Package leaflet: Information for the patient

Entecavir Sandoz® 0,5 mg, filmomhulde tabletten
Entecavir Sandoz® 1 mg, filmomhulde tabletten

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 [Nationally completed name] is and what it is used for

[Nationally completed name] tablets are anti-viral medicines, used to treat chronic (long term) hepatitis B virus (HBV) infection in adults. [Nationally completed 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).

[Nationally completed name] tablets are also used to treat chronic (long term) HBV infection in children and adolescents aged 2 years to less than 18 years. [Nationally completed 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. [Nationally completed 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 [Nationally completed name]

Do not take [Nationally completed name]

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

Warnings and precautions

Talk to your doctor or pharmacist before taking **[Nationally completed name]**

- **if you have ever had problems with your kidneys, tell your doctor. This is important because [Nationally completed name] is eliminated from your body through the kidneys and your dose or dosing schedule may need to be adjusted.**

- **do not stop taking [Nationally completed name] without your doctor's advice** since your hepatitis may worsen after stopping treatment. When your treatment with [Nationally completed 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 [Nationally completed name] treatment may be.

- **if you are also infected with HIV** (human immunodeficiency virus) be sure to tell your doctor. You should not take [Nationally completed 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. [Nationally completed name] will not control your HIV infection.

- **taking [Nationally completed 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.

- **[Nationally completed 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 **[Nationally completed name].**

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

Children and adolescents
[Nationally completed name] should not be used for children below 2 years of age or weighing less than 10 kg.

Other medicines and [Nationally completed name]
Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

[Nationally completed name] with food and drink
In most cases you may take [Nationally completed 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 [Nationally completed name] because the treatment with lamivudine was not successful, you should take [Nationally completed name] on an empty stomach once daily. If your liver disease is very advanced, your doctor will also instruct you to take [Nationally completed name] on an empty stomach. Empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.
[0.5 mg film-coated tablets]
<Children and adolescents (from 2 to less than 18 years of age) can take [Nationally completed name] with or without food.>

Pregnancy, breast-feeding and fertility
If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine. It has not been demonstrated that entecavir is safe to use during pregnancy. [Nationally completed name] must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with [Nationally completed name] use an effective method of contraception to avoid becoming pregnant.

You should not breast-feed during treatment with [Nationally completed name]. Tell your doctor if you are breast- feeding. It is not known whether entecavir, the active ingredient in [Nationally completed 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.

[Nationally completed name] contains lactose
This medicine contains lactose. If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3. How to take [Nationally completed name]

Not all patients need to take the same dose of [Nationally completed 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.

[0.5 mg film-coated tablets]

<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.>

[1 mg film-coated tablets] without a functional score line

<For children and adolescents (from 2 to less than 18 years of age), [Nationally completed name] 0.5 mg tablets are available or 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 [Nationally completed 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 [Nationally completed name] on an empty stomach (see [Nationally completed name] **with food and drink** in **Section 2).** If your doctor instructs you to take [Nationally completed name] on an empty stomach, empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

If you take more [Nationally completed name] than you should
Contact your doctor at once.

If you forget to take [Nationally completed name]
It is important that you do not miss any doses. If you miss a dose of [Nationally completed 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.

If you stop taking [Nationally completed name]
Do not stop [Nationally completed name] without your doctor’s advice.
Some people get very serious hepatitis symptoms when they stop taking entecavir. 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. Patients treated with entecavir have reported the following side effects:

Adults

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), and 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 (at least 1 in 10 patients): low levels of neutrophils (one type of white blood cells, which are important in fighting infection).

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. 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 [Nationally completed 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 bottle, carton box and blister after "EXP". The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

After first opening of the bottle, please use within 6 months.

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 [Nationally completed name] contains

- The active substance is entecavir.
Each film-coated tablet contains 0.5 mg of entecavir (as monohydrate).
Each film-coated tablet contains 1 mg of entecavir (as monohydrate).

- The other ingredients are:
Tablet core: lactose monohydrate, microcrystalline cellulose, crospovidone (Type A), magnesium stearate,
Tablet coating: hypromellose 2910, macrogol 6000, titanium dioxide (E 171), talc,
[Nationally completed name] 1 mg film-coated tablets additionally contain iron oxide red (E 172) and iron oxide yellow (E 172)

What [Nationally completed name] looks like and contents of the pack

[Nationally completed name] 0.5 mg film-coated tablets
White, round, film-coated tablet with debossment on both sides, "SZ" on one side and "108" on the other side with diameter approximately 8.0 mm.

[Nationally completed name] 1 mg film-coated tablets
Pink, round, film-coated tablet with debossment on both sides, "SZ" on one side and "109" on the other side with diameter approximately 10.0 mm.

[NL/H/3848] [NL/H/3850]
The film-coated tablets are packed in OPA/Aluminium/PVC-Aluminium blisters or are packed in a HDPE bottle with polypropylene child resistant screw cap and inserted in a carton.

[NL/H/3849]
The film-coated tablets are packed in Aluminium/Aluminium blisters and inserted in a carton.

[NL/H/3848]
Pack sizes:
Blister: 10, 30 and 90 film-coated tablets
Bottle: 30 film-coated tablets

[NL/H/3849]
Pack sizes:
10, 30 and 90 film-coated tablets

[NL/H/3850]
Pack sizes:
Blister: 30 and 90 film-coated tablets
Bottle: 30 film-coated tablets

Not all pack sizes may be marketed.

Houder van de vergunning voor het in de handel brengen en fabrikant

Houder van de vergunning voor het in de handel brengen
Sandoz B.V.
Veluwezoom 22
1327 AH Almere

Nederland

Fabrikant
Lek Pharmaceuticals d.d.
Verovškova ulica 57
1526 Ljubljana
Slovenië

In het register ingeschreven onder:
Entecavir Sandoz 0,5 mg, filmomhulde tabletten: RVG 119696.
Entecavir Sandoz 1 mg, filmomhulde tabletten: RVG 119700.

Dit geneesmiddel is geregistreerd in lidstaten van de EEA onder de volgende namen:

Nederland	Entecavir Sandoz 0,5 mg, 1 mg, filmomhulde tabletten
België	Entecavir Sandoz 0,5 mg, 1 mg, filmomhulde Tabletten
Tsjechië	Entecavir Sandoz
	Entecavir Sandoz
Griekenland	Entecavir/Sandoz
Frankrijk	ENTECAVIR SANDOZ 0,5 mg, 1 mg, comprimé pelliculé
Ierland	Entecavir Rowex 500 micrograms, 1 mg, Film-coated tablets
Litouwen	Entecavir Sandoz 0,5 mg, 1 mg, plėvele dengtos tabletės
Letland	Entecavir Sandoz 0,5 mg, 1 mg, apvalkotās tabletes
Slovenië	Entekavir Sandoz 0,5 mg, 1 mg, filmsko obložene tablete

Deze bijsluiter is voor het laatst goedgekeurd in februari 2021.