

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

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**ELLIOTTS B<sup>®</sup> SOLUTION (buffered intrathecal electrolyte/dextrose injection)**  
**Rx Only**

**DESCRIPTION**

Elliotts B<sup>®</sup> 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 <sub>2</sub> O, USP	3 mg
Potassium Chloride, USP	3 mg
Calcium Chloride • 2H <sub>2</sub> O, USP	2 mg
Sodium Phosphate, dibasic • 7H <sub>2</sub> 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 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:

<b>INGREDIENT</b>	<b>MOLECULAR FORMULA</b>	<b>MOLECULAR WEIGHT</b>
Sodium Chloride	NaCl	58.44
Sodium Bicarbonate	NaHCO <sub>3</sub>	84.01
Dextrose	C <sub>6</sub> H <sub>12</sub> O <sub>6</sub>	180.16
Magnesium Sulfate • 7H <sub>2</sub> O	Mg <sub>2</sub> SO <sub>4</sub> • 7H <sub>2</sub> O	246.48
Potassium Chloride	KCl	74.55
Calcium Chloride • 2H <sub>2</sub> O	CaCl <sub>2</sub> • 2H <sub>2</sub> O	147.01
Sodium Phosphate, dibasic • 7H <sub>2</sub> O	Na <sub>2</sub> HPO <sub>4</sub> • 7H <sub>2</sub> 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 <sup>+</sup> mEq/L	K <sup>+</sup> mEq/L	Ca <sup>++</sup> mEq/L	Mg <sup>++</sup> mEq/L	HCO <sub>3</sub> <sup>-</sup> mEq/L	Cl <sup>-</sup> 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	2.7	2.4	22.6	132	6.0-7.5	2.3	80

The approximate buffer capacity of Elliotts B Solution is  $1.1 \times 10^{-2}$  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.<sup>1</sup>

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**

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

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<b>NDC</b>	<b>SIZE</b>
55792-007-10	10 mL ampule

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

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

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

### **Distributed by:**

Lukare Medical, LLC  
Ponte Vedra Beach, FL 32082  
1-855-752-9317  
[www.elliottsbsolution.com](http://www.elliottsbsolution.com)

## REFERENCES:

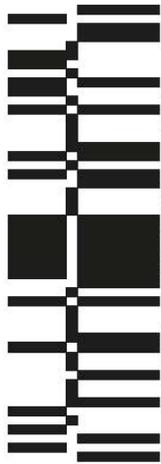
1. Cradock JC, et al. Evaluation of some pharmaceutical aspects of intrathecal methotrexate sodium, cytarabine and hydrocortisone sodium succinate. American Journal of Hospital Pharmacy (1978); 35:402.

Rev. 05/2024

## PACKAGING

### **Ampule labeling:**

**Distributed by:**  
Lukare Medical, LLC  
Ponte Vedra Beach,  
FL 32082



0100355792007011

NDC 55792-007-01

Sterile  
**Elliotts B<sup>®</sup>**  
**Solution**

(buffered intrathecal  
electrolyte/dextrose  
injection)

