Diavix®

Tablet

Description

Diavix tablets is a fixed dose combination drug containing Lamivudine INN 150 mg and Zidovudine USP 300 mg.

Indications

Diavix is indicated for the treatment of HIV infection.

Dosage and Administration

The recommended oral dose of Diavix for adults and adolescents (at least 12 years of age) is one tablet.

Dose adjustment : As it is a fixed-dose combination, Diavix should not be prescribed for patients requiring dosage adjustment such as those with reduced renal function (creatinine clearance < 50 ml/min), those with low body weight (< 50 kg or 110 lb), or those experiencing dose-limiting adverse events.

Diavix is not recommended for patients with impaired hepatic function, as Diavix is a fixed-dose combination that cannot be adjusted for this patient population.

Contraindications

Diavix is contraindicated in patients with previously demonstrated clinically significant hypersensitivity to any of the components of the product.

General : Reduction of doses of Lamivudine is recommended for patients with low body weight (less than 50 kg or 110 lb); therefore, patients with low body weight should not receive Diavix.

Precautions

Zidovudine, one of the two active ingredients in Diavix, has been associated with haematologic toxicity including neutropenia and severe anaemia, particularly in patients with advanced HIV disease. Prolonged use of Zidovudine has been associated with symptomatic myopathy.

Post-treatment exacerbations of hepatitis : In clinical trials in non-HIV-infected patients treated with Lamivudine for chronic hepatitis B, clinical and laboratory evidence of exacerbations of hepatitis have occurred after discontinuation of Lamivudine. These exacerbations have been detected primarily by serum ALT elevations in addition to re-emergence of hepatitis B viral DNA (HBV DNA). Although most events appear to have been self-limited, fatalities have been reported in some cases. Similar events have been reported from post-marketing experience after changes from Lamivudine-containing HIV treatment regimens to non-Lamivudine-containing regimens in patients infected with both HIV and HBV. Patients should be closely monitored with both clinical and laboratory follow-up for at least several months after stopping treatment. There is insufficient evidence to determine whether re-initiation of Lamivudine alters the course of post-treatment exacerbations of hepatitis.

Ordinarily, Diavix should not be administered concomitantly with either Lamivudine or Zidovudine.

Bone Marrow Suppression : Diavix should be used with caution in bone marrow compromised patients evidenced by granulocyte count < 1,000 cells/mm^3 or haemoglobin < 9.5 g/dl.

Frequent blood counts are strongly recommended in patients with advanced HIV disease who are treated with Diavix. For HIV-infected individuals and patients with asymptomatic or early HIV disease, periodic blood counts are recommended.

Lactic acidosis/Severe hepatomegaly with steatosis : Lactic acidosis and severe hepatomegaly with steatosis, including fatal cases have been reported with the use of antiretroviral nucleoside analogues alone or in combination, including Zidovudine and Lamivudine. A majority of these cases have been in women. Caution should be exercised when administering Diavix to any patient, and particularly to those with known risk factors for liver disease. Treatment with Diavix should be suspended in any patient who develops clinical or laboratory findings suggestive of lactic acidosis or hepatotoxicity.

Patients with HIV and Hepatitis B virus co-infection : Safety and efficacy of Lamivudine have not been established for treatment of chronic hepatitis B in patients dually infected with HIV and HBV. In non-HIV-infected patients treated with Lamivudine for chronic hepatitis B, emergence of Lamivudine-resistant HBV has been detected and has been associated with diminished treatment response. Emergence of hepatitis B virus variants associated with resistance to Lamivudine has also been reported in HIV-infected patients who have received Lamivudine-containing antiretroviral regimens in the presence of concurrent infection with hepatitis B virus. Post-treatment exacerbations of hepatitis have also been reported.

Side Effects

General : Headache, malaise, fatigue, fever or chills, weakness. *Gastrointestinal* : Nausea and vomiting, diarrhoea, anorexia and/or decreased appetite, abdominal pain or cramps, dyspepsia. *Nervous system* : Neuropathy, insomnia and other sleep disorders, dizziness, depressive disorders. *Respiratory* : Nasal signs and symptoms, cough. *Skin* : Skin rashes. *Musculoskeletal* : Musculoskeletal pain, myalgia, arthralgia.

The following events have been chosen for inclusion due to their seriousness, frequency of reporting, causal connection to Lamivudine and/or Zidovudine or a combination of these factors. *Cardiovascular* : Cardiomyopathy, vasculitis. *Endocrine and Metabolic* : Gynaecomastia, hyperglycaemia. *Gastrointestinal* : Oral mucosal pigmentation, stomatitis. *Haemic and Lymphatic* : Aplastic anaemia, anaemia, lymphadenopathy, pure red cell aplasia, spleenomegaly. *Hepatic and Pancreatic* : Lactic acidosis and hepatic steatosis, steatosis, pancreatitis, post-treatment exacerbation of hepatitis B infection. *Hypersensitivity* : Sensitisation reactions (including anaphylaxis), urticaria. *Musculoskeletal* : Muscle weakness, elevation of creatinephosphokinase (CPK), rhabdomyolysis. *Nervous system* : Paraesthesia, peripheral neuropathy, seizures. *Respiratory system* : Abnormal breath sounds/wheezing. *Skin* : Alopecia, erythema multiforme, Stevens-Johnson syndrome.

Commercial Pack

Diavix® Tablet : Each box contains 1 x 10's tablets in blister strip. Each tablet contains Lamivudine INN 150 mg and Zidovudine USP 300 mg.