

WHO-PQ RECOMMENDED PATIENT INFORMATION LEAFLET

*This patient information leaflet focuses on uses of the medicine covered by WHO's Prequalification Team - Medicines. The recommendations for use are based on WHO guidelines and on information from stringent regulatory authorities.**

The medicine may be authorised for additional or different uses by national medicines regulatory authorities.

* https://extranet.who.int/prequal/sites/default/files/document_files/75%20SRA%20clarification_Feb2017_newtempl.pdf

Information for the patient

[HP035 trade name][†]
Entecavir

If you are a carer or parent looking after the person who takes this medicine, use this leaflet to give the medicine correctly and take note of the warnings and side effects.

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have questions about the medicine, ask your health care provider.
- This medicine is for you only. Do not pass it on to others. It may harm them, even if their illness seems to be the same as yours.
- If you are concerned about any side effects, talk to your health care provider. This includes unwanted effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What [HP035 trade name] is and what it is used for
2. What you need to know before you take [HP035 trade name]
3. How to take [HP035 trade name]
4. Possible side effects
5. How to store [HP035 trade name]
6. Contents of the pack and other information

1. What [HP035 trade name] is and what it is used for

[HP035 trade name] contains the active substance entecavir.

[HP035 trade name] is used to treat chronic (long term) hepatitis B virus (HBV) infection. It can be used in people whose liver is damaged but still works well enough (compensated liver disease) and in people whose liver is damaged and does not work properly (decompensated liver disease).

Infection with the hepatitis B virus can damage the liver. [HP035 trade name] reduces the amount of virus in your body, and helps the liver recover.

2. What you need to know before you take [HP035 trade name]

Do not take [HP035 trade name]

- if you are allergic (hypersensitive) to entecavir or to any of the other ingredients of [HP035 trade name] listed at the end of this leaflet.

Warning and precautions

Talk to your health care provider before taking [HP035 trade name]

- if you have ever had problems with your kidneys. This is important because your kidneys remove [HP035 trade name] from your body. Your health care provider may adjust your dose if your kidneys are not working well enough.
- do not stop taking [HP035 trade name] without checking with your health care provider. Your hepatitis may worsen if you stop taking [HP035 trade name]. If your health care provider stops [HP035 trade

[†] Trade names are not prequalified by WHO. This is the national medicines regulatory agency's responsibility.

name] treatment, you may still need to continue seeing your health care provider and have blood tests to pick up any problems with your liver.

- if you have ever taken another medicine for chronic hepatitis B.
- talk with your health care provider about any liver problems and the possible effect of [HP035 trade name] treatment on your liver

Taking [HP035 trade name] will not stop you from passing on the hepatitis B virus to other people through sexual contact or body fluids (including blood contamination). So, you must continue to take precautions so you do not pass on the virus to another person.

See your health care professional at once if you have nausea (feeling sick), vomiting (being sick) or belly pain. These may be a sign of a very serious side-effect called lactic acidosis.

- if you have previously received treatment for chronic hepatitis B, please inform your doctor.

Children and adolescents

[HP035 trade name] is not suitable for children and teenagers weighing less than 30 kg.

Other medicines and [HP035 trade name]

Tell your health care provider if you are taking any other medicine or if you have recently taken other medicines. Talk to your health care provider before you take any other medicine during treatment with [HP035 trade name].

[HP035 trade name] with food and drink

In most cases you may take [HP035 trade name] with food or between meals. If your liver disease is very advanced, your health care provider will instruct you to take [HP035 trade name] on an empty stomach. Empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

Children weighing at least 30 kg can take [HP035 trade name] with food or between meals.

Pregnancy, breast-feeding and fertility

Tell your health care provider if you are pregnant or planning to become pregnant.

You must not take [HP035 trade name] during pregnancy unless your health care provider has recommended that you take it during your pregnancy. Women who are able to have children and are taking [HP035 trade name] must use an effective method of contraception to avoid becoming pregnant.

Tell your health care provider if you are breast-feeding your baby. You should not breast-feed during treatment with [HP035 trade name] unless you have checked with your health care provider.

Driving and using machines

Dizziness, tiredness and sleepiness, which are common side effects of [HP035 trade name] can affect your ability to drive and use machines.

[HP035 trade name] contains lactose

Lactose is a source of glucose and galactose. The small amount of lactose in each dose is unlikely to cause symptoms of lactose intolerance. If, however, you have one of the rare genetic disorders galactosaemia, glucose-galactose intolerance or congenital lactase deficiency you must talk to your health care provider before taking this medicine.

This medicine may contain traces of cow's milk proteins. If you are allergic to cow's milk, talk to your health care provider before taking this medicine.

