

Package leaflet: Information for the user

Entecavir STADA 0.5 mg film-coated tablets

Entecavir STADA 1 mg film-coated tablets

Entecavir

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 any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What <Product name> is and what it is used for

<Product name> tablets are anti-viral medicines, used to treat chronic (long-term) hepatitis B virus (HBV) infection in adults.

<Product name> can be used in people whose liver is damaged but still functions properly (compensated liver disease) and in people whose liver is damaged and does not function properly (decompensated liver disease).

<Product name> tablets are also used to treat chronic (long-term) HBV infection in children and adolescents aged 2 years to less than 18 years.

<Product name> can be used in children whose liver is damaged but still functions properly (compensated liver disease).

Infection by the hepatitis B virus can lead to damage to the liver. <Product name> reduces the amount of virus in your body, and improves the condition of the liver.

2. What you need to know before you take <Product name>

DO NOT take <Product name>

- if you are allergic to entecavir or any of the other ingredients of this medicine (listed in section 6).

Warning and precautions

Talk to your doctor or pharmacist before taking <Product name>

- **if you have ever had problems with your kidneys**, tell your doctor. This is important because <Product name> is eliminated from your body through the kidneys and your dose or dosing schedule may need to be adjusted.
- **do not stop taking <Product name> without your doctor's advice** since your hepatitis may worsen after stopping treatment. When your treatment with <Product name> is stopped, your doctor will continue to monitor you and take blood tests for several months.

- **discuss with your doctor whether your liver functions properly** and, if not, what the possible effects on your <Product name> treatment may be.
- **if you are also infected with HIV** (human immunodeficiency virus) be sure to tell your doctor. You should not take <Product name> to treat your hepatitis B infection unless you are taking medicines for HIV at the same time, as the effectiveness of future HIV treatment may be reduced. <Product name> will not control your HIV infection.
- **taking <Product name> will not stop you from infecting other people with hepatitis B virus (HBV)** through sexual contact or body fluids (including blood contamination). So, it is important to take appropriate precautions to prevent others from becoming infected with HBV. A vaccine is available to protect those at risk from becoming infected with HBV.
- **<Product name> belongs to a class of medicines that can cause lactic acidosis** (excess of lactic acid in your blood) and enlargement of the liver. Symptoms such as nausea, vomiting and stomach pain might indicate the development of lactic acidosis. This rare but serious side effect has occasionally been fatal. Lactic acidosis occurs more often in women, particularly if they are very overweight. Your doctor will monitor you regularly while you are receiving <Product name>.
- **if you have previously received treatment for chronic hepatitis B**, please inform your doctor.

Children and adolescents

<Product name> should not be used for children below 2 years of age or weighing less than 10 kg.

Other medicines and <Product name>

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

<Product name> with food and drink

In most cases you may take <Product name> with or without food. However, if you have had a previous treatment with a medicine containing the active substance lamivudine you should consider the following. If you were switched over to <Product name> because the treatment with lamivudine was not successful, you should take <Product name> on an empty stomach once daily. If your liver disease is very advanced, your doctor will also instruct you to take <Product 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 and adolescents (from 2 to less than 18 years of age) can take <Product name> with or without food.

Pregnancy, breast-feeding and fertility

Tell your doctor if you are pregnant or planning to become pregnant. It has not been demonstrated that <Product name> is safe to use during pregnancy. <Product name> must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with <Product name> use an effective method of contraception to avoid becoming pregnant.

You should not breast-feed during treatment with <Product name>. Tell your doctor if you are breast-feeding. It is not known whether entecavir, the active ingredient in <Product name>, is excreted in human breast milk.

Driving and using machines

Dizziness, tiredness (fatigue) and sleepiness (somnolence) are common side effects which may impair your ability to drive and use machines. If you have any concerns consult your doctor.

<Product name> contains lactose

This medicinal product contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicinal product.

3. How to take <Product name>**Not all patients need to take the same dose of <Product name>.**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

For adults the recommended dose is either 0.5 mg or 1 mg once daily orally (by mouth).

Your dose will depend on:

- whether you have been treated for HBV infection before, and what medicine you received.
- whether you have kidney problems. Your doctor may prescribe a lower dose for you or instruct you to take it less often than once a day.
- the condition of your liver.

