DESCRIPTION

Elliotts B® Solution is a sterile, nonpyrogenic, isotonic solution containing no bacteriostatic preservatives. Elliotts B Solution is a diluent for intrathecal administration of methotrexate sodium and cytarabine.

Each 10 mL of Elliotts B Solution contains:

- Sodium Chloride, USP: 73 mg
- Sodium Bicarbonate, USP: 19 mg
- Dextrose, USP: 8 mg
- Magnesium Sulfate • 7H₂O, USP: 3 mg
- Potassium Chloride, USP: 3 mg
- Calcium Chloride • 2H₂O, USP: 2 mg
- Sodium Phosphate, dibasic • 7H₂O, USP: 2 mg
- Water for Injection, USP: qs 10 mL

Concentration of Electrolytes:

<table>
<thead>
<tr>
<th>Electrolyte</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sodium</td>
<td>149 mEq/liter</td>
</tr>
<tr>
<td>Potassium</td>
<td>4.0 mEq/liter</td>
</tr>
<tr>
<td>Calcium</td>
<td>2.7 mEq/liter</td>
</tr>
<tr>
<td>Magnesium</td>
<td>2.4 mEq/liter</td>
</tr>
<tr>
<td>Bicarbonate</td>
<td>22.6 mEq/liter</td>
</tr>
<tr>
<td>Chloride</td>
<td>132 mEq/liter</td>
</tr>
<tr>
<td>Sulfate</td>
<td>2.4 mEq/liter</td>
</tr>
<tr>
<td>Phosphate</td>
<td>1.5 mEq/liter</td>
</tr>
</tbody>
</table>

The formulae and molecular weights of the ingredients are:
The pH of Elliotts B Solution is 6.0-7.5, and the osmolarity is 288 mOsmol per liter (calculated).

**CLINICAL PHARMACOLOGY**

Elliotts B Solution provides a buffered salt solution for use as a diluent for the intrathecal administration of methotrexate sodium and cytarabine. It has been demonstrated that Elliotts B Solution is comparable to cerebrospinal fluid in pH, electrolyte composition, glucose content, and osmolarity:

Comparison of Electrolyte Composition, pH and Nonelectrolytic Constituents of Elliotts B Solution and CSF

<table>
<thead>
<tr>
<th>Solution</th>
<th>Na⁺ mEq/L</th>
<th>K⁺ mEq/L</th>
<th>Ca²⁺ mEq/L</th>
<th>Mg²⁺ mEq/L</th>
<th>HCO₃⁻ mEq/L</th>
<th>Cl⁻ mEq/L</th>
<th>pH</th>
<th>Phosphorus mg/dL</th>
<th>Glucose mg/dL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cerebrospinal Fluid</td>
<td>117-137</td>
<td>2.3-4.6</td>
<td>2.2</td>
<td>2.2</td>
<td>22.9</td>
<td>113-127</td>
<td>7.31</td>
<td>1.2-2.1</td>
<td>45-80</td>
</tr>
<tr>
<td>Elliotts B Solution</td>
<td>149</td>
<td>4.0</td>
<td>2.7</td>
<td>2.4</td>
<td>22.6</td>
<td>132</td>
<td>6.0-7.5</td>
<td>2.3</td>
<td>80</td>
</tr>
</tbody>
</table>

The approximate buffer capacity of Elliotts B Solution is $1.1 \times 10^{-2}$ equivalents when the challenge solution is 0.01 N HCl and $7.8 \times 10^{-3}$ equivalents when the challenge solution is 0.01 N NaOH.¹

Compatibility studies with methotrexate sodium and cytarabine indicate these drugs are physically compatible with Elliotts B Solution.

**INDICATIONS AND USAGE**

Elliotts B Solution is indicated as a diluent for the intrathecal administration of methotrexate sodium and cytarabine for the prevention or treatment of meningeal leukemia or lymphocytic lymphoma.

**CONTRAINDICATIONS**

None known.

**WARNINGS**

Intrathecal administration of drugs such as methotrexate sodium and cytarabine should be performed by personnel skilled in the technique of lumbar puncture under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents. The labeling for methotrexate sodium and cytarabine should be consulted.

**PRECAUTIONS**

**General**

Particular attention should be taken to assure the maintenance of sterile technique throughout the procedure. (See DOSAGE AND ADMINISTRATION.)

**Carcinogenesis, Mutagenesis, Impairment of Fertility**
No standard mutagenicity or carcinogenicity studies have been conducted with Elliotts B Solution.

**Usage in Pregnancy**

Pregnancy Category C

All components of Elliotts B Solution are normal body constituents. Animal reproduction studies have not been conducted with Elliotts B Solution.

**ADVERSE REACTIONS**

Adverse reactions may occur with any given intrathecal injection due to the chemotherapy or the technique of intrathecal administration. (See product labeling for methotrexate sodium and cytarabine.)

Preservative-free methotrexate sodium and cytarabine should be used to minimize adverse reactions due to preservatives.

If an adverse reaction does occur, discontinue the administration, evaluate the patient, institute appropriate therapeutic countermeasures and, if possible, save the remainder of the unused solution(s) for examination.

