DEXTROSE AND SODIUM CHLORIDE- dextrose and sodium chloride injection, solution

B. Braun Medical Inc.

Dextrose and Sodium Chloride Injections USP

DESCRIPTION

(See chart below for quantitative information.)

Dextrose and Sodium Chloride Injections USP are sterile, nonpyrogenic and contain no bacteriostatic or antimicrobial agents. These products are intended for intravenous administration.

The formulas of the active ingredients are:

Ingredients	Molecular Formula	1olecular Weight
Sodium Chloride USP	NaCl	58.44
Hydrous Dextrose USF		198.17

Composition - Each 100 mL contains:		Concentration of Electrolytes					
Solution	Hydrous Dextrose USP	Sodium Chloride USP		/liter) Chloride	Calories per liter	Calculated Osmolarity mOsmol/liter	рН
3.3% Dextrose and 0.30% Sodium Chloride Injection USP	3.3 g	0.3 g	51	51	110	270	4.5 (3.5- 6.5)
5% Dextrose and 0.9% Sodium Chloride Injection USP	5 g	0.9 g	154	154	170	560	4.4 (3.5- 6.5)
5% Dextrose and 0.45% Sodium Chloride Injection USP	5 g	0.45 g	77	77	170	405	4.4 (3.5- 6.5)
5% Dextrose and							

0.33% Sodium Chloride Injection USP	5	g	0.33 g	56	56	170	365	4.4 (3.5- 6.5)
5% Dextrose and								
0.20% Sodium Chloride Injection								4.4 (3.5-
USP	5	g	0.2 g	34	34	170	320	6.5)
10% Dextrose and								
0.45% Sodium Chloride Injection								4.3 (3.5–
USP	10	g	0.45 g	77	77	340	660	6.5)
10% Dextrose and		-						
0.20% Sodium								4.3
Chloride Injection								(3.5–
USP Water for Inication	10	g	0.2 g	34	34	340	575	6.5)

Water for Injection USP qs

Not made with natural rubber latex, PVC or DEHP.

The plastic container is made from a multilayered film specifically developed for parenteral drugs. It contains no plasticizers and exhibits virtually no leachables. The solution contact layer is a rubberized copolymer of ethylene and propylene. The container is nontoxic and biologically inert. The container-solution unit is a closed system and is not dependent upon entry of external air during administration. The container is overwrapped to provide protection from the physical environment and to provide an additional moisture barrier when necessary.

Addition of medication should be accomplished using complete aseptic technique.

The closure system has two ports; the one for the administration set has a tamper evident plastic protector and the other is a medication addition site. Refer to the Directions for Use of the container.

CLINICAL PHARMACOLOGY

Dextrose and Sodium Chloride Injections USP provide electrolytes and calories and are a source of water for hydration. All are capable of inducing diuresis depending on the clinical condition of the patient.

Sodium, the major cation of the extracellular fluid, functions primarily in the control of water distribution, fluid balance, and osmotic pressure of body fluids. Sodium is also associated with chloride and bicarbonate in the regulation of the acid-base equilibrium of body fluid.

Chloride, the major extracellular anion, closely follows the metabolism of sodium, and changes in the acid-base balance of the body are reflected by changes in the chloride concentration.

Dextrose provides a source of calories. Dextrose is readily metabolized, may decrease losses of body protein and nitrogen, promotes glycogen deposition and decreases or prevents ketosis if sufficient doses are provided.

INDICATIONS AND USAGE

These intravenous solutions are indicated for use in adults and pediatric patients as sources of electrolytes, calories and water for hydration.

CONTRAINDICATIONS

These solutions are contraindicated where the administration of sodium or chloride could be clinically detrimental.

Solutions containing dextrose may be contraindicated in patients with hypersensitivity to corn products.

WARNINGS

The administration of intravenous solutions can cause fluid and/or solute overload resulting in dilution of serum electrolyte concentrations, overhydration, congested states or pulmonary edema. The risk of dilutional states is inversely proportional to the electrolyte concentration. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentration. Solutions containing sodium ions should be used with great care, if at all, in patients with congestive heart failure, severe renal insufficiency, and in clinical states in which there is sodium retention with edema. In patients with diminished renal function, administration of solutions containing sodium ions may result in sodium retention. Infusion of isotonic (0.9%) sodium chloride during or immediately after surgery may result in excessive sodium retention. Use the patient's circulatory system status as a guide.

Excessive administration of potassium-free dextrose solutions may result in significant hypokalemia. Serum potassium levels should be maintained and potassium supplemented as required.

