Cytosor® IV Injection

Cytarabine USP Injection

DESCRIPTION

Cytosor® IV Injection is a preparation of Cytarabine. Cytarabine, a pyrimidine nucleoside analogue, is an antineoplastic agent which inhibits the synthesis of deoxyribonucleic acid. It also has antiviral and immunosuppressant properties. Detailed studies on the mechanism of cytotoxicity in vitro suggests that the primary action of cytarabine is inhibition of deoxycytidine synthesis, although inhibition of cytidylic kinases and incorporation of the compound into nucleic acids may also play a role in its cytostatic and cytocidal actions.

INDICATIONS

Cytarabine is indicated primarily for induction and maintenance of remission in acute non-lymphocytic leukemia of both adults and children. It has also been found useful in the treatment of other leukemias.

DOSAGE AND ADMINISTRATION

Conventional dose: In the induction therapy of acute non-lymphocytic leukemia, the usual Cytarabine dose in combination with other anti-cancer drugs is 100 mg/m^2/day by continuous I.V. infusion (Days 1-7) or 100 mg/m^2 I.V. every 12 hours (Days 1-7).

High dose: 2-3 g/m^2 as an I.V. infusion over 1-3 hours given every 12 hours for 2-6 days with or without additional cancer chemotherapeutic agents.

SC dose: Generally 20-100 mg/m^2 depending on the indication being treated and the regimen being used.

The literature should be consulted for the current recommendations for use in leukemia and pediatric non-Hodgkin's lymphoma.

Intrathecal Use in Meningeal Leukemia: When preparing Cytarabine for intrathecal use, do not use diluents containing benzyl Alcohol.

Cytarabine has been used intrathecally in acute leukemia in doses ranging from 5 mg/m^2 to 75 mg/m^2 of body surface area. The frequency of administration varied from once a day for 4 days to once every 4 days.

The most frequently used dose was 30 mg/m^2 every 4 days until cerebrospinal fluid findings were normal, followed by one additional treatment. The dosage schedule is usually governed by the type and severity of central nervous system manifestations and the response to previous therapy.

Cytarabine has been used intrathecally with hydrocortisone sodium succinate and methotrexate, both as prophylaxis in newly diagnosed children with acute lymphocytic leukemia, as well as in the treatment of meningeal leukemia.

Drug Compatibilities: Cytarabine is compatible with the following drugs, at the specified concentrations, in Dextrose 5% in water for eight hours; Cytarabine 0.8 mg/ml and Sodium Cephalothin 1.0 mg/ml; Cytarabine 0.4 mg/ml and prednisolone sodium phosphate 0.2 mg/ml, Cytarabine 16 mcg/ml and Vincristine Sulfate 4 mcg/ml. Cytarabine is also physically compatible with methotrexate.

CONTRAINDICATIONS

- Hypersensitivity

SIDE EFFECTS

- Blood and lymphatic system disorders
- Infections and infestations
- The Cytarabine syndrome

WARNING AND PRECAUTION

For induction therapy, patients should be treated in a facility with laboratory and supportive resources sufficient to monitor drug tolerance and protect and maintain a patient compromised by drug toxicity. The main toxic effect of Cytarabine is bone marrow suppression with leukopenia, thrombocytopenia and anemia. Less serious toxicity includes nausea, vomiting, diarrhea and abdominal pain, oral ulceration, and hepatic dysfunction. The physician must judge possible benefit to the patient against known toxic effects of this drug in considering the advisability of therapy with Cytarabine.

USE IN PREGNANCY AND LACTATION

There are no studies on the use of Cytarabine in pregnant women. Cytarabine is known to be teratogenic in some animal species. Use of this drug in women who are or who may become pregnant should be undertaken only after due consideration of potential benefit and potential hazard to both mother and child. Women of childbearing potential should be advised to avoid becoming pregnant.

PHARMACEUTICAL PRECAUTION

Storage condition: Will be confirmed later

PACKAGING

Gemtor® 200 IV Injection : Each box contains 1 vial of Gemcitabine USP 200 mg injection.

Gemtor® 1g IV Injection : Each box contains 1 vial of Gemcitabine USP 1 gm injection.

SK+F ONCOLOGY

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
RUPGANJ, NARAYANGANJ, BANGLADESH
® REGD. TRADEMARK
R/PM0000 V01