

ELLIOTTS B - sodium cation, sodium bicarbonate, anhydrous dextrose, magnesium sulfate, potassium chloride, calcium chloride, sodium phosphate injection
QOL Medical, LLC

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

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 1.1×10^{-2} equivalents when the challenge solution is 0.01 N HCl and 7.8×10^{-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

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.

Distributed by:

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

REFERENCES:

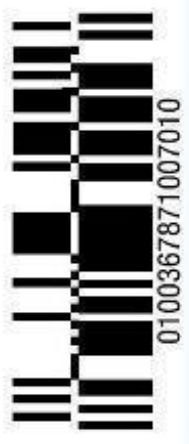
1. Cradock JC, et al. Evaluation of some pharmaceutical aspects of intrathecal methotrexate sodium, cytarabine and hydrocortisone sodium succinate. *American Journal of Hospital Pharmacy* (1978); 35:402.

Rev. 12/11
Part No. 210

PACKAGING

Ampule labeling:

Distributed by:
GOL Medical, LLC
Vero Beach, FL 32963
Part No. 220 / Rev. 12/11



NDC 67871-007-01

Sterile
**Elliotts B[®]
Solution**
(buffered 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

**FOR INTRATHECAL
USE ONLY**

**Dosage and
administration:**
See prescribing
information for
administration
instructions.
Store at Controlled
Room Temperature,
20°–25°C (68°–77°F).

228001

Box labeling:

Elliotts B[®] Solution
*(buffered intrathecal
electrolyte/dextrose injection)*

Part No. 230
Rev. 12/11

TEN 10 mL SINGLE USE AMPULES



NDC 67871-007-10

TEN 10 mL
SINGLE USE AMPULES

Sterile

**Elliotts B[®]
Solution**

*(buffered intrathecal
electrolyte/dextrose
injection)*

Each milliliter 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

FOR INTRATHECAL USE ONLY

Dosage and administration:

See prescribing information for administration instructions.
Store at Controlled Room Temperature, 20°–25°C (68°–77°F).

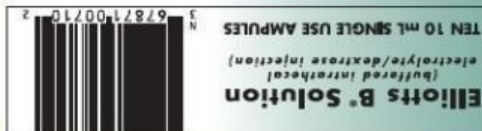
Distributed by:

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1.866.528.4750
www.elliottsbolution.com
Product of Canada

Rx only

Elliotts B[®] Solution
*(buffered intrathecal
electrolyte/dextrose injection)*

TEN 10 mL SINGLE USE AMPULES



NDC 67871-007-10

TEN 10 mL
SINGLE USE AMPULES

Sterile

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electrolyte/dextrose
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Product of Canada

Rx only

TEN 10 mL SINGLE USE AMPULES

Elliotts B[®] Solution
*(buffered intrathecal
electrolyte/dextrose injection)*

Lot
Exp



ELLIOTTS B

sodium cation, sodium bicarbonate, anhydrous dextrose, magnesium sulfate, potassium chloride, calcium chloride,

sodium phosphate injection

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:67871-007
Route of Administration	INTRATHECAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
sodium chloride (UNII: 451W47IQ8X) (sodium cation - UNII:LYR4M0NH37, chloride ion - UNII:Q32ZN48698)	sodium chloride	73 mg in 10 mL
sodium bicarbonate (UNII: 8MDF5V39QO) (bicarbonate ion - UNII:HN1ZRA3Q20)	sodium bicarbonate	19 mg in 10 mL
anhydrous dextrose (UNII: 5SL0G7R0OK) (anhydrous dextrose - UNII:5SL0G7R0OK)	anhydrous dextrose	8 mg in 10 mL
magnesium sulfate (UNII: DE08037SAB) (magnesium cation - UNII:T6V3LHY838)	magnesium sulfate	3 mg in 10 mL
potassium chloride (UNII: 660YQ98I10) (potassium cation - UNII:295O53K152)	potassium chloride	3 mg in 10 mL
calcium chloride (UNII: M4I0D6VV5M) (calcium cation - UNII:2M83C4R6ZB)	calcium chloride	2 mg in 10 mL
sodium phosphate (UNII: SE337SVY37) (phosphate ion - UNII:NK08V8K8HR)	sodium phosphate	2 mg in 10 mL

Inactive Ingredients

Ingredient Name	Strength
Water (UNII: 059QF0KO0R)	10 mL in 10 mL

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:67871-007-10	10 in 1 BOX		
1	NDC:67871-007-01	10 mL in 1 AMPULE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020577	09/27/2006	

Labeler - QOL Medical, LLC (140026258)