Solutions containing dextrose and low electrolyte concentrations should not be administered simultaneously with blood through the same infusion set because of the possibility of pseudoagglutination or hemolysis.

PRECAUTIONS

General

These solutions should be used with care in patients with hypervolemia, renal insufficiency, urinary tract obstruction, or impending or frank cardiac decompensation. Extraordinary electrolyte losses such as may occur during protracted nasogastric suction, vomiting, diarrhea or gastrointestinal fistula drainage may necessitate additional electrolyte supplementation.

Additional essential electrolytes, minerals and vitamins should be supplied as needed. Sodium-containing solutions should be administered with caution to patients receiving corticosteroids or corticotropin, or to other salt-retaining patients. Care should be exercised in administering solutions containing sodium to patients with renal or cardiovascular insufficiency, with or without congestive heart failure, particularly if they are postoperative or elderly.

Infusion of more than one liter of isotonic (0.9%) sodium chloride per day may supply more sodium and chloride than normally found in serum, and can exceed normal tolerance, resulting in hypernatremia; this may also cause a loss of bicarbonate ions, resulting in an acidifying effect.

Solutions containing dextrose should be used with caution in patients with overt or known subclinical diabetes mellitus, or carbohydrate intolerance for any reason. Hypokalemia may develop during parenteral administration of hypertonic dextrose solutions. Sufficient amounts of potassium should be added to dextrose solutions administered to fasting patients with good renal function, especially those on digitalis therapy.

To minimize the risk of possible incompatibilities arising from mixing any of these solutions with other additives that may be prescribed, the final infusate should be inspected for cloudiness or precipitation immediately after mixing, prior to administration and periodically during administration.

Do not use plastic containers in series connection.

If administration is controlled by a pumping device, care must be taken to discontinue pumping action before the container runs dry or air embolism may result. If administration is not controlled by a pumping device, refrain from applying excessive pressure (>300mmHg) causing distortion to the container such as wringing or twisting. Such handling could result in breakage of the container.

These solutions are intended for intravenous administration using sterile equipment. It is recommended that intravenous administration apparatus be replaced at least once every 24 hours.

Use only if solution is clear and container and seals are intact.

Laboratory Tests

Clinical evaluation and periodic laboratory determinations are necessary to monitor changes in fluid balance, electrolyte concentrations, and acid-base balance during prolonged parenteral therapy or whenever the condition of the patient warrants such evaluation. Significant deviations from normal concentrations may require tailoring of the electrolyte pattern, in these or alternative solutions.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies with Dextrose and Sodium Chloride Injections USP have not been performed to evaluate carcinogenic potential, mutagenic potential, or effects on fertility.

Pregnancy

Teratogenic Effects

Animal reproduction studies have not been conducted with Dextrose and Sodium Chloride Injections USP. It is also not known whether Dextrose and Sodium Chloride Injections USP can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. Dextrose and Sodium Chloride Injections USP should be given to a pregnant woman only if clearly needed.

Labor and Delivery

The effects of Dextrose and Sodium Chloride Injections USP on the duration of labor or delivery, on the possibility that forceps delivery or other intervention or resuscitation of the newborn will be necessary, and on the later growth, development, and functional maturation of the child are unknown.

As reported in the literature, sodium and dextrose containing solutions have been administered during labor and delivery. Caution should be exercised, and the fluid balance, glucose and electrolyte concentrations, and acid-base balance, of both mother and fetus should be evaluated periodically or whenever warranted by the condition of the patient or fetus.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when Dextrose and Sodium Chloride Injections USP are administered to a nursing woman.

Pediatric Use

Safety and effectiveness of Dextrose and Sodium Chloride Injections USP in pediatric patients have not been established by adequate and well-controlled studies.

Dextrose is safe and effective for the stated indications in pediatric patients (see **INDICATIONS AND USAGE**). As reported in the literature, the dosage selection and constant infusion rate of intravenous dextrose must be selected with caution in pediatric patients, particularly neonates and low birth weight infants, because of the increased risk of hyperglycemia/hypoglycemia. Frequent monitoring of serum glucose concentrations is required when dextrose is prescribed to pediatric patients, particularly neonates and low birth weight infants.

In neonates or in very small infants even small volumes of fluid may affect fluid and electrolyte balance. Care must be exercised in treatment of neonates, especially preterm neonates, whose renal function may be immature and whose ability to excrete fluid and solute loads may be limited. Fluid intake, urine output, and serum electrolytes should be monitored closely. See **WARNINGS** and **DOSAGE AND ADMINISTRATION**.

Geriatric Use

Clinical studies of Dextrose and Sodium Chloride Injections USP did not include sufficient numbers of subjects aged 65 and over to determine whether they respond differently from younger subjects. Other reported clinical experience has not identified differences in responses between elderly and younger patients.

