Baraclude

Generic Name: entecavir

Pronunciation: BEAR-ah-klude

Drug Class: Nucleoside/Nucleotide Reverse Transcriptase Inhibitors (NRTIs)

Company: Bristol-Myers Squibb

Approval Status: Approved

Generic Version Available: Yes

Drug Indication

FDA-approved for the treatment of chronic hepatitis B infection in adults and children at least 2 years old with evidence of hepatitis B viral replication and active liver inflammation or damage. Baraclude is not recommended for persons coinfected with HIV/HBV who are not also receiving highly active antiretroviral therapy (HAART).

General Info

- Baraclude was approved by the U.S. Food and Drug Administration for use by adults with chronic hepatitis B on March 29, 2005. Approved for children ≥ 2 years on March 20, 2014.
- In clinical studies, 70 to 72 percent of participants with compensated liver disease who had no prior treatment showed improved liver biopsy results after 48 weeks of therapy.

Dosage

Adult Dose:

Age 16 years and older and no prior treatment with nucleoside-inhibitors: 0.5 mg once daily. If lamivudine- or telbivudine-resistant: 1 mg once daily. For those with decompensated liver disease: 1 mg once daily. Dosage adjustment is recommended for people with kidney disease. Take on empty stomach (at least two hours after a meal and two hours before the next meal).

Pediatric Dose:

Children 2 years and older and weighing at least 10 kg, no prior treatment with nucleoside inhibitors and lamivudine-experienced: weight-based dosing. Take on empty stomach (at least two hours after a meal and two hours before the next meal).

Dosing Info: Treatment length is indefinite and depends on clinical outcomes. Do not change your dose or stop taking Baraclude without talking to your medical provider.

Side Effects

- The most common side effects are headache, fatigue, dizziness and nausea. Less frequently reported side effects include insomnia, diarrhea and stomach upset.
- Baraclude may cause severe liver problems or a serious condition called lactic acidosis (buildup of acid in the blood).

Drug Interactions

- For a review of drug interactions, including prescription and over-the-counter medications and supplements that should not be taken with Baraclude or may require dose adjustments, consult the Baraclude package insert.

Other Info

- There are no adequate, well-controlled studies in pregnant women who have taken Baraclude. Baraclude should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.
- The safety of breast feeding while taking Baraclude has not been established, and it is recommended that Baraclude be discontinued if breast-feeding.

For More Info: http://www.baraclude.bmscustomerconnect.com

Co-Pay Program Info:
https://www.hepmag.com/basics/hepatitis-b-basics/paying-hepatitis-b-treatment

Patient Assistance Program Info:
https://www.hepmag.com/basics/hepatitis-b-basics/paying-hepatitis-b-treatment

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