Cytarabine Injection

PHARMACY BULK PACKAGE – NOT FOR DIRECT INFUSION

CAUTIONS

Currents

Cytarabine Injection is a white to off-white, crystalline powder which is freely soluble in water and slightly soluble in alcohol.

CLINICAL PHARMACOLOGY

Cytarabine is cytotoxic to a wide variety of proliferating mammalian cells in culture and is active against a variety of solid tumors in vivo. It is also active against some avian tumor cell lines.

INDICATIONS AND USAGE

Cytarabine is contraindicated in those patients who are hypersensitive to the drug.

CONTRAINDICATIONS

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The inhibition of DNA polymerase. A limited, but significant, incorporation of cytarabine into both the mechanism of action is not completely understood, it appears that cytarabine acts through

Intradural administration of cytarabine is indicated in the prophylaxis and treatment of meningeal dissemination of acute leukemia.

Cytarabine in combination with other approved anticancer drugs is indicated for remission induction of acute myelogenous leukemia.

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WARNINGS

When large intravenous doses are given quickly, patients are frequently nauseated and may vomit. Narcotics and diazepam have been used in preparatory medication programs in an attempt to reduce nausea and vomiting.

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Cytarabine is labeled by deoxyribonucleic acid and other nucleic acid to the nucleotide mixture that becomes DNA. An effect on DNA biosynthesis can be seen after 4-6 hours when cells are frequently detached from the inhibition of DNA polymerase. A limited, but significant, incorporation of cytarabine into both the mechanism of action is not completely understood, it appears that cytarabine acts through

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ADVERSE REACTIONS

The above process should be carried out under a laminar flow hood using aseptic technique.

Hepatic, gastrointestinal, urticaria, rash, erythroderma, cutaneous vasculitis, angioedema, drug fever, or anaphylaxis (see WARNINGS and DEFERRED REACTIONS).

The literature should be consulted for the current recommendations for use in acute lymphocytic leukemia.

Cytarabine Injection is supplied in vials of 25 mg (50 mg/ml) as a pyrogen-free (2 ml) lyophilized (sodium chloride) concentrate in a 2 ml vial. A vial contains 50 mg of cytarabine in each 2 ml of sterile water for injection. The literature should be consulted for the current recommendations for use in acute lymphocytic leukemia.

This chemical stability information in no way indicates that it would be acceptable practice to prepare an intravenous or intrathecal dose of cytarabine injection in these infusion solutions. However, if the infusion solutions listed in Table 1 are employed, it is recommended that the cytarabine be diluted in the infusion solution at the time of administration. It is also recommended that these solutions be used within the time periods listed in Table 1. The literature should be consulted for the current recommendations for use in acute lymphocytic leukemia.

Experimental Dose: Cytarabine, 85 mg/m^2 of body surface area (different from that used with conventional therapy regimens of cytarabine) has been reported following some experimental dose schedules of Cytarabine. These toxic effects were similar to those noted in patients receiving the drug by conventional routes, but may be prevented or diminished by prophylaxis with a local corticosteroid eye drop; the drug should be started on the first day of a 4-day regimen and continued for 1 week after completion of the 4-day course.

Severe: painful, paresthesias, spasticity of proximal muscles, tremor, myoclonus, and seizures, progressing to a vegetative state; aspiration pneumonia, pulmonary edema, and death. These toxic effects were similar to those noted in patients receiving the drug by conventional routes, but may be prevented or diminished by prophylaxis with a local corticosteroid eye drop; the drug should be started on the first day of a 4-day regimen and continued for 1 week after completion of the 4-day course.

Intravenous (IV) every 12 hours (Days 1-7).

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, and because of the potential for serious adverse reactions in nursing infants from cytarabine, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

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Cytarabine has been used intrathecally in acute leukemia in doses ranging from 5 mg/m^2 to 100 mg/m^2 administered during a 15-minute period. Toxic effects of this nature may occur days to weeks after the initial intrathecal injection. The incidence of these toxic effects may be reduced by the use of cytarabine with radiotherapy.