

Package leaflet: Information for the user

Entecavir Aristo 0.5 mg film-coated tablets Entecavir Aristo 1.0 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 Entecavir Aristo is and what it is used for
2. What you need to know before you take Entecavir Aristo
3. How to take Entecavir Aristo
4. Possible side effects
5. How to store Entecavir Aristo
6. Contents of the pack and other information

1. What Entecavir Aristo is and what it is used for

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

Entecavir Aristo tablets are also used to treat chronic (long term) HBV infection in children and adolescents. Entecavir Aristo 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. Entecavir Aristo reduces the amount of virus in your body, and improves the condition of the liver.

2. What you need to know before you take Entecavir Aristo

Do not take Entecavir Aristo

- 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 Entecavir Aristo

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

Children and adolescents

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

Other medicines and Entecavir Aristo

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

Entecavir Aristo with food and drink

In most cases you may take this medicine 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 Entecavir Aristo because the treatment with lamivudine was not successful, you should take Entecavir Aristo on an empty stomach once daily. If your liver disease is very advanced, your doctor will also instruct you to take Entecavir Aristo 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 Entecavir Aristo 0.5 mg tablets 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. Entecavir Aristo must not be used during pregnancy unless specifically directed by your doctor. It is important that women of childbearing age receiving treatment with this medicine use an effective method of contraception to avoid becoming pregnant.

You should not breast-feed during treatment with this medicine.

It is not known whether entecavir, the active ingredient in Entecavir Aristo, 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.

Entecavir Aristo 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 medicinal product.

3. How to take Entecavir Aristo

Not all patients need to take the same dose of Entecavir Aristo.

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.

For 0.5 mg tablet: 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 1 mg tablet: Entecavir Aristo 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.

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

If you forget to take Entecavir Aristo

It is important that you do not miss any doses. If you miss a dose of Entecavir Aristo, 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 Entecavir Aristo

Do not stop Entecavir Aristo 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:

Common (at least 1 in 100 patients):

- headache, insomnia (inability to sleep), fatigue (extreme tiredness), dizziness, somnolence (sleepiness),
- vomiting, diarrhoea, nausea, dyspepsia (indigestion)
- 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.

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 Yellow Card Scheme at: www.mhra.gov.uk/yellowcard. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Tenofovir disoproxil Aristo

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, blister or box after EXP. The expiry date refers to the last day of that month.

After first opening of the bottle, the tablets should be used within 30 days.

This medicine 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 Aristo contains

- The active substance is entecavir.
Each tablet of Entecavir Aristo 0.5 mg contains entecavir monohydrate equivalent to 0.5 mg of entecavir.
Each tablet of Entecavir Aristo 1.0 mg contains entecavir monohydrate equivalent to 1 mg of entecavir.

- The other ingredients are:

Entecavir Aristo 0.5 mg

Tablet core: Lactose monohydrate, Cellulose Microcrystalline, Crospovidone (type A), Hydroxypropyl cellulose (type L) and Magnesium stearate

Coating medium (white): Titanium dioxide (E171), Lactose monohydrate, Hypromellose, Macrogol 4000

Entecavir Aristo 1.0 mg

Tablet core: Lactose monohydrate, Cellulose Microcrystalline, Crospovidone (type A), Hydroxypropyl cellulose (type L) and Magnesium stearate

Coating medium (pink): Hypromellose, Titanium dioxide (E171), Polydextrose, Talc, Maltodextrin, Triglycerides, medium chain, Iron oxide red (E172), Iron oxide yellow (E172)

What Entecavir Aristo looks like and contents of the pack

Entecavir Aristo 0.5 mg film-coated tablets are presented as white to off white triangular-shaped tablets debossed with "0.5" on one side, with the following dimensions median 8.4mm±0.2 mm and thickness 3.7mm±0.3 mm.

Entecavir Aristo 1.0 mg film-coated tablets are presented as pink triangular-shaped tablets debossed with "1" on one side, with the following dimensions median 10.6mm±0.2 mm and thickness 4.5mm±0.3 mm.

Entecavir Aristo is supplied in a cardboard box containing OPA/ALU/PVC - Aluminium foil blisters or a white HDPE bottle with PP child resistant cap and induction sealing.

Pack sizes

30 tablets (blister)

90 tablets (blister)

30 tablets (bottle)

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Aristo Pharma GmbH
Wallenroder Straße 8–10
13435 Berlin
Germany

ARISTO

This leaflet was last revised in August 2017.