

ENTECAVIR VIATRIS

Entecavir film coated tablet 0.5 mg & 1 mg



What is in this leaflet

Please read this leaflet carefully before you start taking Entecavir Viatris.

This leaflet answers some common questions about Entecavir Viatris.

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 Viatris 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 Viatris is used for

Entecavir Viatris is used to treat

- Adults infected with hepatitis B virus.

Entecavir Viatris contains the active ingredient entecavir. It belongs to a group of medicines called antiviral medicines.

Infection by the hepatitis B virus can lead to damage to the liver. Entecavir Viatris works by reducing 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 Viatris is when taken for long period.

Your doctor may have prescribed this medicine for another reason.

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

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

Entecavir Viatris is not addictive.

Before you take Entecavir Viatris

When you must not take it

Do not take Entecavir Viatris if you have an allergy to:

- any medicine containing entecavir.
- any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include: shortness of breath; wheezing or difficulty breathing; swelling of the face, lips, tongue or other parts of the body; rash, itching or hives on the skin.

Do not give this medicine to a child under the age of 16 years. Safety and effectiveness in children younger than 16 years have not been established.

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.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if you have allergies to any other medicines, foods, preservatives or dyes.

Symptoms of severe allergic reaction may include: chills, fever, fast heartbeat, wheezing or coughing, difficulty breathing, dizziness, flushing, sweating and swelling of the face, tongue or other parts of the body.

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Experience is limited with the use of entecavir 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 Viatris during pregnancy, your doctor will discuss with you the benefits and risks of taking it.

It is not known whether Entecavir Viatris passes into breast milk. Therefore to avoid possible side effects in the nursing infant, mothers should stop breastfeeding if they are taking Entecavir Viatris.

Tell your doctor if you currently experience or have experienced any medical conditions especially any problems with your kidney.

Tell your doctor if you have HIV and you are not currently on HIV treatment. Entecavir Viatris is not recommended in patients who have both HIV and Hepatitis B and who are not currently receiving anti-HIV treatment. Entecavir Viatris may affect your HIV virus which could impact on future treatment options for HIV.

Tell your doctor if you are lactose intolerant. Entecavir Viatris contains lactose and should be

used with caution in patients who are lactose intolerant.

If you have not told your doctor about any of the above, tell them before you start taking Entecavir Viatris.

Taking other medicines

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

You should also tell any health professional who is prescribing a new medication for you that you are taking Entecavir Viatris.

Your doctor and pharmacist have more information on medicines to be careful with or avoid while taking this medicine.

How to take Entecavir Viatris

Follow all directions given to you by your doctor or pharmacist carefully.

They may differ from the information contained in this leaflet.

If you do not understand the instructions on the box, ask your doctor or pharmacist for help.

How much to take

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

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

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

Please talk to your doctor or pharmacist for more information.

How to take it

Swallow the tablets whole with a full glass of water.

When to take it

Take your medicine at about the same time each day.

Taking it at the same time each day will have the best effect. It will also help you remember when to take it.

Take your medicine on an empty stomach, for example, 2 hours before food or 2 hours after food.

Food can interfere with the absorption of this medicine.

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

How long to take it

Continue taking your medicine for as long as your doctor tells you.

This medicine helps to control your condition but does not cure it. It is important to keep taking your medicine even if you feel well.

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

Entecavir Viatris 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 Viatris without discussing it with your doctor. If Entecavir Viatris 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 Viatris 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.

Continue taking your medicine until you finish the pack.

Do not stop taking Entecavir Viatris 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 your medicine as you would normally.

Do not take a double dose to make up for the dose that 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 to take your medicine, ask your pharmacist for some hints.

While you are taking Entecavir Viatris

Things you must do

If you are about to be started on any new medicine, tell your doctor and pharmacist that you are taking Entecavir Viatris.

Tell any other doctors, dentists, and pharmacists who treat you that you are taking this medicine.

If you are going to have surgery, tell the surgeon or anaesthetist that you are taking this medicine. It may affect other medicines used during surgery.

