

Package leaflet: Information for the user

Baraclude 0.5 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 Baraclude is and what it is used for
2. What you need to know before you take Baraclude
3. How to take Baraclude
4. Possible side effects
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1. What BARACLUDGE is and what it is used for

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

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

2. What you need to know before you take BARACLUDGE

Do not take Baraclude

- **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 Baraclude

- **if you have ever had problems with your kidneys**, tell your doctor. This is important because Baraclude is eliminated from your body through the kidneys and your dose or dosing schedule may need to be adjusted.
- **do not stop taking Baraclude without your doctor's advice** since your hepatitis may worsen after stopping treatment. When your treatment with Baraclude 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 Baraclude treatment may be.

- **if you are also infected with HIV** (human immunodeficiency virus) be sure to tell your doctor. You should not take Baraclude 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. Baraclude will not control your HIV infection.
- **taking Baraclude 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.
- **Baraclude 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 Baraclude.
- **if you have previously received treatment for chronic hepatitis B**, please inform your doctor.

Children and adolescents

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

Other medicines and Baraclude

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

Baraclude with food and drink

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

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

Baraclude 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 BARACLUDE

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

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. The Baraclude oral solution is recommended for patients weighing from 10 kg to 32.5 kg. Children weighing at least 32.6 kg may take the oral solution or the 0.5 mg tablet. All dosing will be taken once daily orally (by mouth). There are no recommendations for Baraclude in children less than 2 years of age or weighing less than 10 kg.

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

Contact your doctor at once.

If you forget to take Baraclude

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

Some people get very serious hepatitis symptoms when they stop taking Baraclude. 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 Baraclude have reported the following side effects:

Adults

- 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.

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).

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 (see details below). By reporting side effects you can help provide more information on the safety of this medicine.

United Kingdom

Yellow Card Scheme

Website: at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store

5. How to store BARACLUDE

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 carton after EXP. That expiry date refers to the last day of that month.

Blister packs: do not store above 30°C. Store in the original carton.

Bottle packs: do not store above 25°C. Keep the bottle tightly closed.

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 Baraclude contains

- The active substance is entecavir. Each film-coated tablet contains 0.5 mg entecavir.
- The other ingredients are:
Tablet core: crospovidone, lactose monohydrate, magnesium stearate, cellulose microcrystalline and povidone.
Tablet coating: hypromellose, macrogol 400, titanium dioxide (E171), and polysorbate 80 (E433).

What Baraclude looks like and contents of the pack

The film-coated tablets (tablets) are white to off-white and triangular-shaped. They are marked with “BMS” on one side and “1611” on the other. Baraclude 0.5 mg film-coated tablets are supplied in cartons containing 30 x 1 or 90 x 1 film-coated tablet (in unit-dose blisters) and in bottles containing 30 film-coated tablets.

Not all pack sizes may be marketed in your country.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Bristol-Myers Squibb Pharma EEIG

Plaza 254

Blanchardstown Corporate Park 2

Dublin 15, D15 T867
Ireland

Manufacturer:
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Italy

Swords Laboratories T/A Bristol-Myers Squibb Pharmaceutical Operations, External Manufacturing
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For any information about this medicine, please contact the local representative of the Marketing Authorisation Holder.

United Kingdom

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Other sources of information

Detailed information on this medicine is available on the European Medicines Agency web site:
<http://www.ema.europa.eu/>.