you have spoken with your doctor. Your hepatitis condition can worsen following treatment being stopped.

Things to be careful of

- Take care when driving or using machinery until you are aware of how this medicine may affect you.

There have been reports of several patients experiencing dizziness when taking entecavir. It is not known if entecavir was the cause. Make sure you know how you react to this medicine before driving a car, operating machinery or doing anything else that could be considered dangerous if you are not alert.

- Make sure that you regularly visit your doctor during your complete course of entecavir treatment.

When your entecavir treatment has finished, your doctor will complete blood tests over the following months to monitor your progress.

- There is no evidence that entecavir decreases the risk of infection in others with hepatitis B through body fluids, sexual contact or blood contamination.

Therefore, it is extremely important to exercise suitable protection to prevent other people being infected with hepatitis B. Discuss with your doctor regarding safe sexual practices that can protect your partner. Do not share needles. Never share personal items that may have bodily fluids or blood on them, for example, razors and toothbrushes. A hepatitis B vaccination is available to protect people at risk of becoming infected.

Side effects

Discuss with your doctor as soon as possible if you experience any changes to your condition or you do not feel well while taking this medicine.

Entecavir benefits the majority of people with hepatitis B infection, but it can have unwanted side effects in a few people.

Discuss with your doctor or pharmacist any questions or concerns you may have.

All medications can have side effects. For most people who experience side effects they are usually mild and pass over a short time. At times they can be serious, and some side effects may require you to have medical treatment.

Go immediately to your nearest Accident and Emergency Department if you experience any of the following side effects of a sudden life-threatening allergic reaction:

- **Fever or chills**
- **Increased heartbeat**
- **Swelling of the tongue, face, or other areas of the body**
- **Flushing or sweating**
- **Increase in wheezing, coughing and/or shortness of breath**
- **Dizziness**

Some patients who have received entecavir treatment or other similar medicines, have developed lactic acidosis which is a serious medical emergency that can result in death.

It is essential that lactic acidosis is treated in hospital.

Reports of lactic acidosis linked with entecavir usually involve people who are seriously ill with liver disease or another medical condition.

If you experience any of the below signs or symptoms of lactic acidosis, call your doctor immediately:

- Unfamiliar muscle pain
- Stomach pain with vomiting and nausea
- Feeling very tired or weak
- Feeling cold (particularly in your legs and arms)
- Feeling light-headed or dizzy
- Trouble breathing
- Experiencing a fast or irregular heartbeat

Some patients who have received entecavir treatment or other similar medicines have developed hepatotoxicity, a serious liver problem which results in enlargement of the liver (hepatomegaly) and fat in the liver (steatosis). Hepatomegaly combined with steatosis is a serious medical emergency that can result in death.

If you experience any of the below signs or symptoms of liver problems, call your doctor immediately:

- Dark urine
- The white part of your eyes and/or your skin turns yellow (jaundice)
- Your stools (bowel movements) are light in colour
- Decreased appetite over several days or longer
- Lower stomach pain
- Nausea

You may be more at risk of getting lactic acidosis or serious liver problems if you are very overweight, female, or have been using medication, like entecavir, over a long period of time.

The most common side-effects are headache, diarrhoea, feeling tired and indigestion.

This is not a complete list of side effects you may experience with entecavir; other side effects may also occur in some patients.

Discuss with your doctor if you experience anything that is causing you to feel unwell.

Do not be concerned by the side effects above, however, if you experience any of these side effects and they are causing concern, please talk to your doctor or pharmacist.

After using this medicine

Storage of Entecavir Tablets

Keep out of reach of children by storing Entecavir in a locked cabinet at a height that is hard to reach for children.

Avoid direct sunlight or heat. Do not store Entecavir in your car on a hot day or on a windowsill.

Store Entecavir below 30°C. Protect from light and moisture by not storing them near the kitchen sink or in the bathroom. Dampness and heat can damage some medicines.

Keep Entecavir tablets in their pack until you are about to take one. If tablets are removed from their blister, they may not store as well.

Disposal

If your doctor advises you to stop taking this medicine, or they have exceeded their expiry date, request information from your pharmacist on what to do with any product that is left over.

Product description

What this medicine looks like

Entecavir 0.5 mg tablet: White to off-white, triangular shaped, biconvex, film coated tablet, debossed with 'E' on one side and plain on other side.

Entecavir 1 mg tablet: Pink coloured, triangular shaped, biconvex, film coated tablet, debossed with "E" on one side and "1" on the other side.

Ingredients

Each Entecavir 0.5 mg tablet contains 0.5 mg of entecavir as the active ingredient.

Other ingredients: crospovidone, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, titanium dioxide, macrogol/PEG.

Each Entecavir 1 mg tablet contains 1 mg of entecavir as the active ingredient.

Other ingredients: crospovidone, hypromellose, lactose monohydrate, magnesium stearate, microcrystalline cellulose, titanium dioxide, macrogol/PEG, iron oxide red.

Each 0.5 mg film-coated tablet contains 119.468 mg of lactose.

Each 1 mg film-coated tablet contains 238.936 mg of lactose

Sponsor Details

Entecavir tablets are is supplied in New Zealand by:

REX Medical Ltd
P O Box 18119
Glen Innes
AUCKLAND 1743

Ph (09) 574 6060
Email: admin@rexmed.co.nz

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