Cytarabine Syndrome

Sometimes the following side effects can happen together 6 to 12 hours after receiving Cytarabine. Feeling generally unwell with a high temperature, pain in bones, muscle and tendons of the chest, brain, liver, spleen or kidneys. This is called “Cytarabine Syndrome” and can be fatal. It is important you ask your doctor or nurse for help if you notice any side effects not listed in this leaflet, but feel your doctor or nursing staff immediately. 

5. How to store Cytarabine

Keep out of the reach and sight of children.

Hospital staff will store your medicine safely. The ampouled form should be stored in the original container between 15ºC and 25ºC until the time of use. Cytarabine should not be stored after the expiry date which is marked on the pack. Cytarabine should not be used after 30 days of the expiry date or 1 year from the last production date. 

Ampoules should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. Further Information

What Cytarabine contains

The active ingredient in Cytarabine is cytarabine. The other ingredients in Cytarabine 20mg/ml are hydrochloric acid, sodium hydroxide, methanol, water for injections and sodium metabisulphite. The other ingredients in Cytarabine 100mg/ml are hydrochloric acid, sodium hydroxide, sodium metabisulphite and water for injections.

What Cytarabine looks like and contents of the pack

Cytarabine is supplied as a sterile solution for injection in ampoules containing 20mg/ml or 100mg/ml of Cytarabine. Cytarabine containing 20mg/ml is supplied in plastic ampoules containing 10mg (1ml) or 20mg (2ml). Cytarabine containing 100mg/ml is supplied in plastic ampoules containing 100mg (1ml) or 200mg (2ml).

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A drug related syndrome without clear cause that may have been related to cytarabine was reported in a number of patients (unpublished data). The incidence and mechanism of occurrence are not well understood. It has been reported that this syndrome is characterised by high temperature, myalgia, back pain, abdominal pain, nausea, malaise, headache, anorexia and diarrhoea which may occur together. The syndrome has been reported by clinicians worldwide. The condition may cause malaise, fever, diarrhoea, myalgia and sometimes mental changes that result in mental confusion, loss of recollection and in some cases, loss of consciousness. Some cases have been fatal. 

In the absence of clinical examination, the medical professional must be asked about the products and formulation in section 4.4. 

5.3 Precautionary Data

Cytarabine is a mutagen, teratogenic and embryotoxic in rats and mice and also mutagenic in bacteria. It is teratogenic in animals but there are no adequate and well-controlled studies in pregnant women. If you are pregnant or planning to get pregnant, your doctor should discuss the benefits and risks of using this medicine. 

Cytarabine is a mutagen and embryotoxic and produces malignant transformation in mice and rats.

6. PHARMACOLOGICAL PARTICULARS

6.1. Route of administration

Cytarabine (Hydrochloride) Injection contains:

Cytarabine (Hydrochloride) Injection 20mg/ml
Cytarabine (Hydrochloride) Injection 100mg/ml

6.2. Incompatibilities

The following incompatibilities have been reported:

- Cytarabine (Hydrochloride) should not be mixed with aminohexadodecane, amidoxime, adrenaline or amphetamines including the methyl salts. 
- Cytarabine (Hydrochloride) should not be mixed with allopurinol, azathioprine, barbiturates, calcium gluconate, carbamazepine, chlorpropramidine, diazepam, folic acid, hydrocortisone, isoniazid, meloxicam, methotrexate, morphine, nafcillin, penicillin, prednisolone, salicylates, sterols, sphenamine, theophylline.