

# ENTECAVIR VIATRIS

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## **Consumer Medicine Information (CMI) summary**

The [full CMI](#) on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

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### **1. Why am I taking ENTECAVIR VIATRIS?**

ENTECAVIR VIATRIS contains the active ingredient entecavir (as monohydrate). ENTECAVIR VIATRIS is used to treat adults infected with hepatitis B virus.

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

### **2. What should I know before I take ENTECAVIR VIATRIS?**

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

### **3. What if I am taking other medicines?**

Some medicines may interfere with ENTECAVIR VIATRIS 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 take ENTECAVIR VIATRIS?**

- The usual dose of ENTECAVIR VIATRIS is 0.5 mg or 1 mg once a day on an empty stomach.
- Swallow the tablets whole with a full glass of water.

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

### **5. What should I know while taking ENTECAVIR VIATRIS?**

<b>Things you should do</b>	
	<ul style="list-style-type: none"><li>• Tell any other doctors, dentists and pharmacists who treat you that you are taking ENTECAVIR VIATRIS.</li><li>• If you are going to have surgery, tell the surgeon</li></ul>

	<p>or anaesthetist that you are taking this medicine.</p> <ul style="list-style-type: none"> <li>• If you become pregnant while taking this medicine, tell your doctor immediately.</li> </ul>
<b>Things you should not do</b>	<ul style="list-style-type: none"> <li>• Do not take ENTECAVIR VIATRIS to treat any other complaints unless your doctor tells you to.</li> <li>• Do not give your medicine to anyone else, even if they have the same condition as you.</li> <li>• Do not stop taking your medicine or change the dosage without checking with your doctor.</li> </ul>
<b>Driving or using machines</b>	<ul style="list-style-type: none"> <li>• Be careful before you drive or use any machines or tools until you know how ENTECAVIR VIATRIS affects you.</li> </ul>
<b>Looking after your medicine</b>	<ul style="list-style-type: none"> <li>• Keep your tablets in the blister pack until it is time to take them.</li> </ul>

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|  | <ul style="list-style-type: none"><li>• Store your tablets in a cool dry place below 25°C.</li></ul> |
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For more information, see Section [5. What should I know while taking ENTECAVIR VIATRIS?](#) in the full CMI.

## 6. Are there any side effects?

**Less serious side effects:** diarrhoea; indigestion; tiredness; headache. **Serious side effects:** skin and the white part of eyes turns yellow (jaundice); urine turns dark; bowel movement (stool) turn light in colour; loss of appetite; nausea; lower stomach pain; lactic acidosis; serious liver problems; feeling cold (especially in arms and legs); feeling dizzy or light-headed; chills; fever; fast heartbeat; wheezing or coughing; difficulty breathing; dizziness; flushing; sweating and swelling of the face, tongue or other parts of the body. 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 VIATRIS

**Active ingredient(s):** *Entecavir (as monohydrate)*

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## Consumer Medicine Information (CMI)

This leaflet provides important information about taking ENTECAVIR VIATRIS. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about taking ENTECAVIR VIATRIS.**

**Where to find information in this leaflet:**

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

## 1. Why am I taking ENTECAVIR VIATRIS?

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

**ENTECAVIR VIATRIS is used to treat adults infected with hepatitis B virus.**

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

Ask your doctor if you have any questions about why ENTECAVIR VIATRIS has been prescribed for you.

Your doctor may have prescribed it for another reason.

ENTECAVIR VIATRIS is not addictive.

## **2. What should I know before I take ENTECAVIR VIATRIS?**

### **Warnings**

#### **Do not take ENTECAVIR VIATRIS if:**

- you have an allergy to:
  - any medicine containing entecavir monohydrate
  - any of the ingredients listed at the end of this leaflet

Some of the symptoms of an allergic reaction may include:

- chills, fever
- fast heartbeat

- wheezing or coughing
- difficulty breathing
- dizziness
- flushing
- sweating and swelling of the face, lips, tongue or other parts of the body

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

- the expiry date printed on the pack has passed 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.

## **Check with your doctor if you:**

- have allergies to any other medicines, foods, preservatives or dyes
- have or have had any of the following medical conditions:
  - currently experience or have experienced any medical conditions especially any problems with your kidneys
  - have HIV (human immunodeficiency virus) 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.

- are lactose intolerant. ENTECAVIR VIATRIS contains lactose.
- take any medicines for any other condition.

If you have not told your doctor about any of the above, tell him/her before you start taking ENTECAVIR VIATRIS.

It is important to remain under the care of your doctor during ENTECAVIR VIATRIS therapy and after stopping ENTECAVIR VIATRIS. You should report any new symptoms, medication or any other aspects affecting your health to your doctor. Your hepatitis B virus infection may get worse if you stop taking ENTECAVIR VIATRIS. If your doctor advises you to stop ENTECAVIR VIATRIS, they will monitor your health and perform regular blood tests to monitor your liver.

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**

**Tell your doctor if you are pregnant or plan to become pregnant.**

Experience is limited with the use of ENTECAVIR VIATRIS 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 risks and benefits involved. If you take ENTECAVIR VIATRIS while you are pregnant, talk to your doctor about how you can take part in the entecavir Pregnancy Registry. The purpose of the Pregnancy Registry is to collect information about the health of you and your baby.

**Tell your doctor if you are breastfeeding or plan to breastfeed.**

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

## **Children**

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

### **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 VIATRIS.**

## **4. How do I take ENTECAVIR VIATRIS?**

### **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.

### **When to take ENTECAVIR VIATRIS**

- Take your medicine any time of day provided it is on an empty stomach. Empty stomach means at least 2 hours before food or 2 hours after food.
- Talk to your doctor or pharmacist to work out when it is best for you to take your dose of ENTECAVIR VIATRIS.