**10 mL**

Single-Dose Ampule.  
Discard Unused Portion

**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 mL

Rx only

**FOR INTRATHECAL USE ONLY**

**Recommended Dosage:**  
see Prescribing Information.

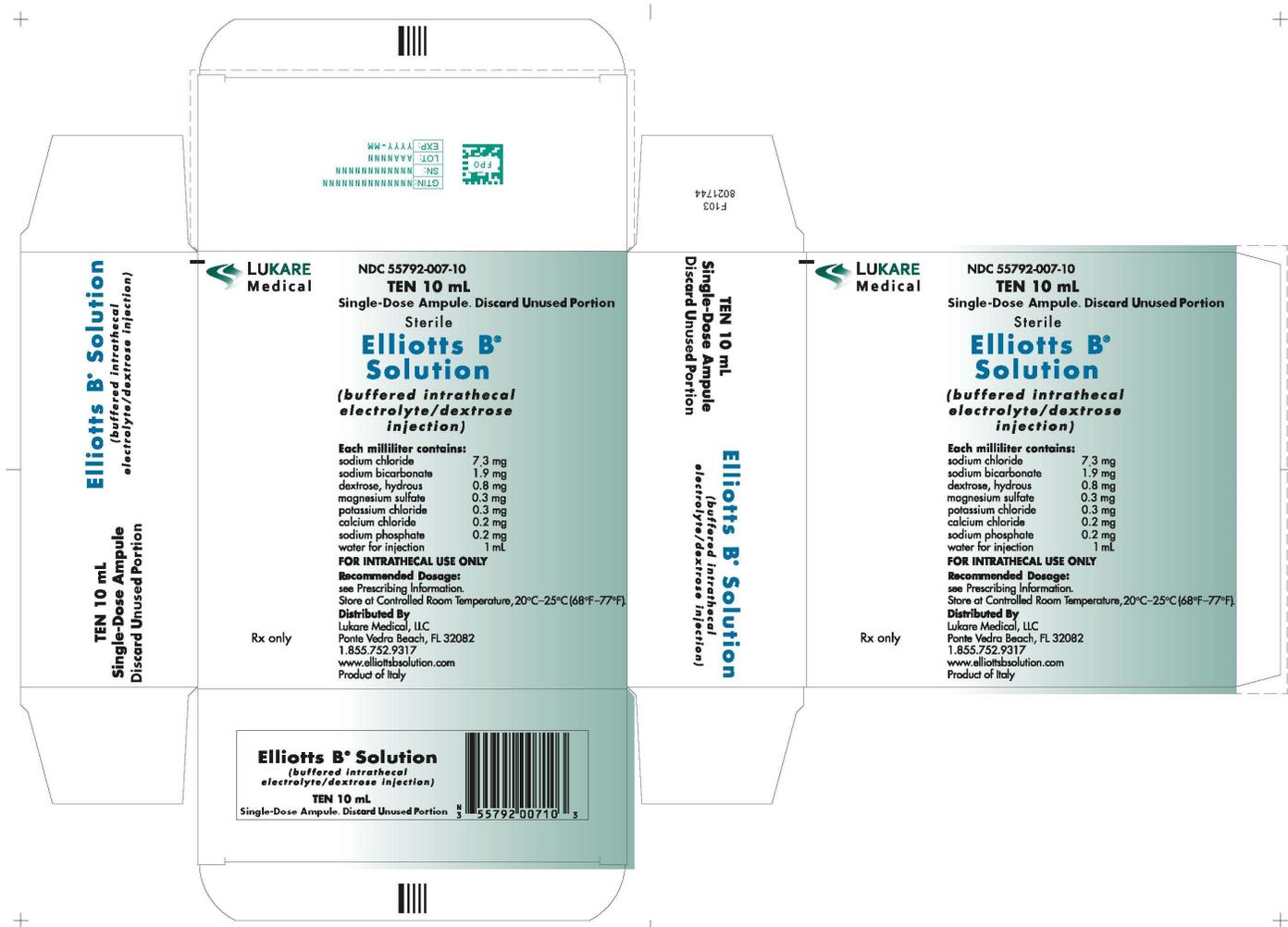
Store at Controlled Room  
Temperature, 20°C–25°C  
(68°F–77°F).

8021743

Lot:

EXP: YYYY - MM - DD

**Box labeling:**



## ELLIOTTS B

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

### Product Information

<b>Product Type</b>	HUMAN PRESCRIPTION DRUG	<b>Item Code (Source)</b>	NDC:55792-007
<b>Route of Administration</b>	INTRATHECAL		

### Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
<b>sodium chloride</b> (UNII: 451W47IQ8X) (sodium cation - UNII:LYR4M0NH37, chloride ion - UNII:Q32ZN48698)	sodium chloride	73 mg in 10 mL
<b>sodium bicarbonate</b> (UNII: 8MDF5V39QO) (bicarbonate ion - UNII:HN1ZRA3Q20)	sodium bicarbonate	19 mg in 10 mL
<b>anhydrous dextrose</b> (UNII: 5SLOG7R0OK) (anhydrous dextrose - UNII:5SLOG7R0OK)	anhydrous dextrose	8 mg in 10 mL
<b>MAGNESIUM SULFATE, UNSPECIFIED FORM</b> (UNII: DE08037SAB) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE, UNSPECIFIED FORM	3 mg in 10 mL
<b>potassium chloride</b> (UNII: 660YQ98110) (potassium cation - UNII:295O53K152)	potassium chloride	3 mg in 10 mL

<b>calcium chloride</b> (UNII: M4I0D6VW5M) (calcium cation - UNII:2M83C4R6ZB)	calcium chloride	2 mg in 10 mL
<b>sodium phosphate</b> (UNII: SE337SVY37) (phosphate ion - UNII:NK08V8K8HR)	sodium phosphate	2 mg in 10 mL

### Inactive Ingredients

Ingredient Name	Strength
<b>Water</b> (UNII: 059QF0K00R)	10 mL in 10 mL

### Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:55792-007-10	10 in 1 BOX	06/04/2013	
1	NDC:55792-007-01	10 mL in 1 AMPULE; Type 0: Not a Combination Product		

### Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA020577	06/04/2013	

**Labeler** - Lukare Medical, LLC (062862393)

**Registrant** - Lukare Medical, LLC (062862393)

### Establishment

Name	Address	ID/FEI	Business Operations
Neopharm Labs Inc.		243379372	ANALYSIS(55792-007)

### Establishment

Name	Address	ID/FEI	Business Operations
Nelson Laboratories, LLC		151663234	ANALYSIS(55792-007)

### Establishment

Name	Address	ID/FEI	Business Operations
LabAnalysis s.r.l.		338466205	ANALYSIS(55792-007)

### Establishment

Name	Address	ID/FEI	Business Operations
SGS Canada Inc		203668041	ANALYSIS(55792-007)