

ENTECAVIR RBX

Consumer Medicine Information (CMI) summary

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

1. Why am I using ENTECAVIR RBX?

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

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

2. What should I know before I use ENTECAVIR RBX?

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

3. What if I am taking other medicines?

Some medicines may interfere with ENTECAVIR RBX 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 use ENTECAVIR RBX?

The usual dose of ENTECAVIR RBX is 0.5 mg (one white tablet) or 1 mg (one pink tablet) once a day. Swallow the tablet whole with a glass of water. The dose of ENTECAVIR RBX should be taken on an empty stomach.

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

5. What should I know while using ENTECAVIR RBX?

Things you should do	<ul style="list-style-type: none">Remind any doctor, dentist or pharmacist you visit that you are using ENTECAVIR RBX.
Things you should not do	<ul style="list-style-type: none">Do not stop using this medicine suddenly or lower the dose without checking with your doctor.
Driving or using machines	<ul style="list-style-type: none">ENTECAVIR RBX may cause use dizziness in some people.
Looking after your medicine	<ul style="list-style-type: none">Store ENTECAVIR RBX tablets in a cool dry place where the temperature stays below 25°C

For more information, see Section [5. What should I know while using ENTECAVIR RBX?](#) in the full CMI.

6. Are there any side effects?

For less serious side effects speak to your doctor if they worry you. For serious side effects you may need urgent medical attention so tell your doctor immediately.

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 RBX

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

Consumer Medicine Information (CMI)

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

Where to find information in this leaflet:

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

1. Why am I using ENTECAVIR RBX?

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

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

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

ENTECAVIR RBX 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 RBX is when taken for long periods.

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

ENTECAVIR RBX is not addictive. This medicine is available only with a doctor's prescription.

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

2. What should I know before I use ENTECAVIR RBX?

Warnings

Do not use ENTECAVIR RBX if:

- you are allergic to entecavir(as monohydrate), or 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.

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

Do not use ENTECAVIR RBX 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 RBX if the packaging is torn or shows signs of tampering.

It is important to remain under the care of your doctor during ENTECAVIR RBX therapy and after stopping ENTECAVIR RBX.

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 RBX. If your doctor advises you to stop ENTECAVIR RBX, they will monitor your health and perform regular blood tests to monitor your liver.

Check with your doctor if you:

- 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.

- have any other medical conditions:
 - especially problems with your kidneys.
 - have HIV and you are not currently on HIV treatment. ENTECAVIR RBX is not recommended in patients who have both HIV and Hepatitis B and who are not currently receiving anti-HIV treatment. ENTECAVIR RBX may affect your HIV virus which could impact on future treatment options for HIV.
- are lactose intolerant. ENTECAVIR RBX tablets contain lactose.
- take any medicines for any other condition

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

Check with your doctor if you are pregnant or intend to become pregnant.

Experience is limited with the use of ENTECAVIR RBX 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 RBX during pregnancy, your doctor will discuss with you the benefits and risks of taking it.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

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

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 RBX.

4. How do I use ENTECAVIR RBX?

How much to take / use

The usual dose of ENTECAVIR RBX 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 RBX tablets.

Your doctor will tell you what dose to take and how often you should take your ENTECAVIR RBX 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 RBX should be taken on an empty stomach.

When to take / use ENTECAVIR RBX

ENTECAVIR RBX 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 RBX.

How long to take it

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

Your doctor has prescribed ENTECAVIR RBX to prevent hepatitis B virus from further damaging your liver.

ENTECAVIR RBX 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 RBX without discussing it with your doctor. If ENTECAVIR RBX 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 RBX 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 RBX 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 use ENTECAVIR RBX

ENTECAVIR RBX should be used regularly at the same time each day. If you miss your dose at the usual time, take it as soon as you remember, and then go back to taking it as you would normally.

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

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 RBX.

If you use too much ENTECAVIR RBX

If you think that you have used too much ENTECAVIR RBX, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), 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 using ENTECAVIR RBX?

Things you should do

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

Things to be careful of

- Make sure that you visit your doctor regularly throughout your entire course of treatment with ENTECAVIR RBX.

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

- There is no evidence that ENTECAVIR RBX 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.

Things you should not do

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

Driving or using machines

Be careful before you drive or use any machines or tools until you know how ENTECAVIR RBX effects you.

ENTECAVIR RBX may cause use dizziness in some people. Some patients taking ENTECAVIR RBX have experienced dizziness. It is not known if this was caused by ENTECAVIR RBX. Make sure you know how you react to ENTECAVIR RBX

before you drive a car, operate machinery or do anything else that could be dangerous if you are dizzy.

Looking after your medicine

Storage

Store ENTECAVIR RBX tablets in a cool dry place where the temperature stays below 25°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.

Follow the instructions in 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.

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

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

Do not use 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.

Less serious side effects

Less serious side effects	What to do
The most common side-effects are diarrhoea, indigestion, tiredness and headache	Speak to your doctor if you have any of these less serious side effects and they worry you.

Serious side effects

Serious side effects	What to do
signs of a sudden life-threatening allergic reaction: chills, fever, fast heart beat, wheezing or coughing, difficulty breathing, dizziness, flushing,	Call your doctor straight away, or go straight to the Emergency Department at

<p>sweating and swelling of the face, tongue or other parts of the body. Some people who have taken ENTECAVIR RBX or medicines like ENTECAVIR RBX 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 RBX generally involved patients who were seriously ill due to their liver disease or other medical condition.</p> <p>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.</p> <p>Some people who have taken medicines like ENTECAVIR RBX 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.</p> <p>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 RBX, for a long time.</p>	<p>your nearest hospital if you notice any of these serious side effects.</p>
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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. 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 RBX contains

Active ingredient (main ingredient)	entecavir (as monohydrate)
Other ingredients (inactive ingredients)	Lactose monohydrate, povidone, crospovidone, microcrystalline cellulose and magnesium stearate. The 0.5 mg tablet coating contains hypromellose, titanium dioxide, macrogol 400 and polysorbate 80. The 1 mg tablet coating contains hypromellose, titanium dioxide, macrogol 400, polysorbate 80 and iron oxide red.
Potential allergens	Lactose monohydrate

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

What ENTECAVIR RBX looks like

ENTECAVIR RBX tablets come in two types:

- ENTECAVIR RBX 0.5 mg tablets are white to off-white, triangular shaped film coated tablets, debossed with 'RL1' on one side and plain on other side
- ENTECAVIR RBX 1 mg tablets are light pink to pink, triangular shaped film coated tablets, debossed with 'RL2' on one side and plain on other side

ENTECAVIR RBX 0.5 mg tablets blister pack 30's
AUST R 256612

ENTECAVIR RBX 0.5 mg tablets bottle pack 30's & 500's
AUST R 256632

ENTECAVIR RBX 1 mg tablets blister pack 30's
AUST R 256652

ENTECAVIR RBX 1 mg tablets bottle pack 30's & 500's
AUST R 256672

Not all pack sizes and presentations are marketed in Australia

Who distributes ENTECAVIR RBX

Sun Pharma ANZ Pty Ltd
Macquarie Park NSW 2113
Australia
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Tel: 1800 726 229

This leaflet was prepared in January 2019