Cytarabine Kabi 100 mg/ml
Trusted Generics: Total Care

Cytarabine Kabi 100 mg/ml
Solution for injection or infusion

FRESENIUS KABI
caring for life
Cytarabine Kabi

Therapeutic class
Pyrimidine nucleoside analogue

Indications
- Remission in acute myeloid leukaemia in adults
- For other acute leukaemias of adults and children

Cytarabine Kabi is available as follows:

<table>
<thead>
<tr>
<th>Strength</th>
<th>Volume</th>
<th>Form</th>
</tr>
</thead>
<tbody>
<tr>
<td>100 mg</td>
<td>1 ml</td>
<td>Vial</td>
</tr>
<tr>
<td>500 mg</td>
<td>5 ml</td>
<td>Vial</td>
</tr>
<tr>
<td>1 g</td>
<td>10 ml</td>
<td>Vial</td>
</tr>
<tr>
<td>2 g</td>
<td>20 ml</td>
<td>Vial</td>
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</tbody>
</table>

Composition
1 ml of solution contains cytarabine 100 mg

Pharmaceutical form
Solution for injection is filled in colourless glass vial closed with bromobutyl rubber stopper, and sealed with green aluminium flip off overseal.

Excipients
Hydrochloric acid (for pH-adjustment), sodium hydroxide (for pH-adjustment), water for injection

Shelf life
18 months (before opening the vial)
Stability
Chemical and physical in-use stability has been demonstrated for 8 days below 25°C.

Cytarabine Kabi in focus
• A pyrimidine nucleoside analogue, is an antineoplastic agent which inhibits the synthesis of deoxyribonucleic acid specifically in the S phase of the cell cycle
• Proven induction of remission benefit in acute myeloid leukaemia in adults and for other acute leukaemias of adults and children*


Manufacturing and safety
Our state of the art cleaning process for finished vials guarantees the removal of all external contamination.

Fresenius Kabi sleeved vials (OncoShield®) offers maximum protection for people working with cytotoxic drugs.
Fertility studies to assess the reproductive toxicity of cytarabine have not been conducted. This product should not normally be administered to patients who are pregnant or to mothers who are breast-feeding.

Men and women have to use effective contraception during and up to 6 months after treatment. Cytarabine is known to be teratogenic in some animal species.

Men and women must be made aware of the potential benefits and hazards. Men and women have to use effective contraception during and up to 6 months after treatment. If contraception is contraindicated or if women are unable or unwilling to use contraception, then male patients and partners of female patients should be advised of the possible risks of sterility.

Undesirable effects:

1) Cardiovascular: Palpitations, tachycardia, hypotension, arrhythmias, angina, ECG changes. Severe cardiac toxicity, including severe cardiomyopathy and rhabdomyolysis and one case of cardiopulmonary arrest and required resuscitation has been reported. Anaphylactic that resulted in acute cardiopulmonary arrest and required resuscitation has been reported. This occurred immediately after the intravenous administration of Cytarabine. These reactions have occurred with cytarabine treatment. Anaphylaxis that resulted in severe respiratory insufficiency have been reported. Cases of cardiomyopathy with subsequent death has been reported following for instance an anthracycline has been used. Additional cycles may be administered at intervals of 2-4 weeks, until remission is achieved or unacceptable toxicity occurs.

2) Maintenance therapy: i) Remissions which have been induced by cytarabine, or by other drugs, may be maintained by intravenous or subcutaneous injection of 1 mg/kg once or twice weekly. Cytarabine may be administered in doses of 100-200 mg/m², as continuous infusion for 5 days at monthly intervals as monotherapy or in combination with other cytostatics. Specia...