Cytosor® IV/IT/SC Injection

Cytarabine Injection

DESCRIPTION

Cytosor® 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

Chemical stability in infusion solutions

Chemical stability studies were performed by a HPLC assay on Cytarabine Injection in infusion solutions. These studies showed that when Cytarabine Injection was diluted with Water for Injection, 5% Dextrose Injection or 0.9% Sodium Chloride Injection, a satisfactory Assay of Cytarabine was found after 8 days storage at room temperature.

This chemical stability information in no way indicates that it would be acceptable practice to infuse a Cytarabine admixture well after the preparation time. Good professional practice suggests that administration of an admixture should be as soon after preparation as feasible.

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions are the responsibility of the user and would normally not be longer than 24 hours at 2-8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

Disposal and Spills

To destroy, place in a high risk (for cytotoxics) waste disposal bag and incinerate at 1100 °C. If spills occur, restrict access to the affected area and adequate protection including gloves and safety spectacles should be worn. Limit the spread and clean the area with absorbent paper/material. Spills may also be treated with 5% sodium hypochlorite. The spill area should be cleaned with copious amounts of water. Place the contaminated material in a leak proof disposal bag for cytotoxics and incinerate at 1100 °C. Wear gloves at all times when handling containers.

STORAGE CONDITION

Do not store above 25 °C temperature, keep away from light and wet place. Keep out of reach of children. Do not refrigerate.

PACKAGING

Cytosor® 100 IV/IT/SC Injection : Each box contains 1 vial of Cytarabine BP 100 mg injection.

Cytosor® 500 IV/IT/SC Injection : Each box contains 1 vial of Cytarabine BP 500 mg injection.

SK+F ONCOLOGY

Manufactured by
ESKAYEF PHARMACEUTICALS LIMITED
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