

Package leaflet: Information for the user

Entecavir Fomed 0,5 mg filmomhulde tabletten

EntecavirFomed1 mg filmomhuldetabletten

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 EntecavirFomed is and what it is used for
2. What you need to know before you take EntecavirFomed
3. How to take EntecavirFomed
4. Possible side effects
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1. What EntecavirFomed is and what it is used for

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

EntecavirFomed tablets are also used to treat chronic (long term) HBV infection in children and adolescents aged 2 years to less than 18 years.EntecavirFomed 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. EntecavirFomed reduces the amount of virus in your body, and improves the condition of the liver.

2. What you need to know before you take EntecavirFomed

Do not take EntecavirFomed

if you are allergic (hypersensitive) 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 EntecavirFomed

- **if you have ever had problems with your kidneys**, tell your doctor. This is important because EntecavirFomed is eliminated from your body through the kidneys and your dose or dosing schedule may need to be adjusted.
- **do not stop taking EntecavirFomed without your doctor's advice** since your hepatitis may worsen after stopping treatment. When your treatment with EntecavirFomed 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 EntecavirFomed treatment may be.
- **if you are also infected with HIV** (human immunodeficiency virus) be sure to tell your doctor. You should not take EntecavirFomed 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. EntecavirFomed will not control your HIV infection.
- **taking EntecavirFomed 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.
- **EntecavirFomed 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 EntecavirFomed.
- **if you have previously received treatment for chronic hepatitis B**, please inform your doctor.

Children and adolescents

EntecavirFomed should not be used for children below 2 years of age or weighing less than 10 kg.

Other medicines and EntecavirFomed

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

EntecavirFomed with food and drink

In most cases you may take EntecavirFomed 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 EntecavirFomed because the treatment with lamivudine was not successful, you should take EntecavirFomed on an empty stomach once daily. If your liver disease is very advanced, your doctor will also instruct you to take EntecavirFomed on an empty stomach. Empty stomach means at least 2 hours after a meal and at least 2 hours before your next meal.

Pregnancy, breast-feeding and fertility

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

You should not breast-feed during treatment with EntecavirFomed. Tell your doctor if you are breastfeeding. It is not known whether entecavir, the active ingredient in EntecavirFomed, 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.

EntecavirFomed 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 EntecavirFomed

Not all patients need to take the same dose of EntecavirFomed.

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), EntecavirFomed 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 EntecavirFomed 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 EntecavirFomed on an empty stomach (see **EntecavirFomed with food and drink** in **Section 2**). If your doctor instructs you to take EntecavirFomed 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 EntecavirFomed than you should Contact your doctor at once.

If you forget to take EntecavirFomed

It is important that you do not miss any doses. If you miss a dose of EntecavirFomed, 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 EntecavirFomed without your doctor's advice

Some people get very serious hepatitis symptoms when they stop taking EntecavirFomed. 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:

common (at least 1 in 100 patients): headache, insomnia (inability to sleep), fatigue (extreme tiredness), dizziness, somnolence (sleepiness), vomiting, diarrhoea, nausea, dyspepsia (indigestion), and increased blood levels of liver enzymes.

uncommon (at least 1 in 1,000 patients): rash, hair loss.

rare (at least 1 in 10,000 patients): severe allergic reaction.

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. 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 EntecavirFomed

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

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

This medicinal product does not require any special storage conditions.

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 Entecavir Fomed contains

- The active substance is entecavir. Each film-coated tablet contains 0.5 mg entecavir (as monohydrate).
- The active substance is entecavir. Each film-coated tablet contains 1 mg entecavir (as monohydrate).
- The other ingredients are:
 - lactose monohydrate
 - microcrystalline cellulose (E 460)
 - crospovidone type B (E 1202)
 - hypromellose (E464)
 - magnesium stearate (E 470b)

hypromellose (E464)
titanium dioxide (E171),
macrogol 400 (E 1521)
polysorbate 80

hypromellose (E464)
titanium dioxide (E171)
macrogol 400 (E 1521)
ironoxide red (E172)

What EntecavirFomed looks like and contents of the pack

White triangular shaped film coated tablets debossed 'A' on one side and '88' on the other side of 8.7 x 8.4 mm.

Pink triangular shaped film coated tablets debossed 'A' on one side and '89' on the other side of 10.9 x 10.5 mm.

EntecavirFomed 0,5 mg film-coated tablets are supplied in cartons containing 30 or 90 film-coated tablets in OPA/Aluminium/PVC-Aluminium blisters.

EntecavirFomed 1 mg film-coated tablets are supplied in cartons containing 30 or 90 film-coated tablets in OPA/Aluminium/PVC-Aluminium blisters.

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:

FOMED PHARMACEUTICALS SL,
Gabriel Garcia Marquez 4, lasRozas, Madrid,
Spanje

Fabrikant:

Pharmacare Premium Ltd.
HHF003 Hal Far Industrial Estate., Hal Far
BBG 3000 Birzebugia
Malta

In het register ingeschreven onder:

RVG119612, Entecavir Fomed 0,5 mg filmomhulde tabletten
RVG119613, Entecavir Fomed 1 mg filmomhulde tabletten

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

Nederland

Entecavir Fomed 0,5 mg filmomhulde tabletten
Entecavir Fomed 1 mg filmomhulde tabletten

Polen

Entecavir Fomed
Entecavir Fomed

Roemenië

Entecavir Fomed 0,5 mg comprimate filmate
Entecavir Fomed 1 mg comprimate filmate

Deze bijsluiter is voor het laatst goedgekeurd in Maart 2020