Virenta®

Entecavir INN film coated tablet

DESCRIPTION

Virenta® is the preparation of Entecavir, a guanosine nucleoside analogue with activity against HBV reverse transcriptase, is efficiently phosphorylated to the active triphosphate form, which has an intracellular half-life of 15 hours. By competing with the natural substrate deoxyguanosine triphosphate, Entecavir triphosphate functionally inhibits all three activities of the HBV reverse transcriptase and thus acts as an antiviral drug.

INDICATIONS

Virenta® is indicated for the treatment of chronic hepatitis B virus infections in adults with evidence of active viral replication or evidence of persistent elevations in serum aminotransferases (ALT or AST) or histologically active disease. The following points should be considered when initiating therapy with **Virenta®**:

- This indication is based on histologic, virologic, biochemical and serologic responses in nucleoside-treatment-naive and lamivudine resistant adult subjects with HBeAg-positive or HBeAg-negative chronic HBV infection and compensated liver disease.
- Virologic, biochemical, serologic and safety data are available from a controlled study in adult subjects with chronic HBV infection and decompensated liver disease.
- Virologic, biochemical, serologic and safety data are available for a limited number of adult subjects with HIV/HBV co-infection who have received prior lamivudine therapy.

DOSAGE AND ADMINISTRATION

Virenta® should be administered on an empty stomach (at least 2 hours after a meal or 2 hours before the next meal).

- Compensated Liver Disease: The recommended dose of **Virenta®** for chronic hepatitis B virus infection in nucleoside-treatment-naive adults and adolescents 16 years of age and older is 0.5 mg once daily. The recommended dose of entecavir in adults and adolescents (at least 16 years of age) with a history of hepatitis B viremia while receiving lamivudine or known lamivudine or telbivudine resistance mutations rtM204I/V with or without rtL180M, rtL80I/V or rtV173L is 1 mg once daily.
- Decompensated Liver Disease: The recommended dose of **Virenta®** for chronic hepatitis B virus infection in adults with decompensated liver disease is 1 mg once daily.
- Renal Impairment: In subjects with renal impairment, the apparent renal clearance of Entecavir decreased as creatinine clearance decreased. Dosage adjustment is recommended for patients with creatinine clearance less than 50 mL/min, including patients on hemodialysis or continuous ambulatory peritoneal dialysis (CAPD).

USE IN PREGNANCY AND LACTATION

Pregnancy Category C. There are no adequate and well-controlled studies of Entecavir in pregnant women. Entecavir should be used during pregnancy only if clearly needed and after careful consideration

of the risks and benefits.

It is not known whether Entecavir is excreted in human milk; however, Entecavir is excreted into the milk of rats. Because many drugs are excreted into human milk and because of the potential for serious adverse reactions in nursing infants from Entecavir, a decision should be made to discontinue nursing or to discontinue Entecavir, taking into consideration the importance of continued hepatitis B therapy to the mother and the known benefits of breastfeeding.

SIDE EFFECTS

- Exacerbations of hepatitis after discontinuation of treatment.
- Lactic acidosis and severe hepatomegaly with steatosis.

PRECAUTIONS

- Severe Acute Exacerbations of Hepatitis B: Severe acute exacerbations of hepatitis B have been reported in patients who have discontinued anti-hepatitis B therapy, including Entecavir. Hepatic function should be monitored closely with both clinical and laboratory follow-up for at least several months in patients who discontinue anti-hepatitis B therapy.
- Patients co-infected with HIV and HBV: Entecavir has not been evaluated in HIV/HBV co-infected patients who were not simultaneously receiving effective HIV treatment. Limited clinical experience suggests there is a potential for the development of resistance to HIV nucleoside in patients with HIV infection that is not being treated.
- Lactic Acidosis and Severe Hepatomegaly with Steatosis: Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases, have been reported with the use of nucleoside analogues, including Entecavir, alone or in combination with anti-retrovirals. A majority of these cases have been in women. Obesity and prolonged nucleoside exposure may be risk factors. Particular caution should be exercised when administering nucleoside analogues to any patient with known risk factors for liver disease.

PHARMACEUTICAL PRECAUTION

Store in a dry place, away from light. Keep out of reach of children.

PACKAGING

Virenta® 0.5 tablet: Box containing 1 strip of 10 tablets. Each film coated tablet contains Entecavir INN 0.5 mg.

SK+F
Manufactured by
ESKAYEF BANGLADESH LIMITED
GAZIPUR, BANGLADESH
® REGD. TRADEMARK
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