3. How to take [HP035 trade name]

Always take this medicine exactly as your health care provider has told you. Check with your health care provider if you are not sure.

For adults and teenagers weighing at least 30 kg, the dose depends on how well your liver is working.

If your liver is damaged but works well enough, the recommended dose is 1 tablet (0.5 mg) once daily. You can take the tablet either with food or between meals.

If your liver is so damaged that it does not work well enough, the recommended dose is 2 tablets (1 mg) once daily. You should take the tablets at least 2 hours after a meal and then wait at least 2 hours before you eat.

Your health care provider may adjust the dose if you have kidney problems.

For children (weighing at least 30 kg) the recommended dose is 1 tablet (0.5 mg) once daily. You can take the tablet either with food or between meals.

[HP035 trade name] is not suitable for children and teenagers weighing less than 30 kg.

If you take more [HP035 trade name] than you should

If you take more [HP035 trade name] than you should, contact your health care provider or your nearest hospital for advice immediately. Take the pack with you so that it is clear what medicine you have taken.

If you forget to take [HP035 trade name]

It is important not to miss doses. If you miss a dose of [HP035 trade name], take it as soon as possible, and then take your next scheduled dose at the usual time.

If it is almost time for your next dose, do not take the missed dose. Wait and take the next dose at the usual time.

Do not take a double dose to make up for a forgotten dose.

Do not stop [HP035 trade name] without checking with your health care provider

Very serious liver damage may occur if you stop taking [HP035 trade name]. Tell your health care provider immediately about any changes in your health after you stop [HP035 trade name] treatment.

If you have any questions about this medicine, ask your health care provider.

4. Possible side effects

Like all medicines, this medicine can cause side effects but not everybody gets them.

The following side effects can occur with entecavir **in adults**:

Common side effects (up to 1 in 10 people can get this side effect)

- headache
- insomnia (difficulty sleeping) or sleepiness
- tiredness
- dizziness
- nausea (feeling sick) and vomiting (being sick)
- diarrhoea
- indigestion
- blood tests showing liver injury.

Uncommon side effects (up to 1 in 100 people can get this side effect)

- rash
- hair loss.

Rare side effects (up to 1 in 1000 people can get this side effect)

- severe allergic reaction.

Similar side effects have been described in **children** and **teenagers**. An additional very common side effect in children and teenagers (at least 1 in 10 can get it) is reduction of neutrophils. Neutrophils are a type white blood cells that are important for fighting infection

If you get any side effects, talk to your health care provider. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get a side effect, talk to your health care provider. This includes side effects not listed in this leaflet. You may also be able to report such effects directly to your national reporting system if one is available. By reporting side effects, you can help to improve the available information on this medicine.

5. How to store [HP035 trade name]

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date stated on the label, carton or bottle after EXP date. The expiry date refers to the last day of that month.

Do not use this medicine if you notice any visible signs of deterioration that it is different from the description below.

Do not throw away any medicines in wastewater or household waste. Ask your health care provider how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What [HP035 trade name] contains

- The active ingredient is entecavir 0.5 mg
- The other ingredients of [HP035 trade name] are microcrystalline cellulose, copovidone, crospovidon, lactose monohydrate, magnesium stearate, hypromellose, titanium dioxide, macrogol/PEG, polysorbate

What [HP035 trade name] looks like and contents of the pack

[HP035 trade name] is white to off-white, round, film-coated tablets. They are biconvex (rounded on top and bottom) with a flat edge. The tablets have 'A' debossed (stamped into) one side and '11' on the other side. [HP035 trade name] is packaged in

Blister pack

Aluminium foil on aluminium foil blister cards, containing 10 tablets. Available in packs of 1x 10 or 3 x10 tablets. Or in

HDPE bottle:

Round, opaque white plastic (HDPE) bottle containing 30 or 100 tablets. It also contains a sachet of desiccant (drying material). The bottle has an aluminium/plastic foil seal and a white, childproof plastic (polypropylene) screw cap.

Supplier and Manufacturer

Supplier

RV Lifesciences Limited
Plot No. H-19, MIDC, Waluj,
Aurangabad 431133,
Maharashtra State,
India
Tel: +91 240 6649311/6649322
Email: contact@rvlifesciences.com

Manufacturer

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Maharashtra State,
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Tel: +91 240 6649311/6649322
Email: contact@rvlifesciences.com

For any information about this medicine, contact the local representative of the supplier.

This leaflet was last revised in March 2025

Detailed information on this medicine is available on the World Health Organization (WHO) website: <https://extranet.who.int/prequal/medicines/prequalified/finished-pharmaceutical-products>