If you become pregnant while taking this medicine, tell your doctor immediately.

If you are about to have any blood tests, tell your doctor that you are taking this medicine.

It may interfere with the results of some tests.

Keep all of your doctor's appointments so that your progress can be checked.

Your doctor may do some tests from time to time to make sure the medicine is working and to prevent unwanted side effects.

Things you must not do

Do not take Entecavir Viatris to treat any other complaints unless your doctor tells you to.

Do not give your medicine to anyone else, even if they have the same condition as you.

Do not stop taking your medicine or lower the dosage without checking with your doctor.

If you stop taking it suddenly, your condition may worsen or you may have unwanted side effects. If possible, your doctor will gradually reduce the amount you take each day before stopping the medicine completely.

Things to be careful of

Be careful driving or operating machinery until you know how Entecavir Viatris affects you.

This medicine may cause dizziness in some people. If you have any of these symptoms, do not drive, operate machinery or do anything else that could be dangerous.

Make sure that you visit your doctor regularly throughout your entire course of treatment with Entecavir Viatris.

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

There is no evidence that Entecavir Viatris 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 fluid on them, like toothbrushes and razor blades. A vaccine is available to protect those at risk of becoming infected with hepatitis B.

If you feel light-headed, dizzy or faint when getting out of bed or standing up, get up slowly. Standing up slowly, especially when you get up from bed or chairs, will help your body get used to the change in position and blood pressure. If this problem continues or gets worse, talk to your doctor.

In case of overdose

If you take too much (overdose)

Immediately telephone your doctor or the National Poisons Centre (telephone 0800 POISON or 0800 764 766), or go to accident and emergency at your nearest hospital, if you think that you or anyone else may have taken too much Entecavir Viatris. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

Side effects

Tell your doctor or pharmacist as soon as possible if you do not feel well while you are taking Entecavir Viatris.

This medicine helps most people with hepatitis B infection but it may have unwanted side effects in a few people.

All medicines can have side effects. Sometimes they are serious, most of the time they are not. You may need medical treatment if you get some of the side effects.

Ask your doctor or pharmacist to answer any questions you may have.

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 heartbeat, 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 Viatris or medicines like Entecavir Viatris 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.

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 Viatris 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 Viatris, 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 or pharmacist if you notice anything that is making you feel unwell.

Other side effects not listed above may also occur in some people. Tell your doctor if you notice any other effects.

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

After taking Entecavir Viatris

Storage

Keep your tablets in the pack until it is time to take them.

If you take the tablets out of the pack they may not keep well.

Keep your tablets in a cool dry place where the temperature stays below 25°C.

Do not store Entecavir Viatris 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 it 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 the expiry date has passed, ask your pharmacist what to do with any medicine that is left over.

Product description

What it looks like

Entecavir Viatris 0.5 mg: white, film-coated, round, biconvex, beveled edge tablet debossed with 'M' on one side of the tablet and 'EV1' on the other side.

Entecavir Viatris 1 mg: white, film-coated, round, biconvex, beveled edge tablet debossed with 'M' on one side of the tablet and 'EV2' on the other side.

Ingredients

Active ingredient:

Entecavir Viatris contains 0.5 mg or 1 mg of entecavir as the active ingredient.

Inactive ingredients:

Entecavir Viatris also contains:

- microcrystalline cellulose
- crospovidone
- lactose monohydrate
- magnesium stearate
- titanium dioxide
- hydroxypropyl methylcellulose 2910/hypromellose 3cp
- hydroxypropyl methyl cellulose 2910/hypromellose 5cp
- macrogol/polyethylene glycol 400
- polysorbate 80.

Contains sugars as lactose.

If you want to know more

Should you have any questions regarding this product, please contact your pharmacist or doctor.

Who supplies this medicine

Entecavir Viatris is supplied in New Zealand by:

Viatris Ltd
PO Box 11-183
Eilerslie
AUCKLAND
www.viatris.co.nz
Telephone 0800 168 169

Date of Preparation

23 January 2023.
(Based on datasheet dated 23 January 2023).