For children and adolescents (from 2 to less than 18 years of age), your child's doctor will decide the right dose based on your child's weight. Children weighing at least 32.6 kg may take the 0.5 mg tablet or an entecavir oral solution may be available. For patients weighing from 10 kg to 32.5 kg, an entecavir oral solution is recommended. All dosing will be taken once daily orally (by mouth). There are no recommendations for entecavir in children less than 2 years of age or weighing less than 10 kg.

Your child's doctor will decide the right dose based on your child's weight.

For children and adolescents (from 2 to less than 18 years of age), weighing at least 32.6 kg and requiring a dose of 0.5 mg (=half a tablet of 1 mg), <Product name> 0.5 mg tablets are also available.

All dosing will be taken once daily orally (by mouth).

For children and adolescents weighing less than 32.6 kg and for dosages below 0.5 mg an entecavir oral solution may be available.

Your child's doctor will decide the right dose based on your child's weight.

Your doctor will advise you on the dose that is right for you. Always take the dose recommended by your doctor to ensure that your medicine is fully effective and to reduce the development of resistance to treatment. Take <Product name> as long as your doctor has told you. Your doctor will tell you if and when you should stop the treatment.

Some patients must take <Product name> on an empty stomach (see **<Product name> with food and drink in Section 2**). If your doctor instructs you to take <Product name> on an empty stomach, empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

The tablet can be divided into equal doses.

If you take more <Product name> than you should

Contact your doctor at once.

If you forget to take <Product name>

It is important that you do not miss any doses. If you miss a dose of <Product name>, take it as soon as possible, and then take your next scheduled dose at its regular time. If it is almost

time for your next dose, do not take the missed dose. Wait and take the next dose at the regular time. Do not take a double dose to make up for a forgotten dose.

Do not stop <Product name> without your doctor's advice

Some people get very serious hepatitis symptoms when they stop taking <Product name>. Tell your doctor immediately about any changes in symptoms that you notice after stopping treatment.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

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

Adults

Patients treated with <Product name> have reported the following side effects:

Common (may affect up to 1 in 10 people)

- headache
- insomnia (inability to sleep)
- fatigue (extreme tiredness)
- dizziness
- somnolence (sleepiness)
- vomiting
- diarrhoea
- nausea
- dyspepsia (indigestion)
- increased blood levels of liver enzymes

Uncommon (may affect up to 1 in 100 people)

- rash
- hair loss

Rare (may affect up to 1 in 1,000 people)

- severe allergic reaction

Children and adolescents

The side effects experienced in children and adolescents are similar to those experienced in adults as described above with the following difference:

Very common (may affect more than 1 in 10 people)

- Low levels of neutrophils (one type of white blood cells, which are important in fighting infection)

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist or. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in [Appendix V](#). By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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

Do not use this medicine after the expiry date which is stated on the blister or carton after EXP. That expiry date refers to the last day of that month.

Do not store above 30 °C. Store in the original package.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist 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 <Product name> contains

<Product name> 0.5 mg:

The active substance is entecavir. Each film-coated tablet contains 0.5 mg entecavir.

The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose, maize starch pregelatinised, crospovidone (Type A) (E1202) and magnesium stearate.

Tablet coating: titanium dioxide (E171), hypromellose (E464), macrogol 400 and polysorbate 80 (E433).

<Product name> 1 mg:

The active substance is entecavir. Each film-coated tablet contains 1 mg entecavir.

The other ingredients are:

Tablet core: lactose monohydrate, microcrystalline cellulose, maize starch pregelatinised, crospovidone (Type A) (E1202) and magnesium stearate.

Tablet coating: titanium dioxide (E171), hypromellose (E464), macrogol 400, polysorbate 80 (E433) and red iron oxide (E172)

What <Product name> looks like and contents of the pack

<Product name> 0.5 mg:

Entecavir film-coated tablets are white and oval-shaped with a score line on both sides.

<Product name> 1 mg:

Entecavir film-coated tablets are pink and oval-shaped with a score line on both sides.

<Product name> film-coated tablets are supplied in cartons containing 30 x 1 or 90 x 1 film-coated tablet in unit-dose blisters.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

[To be completed nationally]

{Name and address}

<{tel}>

<{fax}>

<{e-mail}>

<This medicinal product is authorised in the Member States of the EEA under the following names:>

<{Name of the Member State}> <{Name of the medicinal product}>
<{Name of the Member State}> <{Name of the medicinal product}>

This leaflet was last revised in
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