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy.

These drugs are known to be substantially excreted by the kidney, and the risk of toxic reactions to these drugs may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be

taken in dose selection, and it may be useful to monitor renal function.

See WARNINGS.

ADVERSE REACTIONS

Reactions which may occur because of the solution or the technique of administration include febrile response, infection at the site of injection, venous thrombosis or phlebitis extending from the site of injection, extravasation and hypervolemia.

Too rapid infusion of hypertonic solutions may cause local pain and venous irritation. Rate of administration should be adjusted according to tolerance. Use of the largest peripheral vein and a small bore needle is recommended. (See **DOSAGE AND ADMINISTRATION**.)

Symptoms may result from an excess or deficit of one or more of the ions present in the solution; therefore, frequent monitoring of electrolyte levels is essential.

Hypernatremia may be associated with edema and exacerbation of congestive heart failure due to the retention of water, resulting in an expanded extracellular fluid volume. If infused in large amounts, chloride ions may cause a loss of bicarbonate ions, resulting in an acidifying effect.

The physician should also be alert to the possibility of adverse reactions to drug additives diluted and administered from the plastic container. Prescribing information for drug additives to be administered in this manner should be consulted.

If an adverse reaction does occur, discontinue the infusion, evaluate the patient, institute appropriate therapeutic countermeasures, and save the remainder of the fluid for examination if deemed necessary.

OVERDOSAGE

In the event of a fluid or solute overload during parenteral therapy, reevaluate the patient's condition and institute appropriate corrective treatment.

DOSAGE AND ADMINISTRATION

These solutions are for intravenous use only.

Dosage is to be directed by a physician and is dependent upon age, weight, clinical condition of the patient and laboratory determinations. Frequent laboratory determinations and clinical evaluation are essential to monitor changes in blood glucose and electrolyte concentrations, and fluid and electrolyte balance during prolonged parenteral therapy.

When a hypertonic solution is to be administered peripherally, it should be slowly infused through a small bore needle, placed well within the lumen of a large vein to minimize venous irritation. Carefully avoid infiltration.

In the average adult, daily requirements of sodium and chloride are met by the infusion of one liter of fluid containing 0.9% sodium chloride (154 mEq each of sodium and chloride).

Fluid administration should be based on calculated maintenance or replacement fluid requirements for each patient.

Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

Pediatric Use

There is no specific pediatric dose. The dose is dependent on weight, clinical condition, and laboratory results. See **WARNINGS** and **PRECAUTIONS**.

HOW SUPPLIED

Dextrose and Sodium Chloride Injections USP are supplied sterile and nonpyrogenic in EXCEL[®] Containers. The 1000 mL containers are packaged 12 per case; the 500 mL and 250 mL containers are packaged 24 per case.

Canada DIN	NDC	REF	Size
3.3% Dextrose	and 0.30% Sodiu	m Chloride In	jection USP
01927981	0264-7608-00	L6080-00	1000 mL
	0264-7608-10	L6081-00	500 mL
5% Dextrose ar	nd 0.9% Sodium (Chloride Inject	tion USP
01924435	0264-7610-00	L6100	1000 mL
	0264-7610-10	L6101	500 mL
5% Dextrose ar	nd 0.45% Sodium	Chloride Inje	ction USP
01927531	0264-7612-00	L6120	1000 mL
	0264-7612-10	L6121	500 mL
	0264-7612-20	L6122	250 mL
5% Dextrose ar	nd 0.33% Sodium	Chloride Inje	ction USP
	0264-7614-00	L6140	1000 mL
	0264-7614-10	L6141	500 mL
5% Dextrose ar	nd 0.20% Sodium	Chloride Inje	ction USP
01927558	0264-7616-00	L6160	1000 mL
	0264-7616-10	L6161	500 mL
	0264-7616-20	L6162	250 mL
10% Dextrose a	and 0.45% Sodiur	m Chloride Inj	ection USP
	0264-7622-00	L6220	1000 mL
10% Dextrose a	and 0.20% Sodiur	m Chloride Inj	ection USP
	0264-7623-20	L6232	250 mL

Exposure of pharmaceutical products to heat should be minimized. Avoid excessive heat. Protect from freezing. It is recommended that the product be stored at room temperature (25°C); however, brief exposure up to 40°C does not adversely affect the product.

Rx only

Revised: November 2018 EXCEL is a registered trademark of B. Braun Medical Inc.

Directions for Use of EXCEL[®] Container

Caution: Do not use plastic containers in series connection.

