Triovix®

Tablet

Description

Each Triovix tablet contains Lamivudine INN 150 mg, Zidovudine USP 300 mg and Nevirapine INN 200 mg. A fixed dose combination of Lamivudine, Zidovudine and Nevirapine is recommended for Human Immunodeficiency Virus-1 (HIV-1) infected patients who are able to tolerate standard doses of Lamivudine, Zidovudine and Nevirapine for at least 2 weeks prior to switching over to this fixed dose combination. Patients should have demonstrated adequate tolerability to Nevirapine.

Indications

A fixed dose combination of Lamivudine, Zidovudine and Nevirapine is recommended for HIV-1 infected patients who are able to tolerate maintenance therapy with Nevirapine 200 mg twice daily. All three drugs are to be administered twice daily and each tablet contains half of the daily dose for each component. Twice daily formulation in single tablet for three drugs is convenient for patients to take, ensuring higher rate of compliance.

Dosage and Administration

For treatment of HIV Infection.

Adult dosage : One tablet twice daily. This fixed dose combination is not recommended for patients who have not been on initial lower dose of Nevirapine 200 mg once daily for 2 weeks and / or have not tolerated this dose. After successful therapy with low dose Nevirapine for two weeks, patients can be switched over to 200 mg bid dose provided they have not demonstrated any hypersensitivity reaction (rash, abnormal liver function tests) during their initial exposure to Nevirapine. Monitoring of patients for their liver function tests etc. is desirable prior to initiating therapy with Nevirapine and monitoring at frequent intervals once therapy with fixed dose combination is continued.

Dosage adjustment : Lamivudine : For patients with low body weight (< 50 kg) where dosage adjustment may be required, it is preferable not to use this fixed dose combination.Zidovudine : Because it is a fixed dose combination, this should not be prescribed for patients requiring dosage

adjustment such as those with reduced renal function (creatinine clearance 50 ml/min) or those experiencing dose imiting adverse events.

Nevirapine : For patients who experience severe rash or rash with constitutional complaints during the initial low dose Nevirapine phase of 14 days with once daily dose of 200 mg; neither, dose should be increased to twice daily nor they should receive triple fixed dose combination until the rash is resolved. Similarly for patients with abnormal liver function tests, Nevirapine therapy should be stopped till liver function return to normal and careful restart is advisable after extended observation. In event of recurrence, Nevirapine therapy can not be restarted.

For patients where Nevirapine therapy has to be restarted after an interruption, daily dose of Nevirapine 200 mg for 14 days should be followed with twice daily dose in absence of any hypersensitivity reaction. Studies have not been documented to suggest dosage of Nevirapine in patients with hepatic dysfunction, renal insufficiency or undergoing dialysis.

Contraindications

History of hypersensitivity to Lamivudine, Zidovudine, Nevirapine and to any of the excipients available in formulation. Not to be used as initial therapy because initial therapy requires 200 mg once daily of Nevirapine whereas fixed dose combination allows for 200 mg twice daily of Nevirapine.

Precautions

For the following conditions, assess risk to patient and take action as needed, chronic hepatitis B, hepatomegaly with steatosis, lactic acidosis, liver function impairment, severe renal function impairment, peripheral neuropathy.

Side Effects

Lamivudine : Pancreatitis, paresthesia, peripheral neuropathy, cough, dizziness, fatigue, gastrointestinal problems, headache, insomnia, anaemia, neutropenia, drug induced skin rash, hair loss.

Zidovudine : Headache (which may be severe, has been reported in up to 63% of patients receiving Zidovudine and asthenia has been reported in 9-69%), malaise and fatigue, fever or chills, nausea (61% cases), diaphoresis, dyspnoea, rash and taste perversion have been reported. Skin rashes and myalgia has been reported in patients receiving Zidovudine. Myopathy and myositis with pathologic changes similar to that produced by HIV infection, have been associated with prolonged use of Zidovudine. The major adverse effect is bone marrow toxicity resulting in severe anaemia and/or neutropenia. Patients with low serum folate or vitamin B_{12} concentrations may be at increased risk for developing bone marrow toxicity during Zidovudine therapy. There also are limited data suggesting that bone marrow of patients with fulminant acquired immunodeficiency syndrome (AIDS) may be more sensitive to Zidovudine induced toxicity than that of patients with less advanced disease (eg, AIDS related complex [ARC]). Anaemia and granulocytopenia usually resolve when Zidovudine is discontinued or when dosage is decreased. Lactic acidosis (in the absence of hypoxaemia) and severe hepatomegaly with steatosis, including some fatalities, have been reported in patients receiving Zidovudine.

Nevirapine : More frequent incidences are skin rash, diarrhoea, gastrointestinal problems, headache, nausea and stomach pain. Incidence of less frequents are aphthous stomatitis, fever, hepatitis and Stevens Johnson syndrome.

Commercial Pack

Triovix® Tablet : Each box contains 1 x 10's tablets in Blister strip. Each tablet contains Lamivudine INN 150 mg, Zidovudine USP 300 mg and Nevirapine INN 200 mg.