Ditanex

Ditanex-100 Tablets

Warning

PANCREATITIS, WHICH HAS BEEN FATAL IN SOME CASES, HAS OCCURRED DURING THERAPY WITH DIDANOSINE. DIDANOSINE USE SHOULD BE SUSPENDED IN PATIENTS WITH SIGNS OR SYMPTOMS OF PANCREATITIS AND DISCONTINUED IN PATIENTS WITH CONFIRMED PANCREATITIS (SEE WARNINGS AND PRECAUTIONS). 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 DIDANOSINE

Composition

Each chewable tablet contains: Didanosine 100 mg

Description

Didanosine (formerly called dideoxyinosine-ddI) is a synthetic purine nucleoside analogue of the naturally occurring nucleoside deoxyadenosine, in which the 3" hydroxyl group is replaced by hydrogen. Intracellularly, didanosine is converted by cellular enzymes to the active metabolite, dideoxyadenosine 5"-triphosphate. This metabolite inhibits the activity of HIV-1 reverse transcriptase both by competing with the natural substrate, and by its incorporation into viral DNA. The lack of a 3"-hydroxyl group in the incorporated nucleoside analogue prevents DNA chain elongation and therefore, the viral DNA growth is terminated.

Indications

Ditanex-100 is indicated for the treatment of HIV infection when antiretroviral therapy is warranted.

Dosage and Administration

Adults: Dosage: The dosing interval should be 12 hours. Didanosine should be administered on an empty stomach, at least 30 minutes before or 2 hours after eating. Adult patients should take 2 tablets at each dose so that adequate buffering is provided to prevent gastric acid degradation of didanosine. No more than 4 tablets should be taken at each dose to reduce the risk of gastrointestinal side effects. The recommended starting dose in adults is dependent on weight, as outlined in the table below:

Administration: For full therapeutic effect, 2 tablets must be thoroughly chewed, crushed or dispersed in water before swallowing. The tablets should not be swallowed whole. To disperse the tablets, 2 tablets should be added to 2 tablespoons (30 ml) of water. The water should then be
stirred until a uniform dispersion forms. The entire dispersion should be swallowed immediately.
Dose Adjustment: Clinical signs suggestive of pancreatitis should prompt dose suspension and careful evaluation of the possibility of pancreatitis. Didanosine use should be discontinued in patients with confirmed pancreatitis.
Patients who have presented with symptoms of neuropathy may tolerate a reduced dose of didanosine after resolution of these symptoms upon drug discontinuation.
In adult patients with impaired renal function, the dose of didanosine should be adjusted to compensate for the slower rate of elimination. The recommended doses and dosing intervals of didanosine in adult patients with renal insufficiency are given in the table below:

Patients requiring continuous ambulatory peritoneal dialysis (CAPD) or hemodialysis: It is recommended that one-fourth of the total daily dose of didanosine be administered once a day (See Table 2, recommended dosage for patients with CLCR < 10 mL/min). It is not necessary to administer a supplemental dose of didanosine following hemodialysis.

PAEDIATRICS

Dosage: The recommended dose is 120 mg/m2 twice daily. Didanosine should be administered on an empty stomach, 30 minutes before or 2 hours after food. Tablets should be crushed, chewed or dispersed in water, as described for adults. Use at least 2 tablets per dose to provide adequate
buffering. Maximum 4 tablets per dose.

Contraindications
Ditanex-100 is contraindicated in patients with previously demonstrated clinically significant hypersensitivity to any of the components of the formulation.