### **How to take ENTECAVIR VIATRIS**

- Swallow the tablets whole with a full glass of water on an empty stomach.

### **How long to take ENTECAVIR VIATRIS**

- **Continue taking your medicine for as long as your doctor tells you to.**

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 and for as long as your doctor tells you to.

- **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 important to take ENTECAVIR VIATRIS every day or as directed by your doctor, to not miss doses, and to make sure you have enough supply until you next see your doctor.

- **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.**

It is extremely important that you do not stop without discussing with your doctor because 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 high risk of dying if liver failure develops and liver transplantation may be necessary to save your life.

## **If you forget to take ENTECAVIR VIATRIS**

**If it is almost time for your next dose, skip the dose you missed and take your 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 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.

## **If you take too much ENTECAVIR VIATRIS**

If you think that you or anyone else has taken too much ENTECAVIR VIATRIS, urgent medical attention may be needed.

**You should immediately:**

- phone the Poisons Information Centre **(by calling telephone 13 11 26)** for advice, 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 taking ENTECAVIR VIATRIS?**

### **Things you should do**

- If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking ENTECAVIR VIATRIS.
- Tell any other doctors, dentists and pharmacists who treat you that you are taking ENTECAVIR VIATRIS.
- 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.

### **Things you should 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 change the dosage without checking with your doctor.  
If you stop taking it suddenly, your condition may worsen.

## Things to be careful of

- **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.

- 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 fluids on them, like toothbrushes and razor**

**blades. A vaccine is available to protect those at risk of becoming infected with hepatitis B.**

## **Driving or using machines**

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

ENTECAVIR VIATRIS may cause dizziness in some people. It is not known if this was caused by ENTECAVIR VIATRIS. If you have this symptom, do not drive, operate machinery or do anything else that could be dangerous.

## **Looking after your medicine**

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

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

- Store your tablets below 25°C.

Follow the instructions on 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.

Heat and dampness can destroy some medicines.

**Keep it where young children cannot reach it.**

A locked cupboard at least one-and-a-half metres above the ground is a good place to store medicines.

## **Getting rid of any unwanted medicine**

If you no longer need to take this medicine or it is out of date, take it to any pharmacy for safe disposal.

Do not take 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.

Do not be alarmed by the following list of side effects.

You may not experience any of them.

### **Less serious side effects**

<b>Less serious side effects</b>	<b>What to do</b>
<ul style="list-style-type: none"><li>• diarrhoea</li><li>• indigestion</li><li>• tiredness</li><li>• headache</li></ul>	<b>Speak to your doctor or pharmacist if you have any of these less serious side effects and they worry you.</b>



## Serious side effects

Serious side effects	What to do
<p><b>Signs or symptoms of liver problems:</b></p> <ul style="list-style-type: none"><li>• skin and the white part of eyes turns yellow (jaundice)</li><li>• urine turns dark</li><li>• bowel movement (stool) turn light in colour</li><li>• loss of appetite</li><li>• nausea</li><li>• lower stomach pain</li><li>• lactic acidosis</li><li>• serious liver problems</li></ul> <p><b>Signs or symptoms of lactic acidosis:</b></p> <ul style="list-style-type: none"><li>• feeling very weak or tired</li><li>• unusual muscle pain</li><li>• trouble breathing</li><li>• stomach pain with nausea and vomiting</li><li>• feeling cold (especially in arms and legs)</li></ul>	<p><b>Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these very serious side effects.</b></p>

Serious side effects	What to do
<ul style="list-style-type: none"> <li>• feeling dizzy or light-headed</li> <li>• fast or irregular heartbeat</li> </ul> <p><b>Signs of a sudden life-threatening allergic reaction:</b></p> <ul style="list-style-type: none"> <li>• chills</li> <li>• fever</li> <li>• fast heartbeat</li> <li>• wheezing or coughing</li> <li>• difficulty breathing</li> <li>• dizziness</li> <li>• flushing</li> <li>• sweating and swelling of the face, tongue or other parts of the body.</li> </ul>	

**Lactic acidosis:** It is a serious medical emergency that can cause death. Lactic acidosis must be treated in the hospital. Reports of lactic acidosis with ENTECAVIR VIATRIS generally involved patients who were seriously ill due to their liver disease or other medical condition.

**Liver problems:** 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.

**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](http://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 VIATRIS contains**

<b>Active ingredient (main ingredient)</b>	entecavir (as monohydrate)
<b>Other ingredients</b>	• lactose monohydrate

<b>(inactive ingredients)</b>	<ul style="list-style-type: none"> <li>• microcrystalline cellulose</li> <li>• crospovidone</li> <li>• magnesium stearate</li> <li>• Opadry White YS-1R-7003 (ID: 1625)</li> </ul>
<b>Potential allergens</b>	Sugars as lactose

**Do not take this medicine if you are allergic to any of these ingredients.**

## **What ENTECAVIR VIATRIS looks like**

- **ENTECAVIR VIATRIS 0.5 mg:** A white, film-coated, round, biconvex, beveled edge tablet debossed with 'M' on one side of the tablet and 'EV1' on the other side (AUST R 220090).

Blister pack of 30 tablets.

- **ENTECAVIR VIATRIS 1 mg:** A white, film-coated, round, biconvex, beveled edge tablet debossed with 'M' on one side of the tablet and 'EV2' on the other side (AUST R 220091).

Blister pack of 30 tablets.

## **Who distributes ENTECAVIR VIATRIS**

Alphapharm Pty Ltd trading as Viatris

Level 1, 30 The Bond

30-34 Hickson Road

Millers Point NSW 2000

[www.viatris.com.au](http://www.viatris.com.au)

Phone: 1800 274 276

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