

Entecavir AMNEAL Tablets

Entecavir monohydrate (en-TEH-cuh-veer mon-O-HI-drate)

Consumer Medicine Information

What is in this leaflet

Read this leaflet carefully before taking Entecavir AMNEAL. This leaflet answers some common questions about Entecavir AMNEAL.

It does not contain all the available information.

It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits. Your doctor has weighed the risks of you taking Entecavir AMNEAL against the benefits they expect it will have for you.

If you have any concerns about taking this medicine, ask your doctor or pharmacist.

Keep this leaflet with the medicine. You may need to read it again.

What Entecavir AMNEAL is used for

Entecavir AMNEAL contains entecavir monohydrate and belongs to a group of medicines called antiviral medicines.

Entecavir AMNEAL is used to treat adults infected with hepatitis B virus.

How Entecavir AMNEAL Works

Infection by the hepatitis B virus can lead to damage to the liver.

Entecavir AMNEAL 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 AMNEAL is when taken for long periods.

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

Entecavir AMNEAL is not addictive. This medicine is available only with a doctor's prescription.

Entecavir AMNEAL is not recommended for use in children under 16 years, as there have been no studies of its effects in children...

Before you take Entecavir AMNEAL

It is important that you check the information below before you take Entecavir AMNEAL.

When you must not take Entecavir AMNEAL

You must not take Entecavir AMNEAL if you have a history of severe allergic reactions to Entecavir AMNEAL or to any of the ingredients listed at the end of this leaflet. Symptoms of a severe allergic reaction may include; chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.

Do not use Entecavir AMNEAL after the expiry date printed on the back of the pack. If this medicine is taken after the expiry date has passed, it may not work as well.

Do not take Entecavir AMNEAL if the packaging is torn or shows signs of tampering.

Before you start to take Entecavir AMNEAL

It is important to remain under the care of your doctor during Entecavir AMNEAL therapy and after stopping Entecavir AMNEAL. 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 AMNEAL. If your doctor advises you to stop Entecavir AMNEAL, they will monitor your health and perform regular blood tests to monitor your liver.

Tell your doctor if you:

1. have allergies to:
 - any other medicines you have been given or purchased
 - substances such as foods, preservatives or dyes;**Symptoms of a severe allergic reaction may include; chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.**
2. are pregnant or intend to become pregnant. Experience is limited with the use of Entecavir AMNEAL in pregnant women. Therefore, it should not be used during pregnancy unless it is clearly needed. If there is an urgent need to consider Entecavir AMNEAL during pregnancy, your doctor will discuss with you the benefits and risks of taking it. If you take Entecavir AMNEAL while you are pregnant, talk to your doctor about how you can take part in the Entecavir AMNEAL Pregnancy Registry. The purpose of the pregnancy registry is to collect information about the health of you and your baby.
3. are breast feeding or planning to breast-feed. It is not known whether Entecavir AMNEAL passes into breast milk. Therefore to avoid possible side effects in the nursing infant, mothers should stop breast-feeding if they are taking Entecavir AMNEAL;
4. currently experience or have experienced any medical conditions especially any problems with your kidneys.
5. have HIV and you are not currently on HIV treatment. Entecavir AMNEAL is not recommended in patients who have both HIV and Hepatitis B and who are not currently receiving anti-HIV treatment. Entecavir AMNEAL may affect your HIV virus which could impact on future treatment options for HIV.
6. are lactose intolerant. Entecavir AMNEAL tablets contain lactose.

If you have not told your doctor about any of the above, tell them before you use Entecavir AMNEAL

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How to take Entecavir AMNEAL

Entecavir AMNEAL should be given only when prescribed by your doctor. Follow

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

How much to take

The usual dose of Entecavir AMNEAL is 0.5 mg (one white tablet) or 1 mg (one pink tablet) once a day.

If you have a medical problem with your kidneys your doctor may need to change how often you take your Entecavir AMNEAL tablets.

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

Please talk to your doctor or pharmacist for more information.

How to take it

Swallow the tablet whole with a glass of water. The dose of Entecavir AMNEAL should be taken on an empty stomach.

When to take Entecavir AMNEAL

Entecavir AMNEAL may be taken at any time of day provided it is taken on an empty stomach. Empty stomach means at least 2 hours before or 2 hours after a meal.

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

How long to take it

Entecavir AMNEAL helps control your condition but does not cure it. Therefore you must take Entecavir AMNEAL every day as directed by your doctor. Continue taking Entecavir AMNEAL for as long as your doctor tells you to.

Your doctor has prescribed Entecavir AMNEAL to prevent hepatitis B virus from further damaging your liver.

Entecavir AMNEAL 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 AMNEAL without discussing it with your doctor. If Entecavir AMNEAL is suddenly stopped, 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 AMNEAL every day or as directed by your doctor, to not miss medicine doses, and to make sure you have enough supply until you next see your doctor.

Do not stop taking Entecavir AMNEAL or change the dose unless asked to do so by your doctor, even if you feel better, as it can be very dangerous.

If you forget to take it

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

Otherwise take it as soon as you remember, and then go back to taking it as you would normally.

Do not take a double dose to make up for the dose you missed. This may increase the chance of you getting an unwanted side effect. If you are not sure what to do, ask your doctor or pharmacist.

If you have trouble remembering when to take your medicine, ask your pharmacist for some hints and inform your doctor that you have missed a dose. It is very important not to miss your doses of Entecavir AMNEAL.