**DRUG ABUSE AND DEPENDENCE**

There is no potential for drug abuse or drug dependence.

**OVERDOSAGE**

Elliotts B Solution is a diluent. In the event of a drug, fluid or solute overload following administration, evaluate the patient's condition, and institute appropriate corrective treatment. (See product labeling for methotrexate sodium and cytarabine.)

**DOSAGE AND ADMINISTRATION**

See product labeling for methotrexate sodium and cytarabine.

Elliotts B Solution is intended for intrathecal administration only. Elliotts B Solution does not contain antibacterial preservatives and introduction of contaminated solutions into the cerebrospinal fluid may have extremely serious consequences. Therefore, administration of intrathecal solutions should be accomplished as soon as possible after preparation.

A sterile filter-needle should be used to withdraw the contents of the ampule.

Intrathecal drug products should be inspected visually for particulate matter and discoloration prior to administration.

**Preparation and Administration Precautions**

Elliotts B Solution is a diluent for the cytotoxic anticancer agents, methotrexate sodium and cytarabine.
Care should be exercised in the handling and preparation of infusion solutions with these products. (See product labeling for methotrexate sodium and cytarabine.)

**HOW SUPPLIED**

<table>
<thead>
<tr>
<th>NDC</th>
<th>SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td>67871-007-10</td>
<td>10 mL ampule</td>
</tr>
</tbody>
</table>

Elliotts B Solution is available in single-use clear glass ampules, packaged 10 ampules per box.

Store at controlled room temperature, 20º-25ºC (68º-77ºF) [See USP].

**Preservative Free.** Discard unused portion. Use only if solution is clear and ampule is intact.

**Distributed by:**
QOL Medical, LLC
Vero Beach, FL 32963
1-866-528-4750
www.elliottsbsolution.com

**REFERENCES:**


Rev. 12/11
Part No. 210

**PACKAGING**

Ampule labeling:
**Box labeling:**

**Sterile Elliotts B® Solution**
(buffed intrathecal electrolyte/dextrose injection)

**10 mL**

**Single Use Ampule**

Each mL contains:
- sodium chloride: 7.3 mg
- sodium bicarbonate: 1.9 mg
- dextrose, hydrous: 0.8 mg
- magnesium sulfate: 0.3 mg
- potassium chloride: 0.3 mg
- calcium chloride: 0.2 mg
- sodium phosphate: 0.2 mg
- water for injection: 1.0 mL

Rx only
sodium cation, sodium bicarbonate, anhydrous dextrose, magnesium sulfate, potassium chloride, calcium chloride,
### Product Information

**Product Type**  
HUMAN PRESCRIPTION DRUG

**Route of Administration**  
INTRATHECAL

**Item Code (Source)**  
NDC:67871-007

### Active Ingredient/Active Moiety

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Basis of Strength</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>sodium chloride (UNII: 451W471Q8X) (sodium cation - UNII:LYR4M0NH37, chloride ion - UNII:Q32ZN48698)</td>
<td>sodium chloride</td>
<td>73 mg in 10 mL</td>
</tr>
<tr>
<td>sodium bicarbonate (UNII: 8MDF5V39QO) (bicarbonate ion - UNII:HN1ZRA3Q20)</td>
<td>sodium bicarbonate</td>
<td>19 mg in 10 mL</td>
</tr>
<tr>
<td>anhydrous dextrose (UNII: 5SL0G7R0OK) (anhydrous dextrose - UNII:5SL0G7R0OK)</td>
<td>anhydrous dextrose</td>
<td>8 mg in 10 mL</td>
</tr>
<tr>
<td>magnesium sulfate (UNII: DE08037SAB) (magnesium cation - UNII:T6V3LHY838)</td>
<td>magnesium sulfate</td>
<td>3 mg in 10 mL</td>
</tr>
<tr>
<td>potassium chloride (UNII: 660YQ98I10) (potassium cation - UNII:295053KI52)</td>
<td>potassium chloride</td>
<td>3 mg in 10 mL</td>
</tr>
<tr>
<td>calcium chloride (UNII: M4I0D6VV5M) (calcium cation - UNII:2M83C4R6ZB)</td>
<td>calcium chloride</td>
<td>2 mg in 10 mL</td>
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<tr>
<td>sodium phosphate (UNII: SE337SVY37) (phosphate ion - UNII:NK08V8K8HR)</td>
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<td>2 mg in 10 mL</td>
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</table>

### Inactive Ingredients

<table>
<thead>
<tr>
<th>Ingredient Name</th>
<th>Strength</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water (UNII: 059QF0KO0R)</td>
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### Packaging

<table>
<thead>
<tr>
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<th>Item Code</th>
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<th>Marketing End Date</th>
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<tr>
<td>1</td>
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<td></td>
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<tr>
<td>1</td>
<td>NDC:67871-007-01</td>
<td>10 mL in 1 AMPULE</td>
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### Marketing Information

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<thead>
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<th>Marketing End Date</th>
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<tbody>
<tr>
<td>NDA</td>
<td>NDA020577</td>
<td>09/27/2006</td>
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**Labeler** - QOL Medical, LLC (140026258)

Revised: 8/2012

QOL Medical, LLC