



209900

Elliotts B[®] Solution

(buffered intrathecal electrolyte/dextrose injection)

Rx only

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 • 7H ₂ O, USP | 3 mg |
| Potassium Chloride, USP | 3 mg |
| Calcium Chloride • 2H ₂ O, USP | 2 mg |
| Sodium Phosphate, dibasic • 7H ₂ O, USP | 2 mg |
| Water for Injection, USP | qs 10 mL |

Concentration of Electrolytes:

| | | | |
|-----------|---------------|-------------|----------------|
| Sodium | 149 mEq/liter | Bicarbonate | 22.6 mEq/liter |
| Potassium | 4.0 mEq/liter | Chloride | 132 mEq/liter |
| Calcium | 2.7 mEq/liter | Sulfate | 2.4 mEq/liter |
| Magnesium | 2.4 mEq/liter | Phosphate | 1.5 mEq/liter |



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The formulae and molecular weights of the ingredients are:

| INGREDIENT | MOLECULAR FORMULA | MOLECULAR WEIGHT |
|---|--|------------------|
| Sodium Chloride | NaCl | 58.44 |
| Sodium Bicarbonate | NaHCO ₃ | 84.01 |
| Dextrose | C ₆ H ₁₂ O ₆ | 180.16 |
| Magnesium Sulfate • 7H ₂ O | Mg ₂ SO ₄ • 7H ₂ O | 246.48 |
| Potassium Chloride | KCl | 74.55 |
| Calcium Chloride • 2H ₂ O | CaCl ₂ • 2H ₂ O | 147.01 |
| Sodium Phosphate, dibasic • 7H ₂ O | Na ₂ HPO ₄ • 7H ₂ O | 268.07 |

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

| Solution | Na ⁺ mEq/L | K ⁺ mEq/L | Ca ⁺⁺ mEq/L | Mg ⁺⁺ mEq/L | HCO ₃ ⁻ mEq/L | Cl ⁻ mEq/L | pH | Phosphorus mg/dL | Glucose mg/dL |
|---------------------|--------------------------|-------------------------|---------------------------|---------------------------|--|--------------------------|---------|---------------------|------------------|
| Cerebrospinal Fluid | 117-137 | 2.3-4.6 | 2.2 | 2.2 | 22.9 | 113-127 | 7.31 | 1.2-2.1 | 45-80 |
| Elliotts B Solution | 149 | 4.0 | 2.7 | 2.4 | 22.6 | 132 | 6.0-7.5 | 2.3 | 80 |

The approximate buffer capacity of Elliotts B Solution is 1.1 X 10⁻² equivalents when the challenge solution is 0.01 N HCl and 7.8 X 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.

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

| NDC | SIZE |
|--------------|--------------|
| 67871-007-10 | 10 mL ampule |

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

Store at controlled room temperature, 20°-25°C (68°-77°F) [See USP].

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

Manufactured by: DRAXIS Pharma General Partnership
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REFERENCES:

1. Cradock JC, et al. Evaluation of some pharmaceutical aspects of intrathecal methotrexate sodium, cytarabine and hydrocortisone sodium succinate. American Journal of Hospital Pharmacy (1978); 35:402.