If you take too much (overdose)

Immediately call your doctor or the Poisons Information Centre on 131126 in Australia or 0800 764 766 in New Zealand, or go to the Accident and Emergency Centre at your nearest hospital if you or anyone else takes too much Entecavir AMNEAL

Do this even if there are no signs of discomfort or poisoning.

While you are taking Entecavir AMNEAL

Things you must do

- If you become pregnant while taking Entecavir AMNEAL, tell your doctor immediately.
- If you are about to start taking any new medicines, tell your doctor and pharmacist that you are taking Entecavir AMNEAL. Entecavir AMNEAL may interfere with the medicine you are taking.
- If you are about to have any medical tests, tell your doctor that you are taking Entecavir AMNEAL. Entecavir AMNEAL may interfere with the results of these tests.
- If you plan to have surgery, tell your doctor or dentist that you are taking Entecavir AMNEAL.

Things you must not do

- Do not give Entecavir AMNEAL to anyone else, even if they have the same condition as you.
- Do not use Entecavir AMNEAL to treat any other complaints unless your doctor tells you to.
- Do not stop taking Entecavir AMNEAL or lower the dosage without checking with your doctor. Your hepatitis may worsen after stopping treatment.

Things to be careful of

- Be careful driving or operating machinery until you know how Entecavir AMNEAL affects you. Some patients taking Entecavir AMNEAL have experienced dizziness. It is not known if this was caused by Entecavir AMNEAL. Make sure you know how you react to Entecavir AMNEAL before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.
- Make sure that you visit your doctor regularly throughout your entire course of treatment with Entecavir AMNEAL. When your treatment with Entecavir AMNEAL is stopped, your doctor will continue to monitor you and take blood tests for several months.
- There is no evidence that Entecavir AMNEAL 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.

Side Effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Entecavir AMNEAL. Entecavir AMNEAL helps most people with hepatitis B infection but it may have unwanted side effects in some people. Ask your doctor or pharmacist to answer any questions you may have.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. Some very important side effects are listed below.

Tell your doctor immediately, or go to accident and emergency at your nearest hospital if you notice any of the following signs of a sudden life-threatening allergic reaction:

chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.

Some people who have taken Entecavir AMNEAL or medicines like Entecavir AMNEAL 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 AMNEAL generally involved patients who were seriously ill due to their liver disease or other medical condition.

Call your healthcare provider right away if you get 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.

Some people who have taken medicines like Entecavir AMNEAL have developed serious liver problems called hepatotoxicity, with liver enlargement (hepatomegaly) and fat in the liver (steatosis). Hepatomegaly with steatosis is a serious medical emergency that can cause death.

Call your healthcare provider right away if you get any of the following signs or symptoms of liver problems:

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. You may be more likely to get lactic acidosis or serious liver problems if you are female, very overweight, or have been taking medicines, like Entecavir AMNEAL, for a long time.

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

This is not a complete list of side effects, other side effects not listed above may also occur in some patients.

Tell your doctor if you notice anything that is making you feel unwell.

Do not be alarmed by this list of possible side effects. You may not experience any of them or only some of them.

After taking Entecavir AMNEAL

Storage

Store Entecavir AMNEAL tablets in a cool dry place where the temperature stays below 30°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.

Do not store Entecavir AMNEAL or any other medicine in the bathroom or near the kitchen sink. Do not leave it in the car. Heat and dampness can destroy some medicines.

Do not keep Entecavir AMNEAL tablets where children can reach them. 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 Entecavir AMNEAL, or the tablets have passed their expiry date, ask your pharmacist what to do with what is left over. Entecavir AMNEAL tablets come in two types:

Product description

What it looks like

Entecavir AMNEAL tablets come in two types:

- Entecavir AMNEAL 0.5 mg tablet - White to off-white, triangular-shaped tablet, debossed with "ENT" on one side and "0.5" on the other side
- Entecavir AMNEAL 1 mg tablet - Pink, triangular-shaped tablet, debossed with "ENT" on one side and "1" on the other side

Ingredients

Each tablet contains.

Entecavir AMNEAL 0.5 mg tablet - 0.5 mg of entecavir monohydrate per tablet

Entecavir AMNEAL 1 mg tablet - 1 mg of entecavir monohydrate per tablet

ENTECAVIR AMNEAL 0.5 mg and 1 mg film-coated tablets contain the following inactive ingredients:

Lactose monohydrate, microcrystalline cellulose, crospovidone, Ethyl alcohol anhydrous, and magnesium stearate. The 0.5 mg tablet coating contains Opadry II white 85F28751 (Macrogol/PEG 3000, Talc, titanium dioxide Polyvinyl alcohol partially hydrolyzed), and the 1 mg tablet coating contains Opadry II pink 85F24151 (Polyvinyl alcohol partially hydrolyzed, Titanium dioxide (E171), Macrogol/PEG 3000, Talc, Red Iron oxide)

Available as Blister Packs and HDPE* bottles of 30s (Alu/Alu),

*Bottles not marketed in Australia

Name and Address of the Sponsor

Anneal Pharma Australia Pty Ltd
12 River St
South Yarra
VIC – 3141
Australia

Date of Preparation

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Aust R 259912 (0.5 mg blister)
Aust R 259921 (1 mg blister)
Aust R 259910 (0.5 mg bottle)
Aust R 259917 (1 mg bottle)