To Open

Tear overwrap down at notch and remove solution container. Check for minute leaks by squeezing solution container firmly. If leaks are found, discard solution as sterility may be impaired. If supplemental medication is desired, follow directions below before preparing for administration.

NOTE: Before use, perform the following checks:

Inspect each container. Read the label. Ensure solution is the one ordered and is within the expiration date.

Invert container and carefully inspect the solution in good light for cloudiness, haze, or particulate matter. Any container which is suspect should not be used.

Use only if solution is clear and container and seals are intact.

Preparation for Administration

- 1. Remove plastic protector from sterile set port at bottom of container.
- 2. Attach administration set. Refer to complete directions accompanying set.

To Add Medication

Warning: Some additives may be incompatible.

To Add Medication Before Solution Administration

1. Prepare medication site.

2. Using syringe with 18 – 22 Ga. needle, puncture medication port and inner diaphragm and inject.

3. Squeeze and tap ports while ports are upright and mix solution and medication thoroughly.

To Add Medication During Solution Administration

- 1. Close clamp on the set.
- 2. Prepare medication site.

3. Using syringe with 18 – 22 Ga. needle of appropriate length (at least 5/8 inch), puncture

resealable medication port and inner diaphragm and inject.

4. Remove container from IV pole and/or turn to an upright position.

5. Evacuate both ports by tapping and squeezing them while container is in the upright position.

6. Mix solution and medication thoroughly.

7. Return container to in use position and continue administration.

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In Canada, distributed by: **B. Braun of Canada, Ltd.** Scarborough, Ontario M1H 2W4

Y36-002-948

LD-197-4

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

3.3% Dextrose and 0.30% Sodium Chloride Injection USP

REF L6080-00 NDC 0264-7608-00 DIN 01927981

1000 mL EXCEL® CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 3.3 g; Sodium Chloride USP 0.3 g; Water for Injection USP qs

pH: 4.5 (3.5-6.5); Calc. Osmolarity: 270 mOsmol/liter

Electrolytes (mEq/liter): Na⁺ 51; Cl⁻ 51

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

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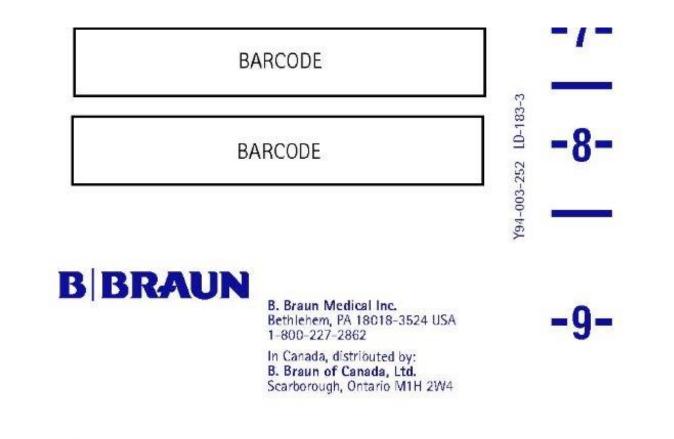
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Y94-003-252 LD-183-3

3.3% Dextrose and 0.30% Sodium Chloride Injection USP

REF L6080-00 NDC 0264-7608-00 DIN 01927981	1000 mL EXCEL® CONTAINER
Each 100 mL contains: Hydro Sodium Chloride USP 0.3 g; V pH: 4.5 (3.5–6.5); Calc. Osm Electrolytes (mEq/liter): Na	Water for Injection USP qs iolarity: 270 mOsmol/lite
Sterile, nonpyrogenic. Single do series connection. For intraveno solution is clear and container	ous use only. Use only if
WARNINGS: Do Not Administe Blood. Some additives may be i pharmacist. When introducing techniques. Mix thoroughly. Do	incompatible. Consult with additives, use aseptic
Recommended Storage: Room excessive heat. Protect from fre	temperature (25°C). Avoid
Do not remove overwrap until ready overwrap, check for minute leaks by leaks are found, discard solution as	squeezing container firmly. If
Not made with natural rubber latex,	terrespond and the second s
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EXP LOT

PRINCIPAL DISPLAY PANEL - 500 mL Container Label

3.3% Dextrose and 0.30% Sodium Chloride Injection USP

REF L6081-00 NDC 0264-7608-10 DIN 01927981

500 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 3.3 g; Sodium Chloride USP 0.3 g; Water for Injection USP qs

pH: 4.5 (3.5-6.5); Calc. Osmolarity: 270 mOsmol/liter

Electrolytes (mEq/liter): Na⁺ 51; Cl⁻ 51

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute

leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

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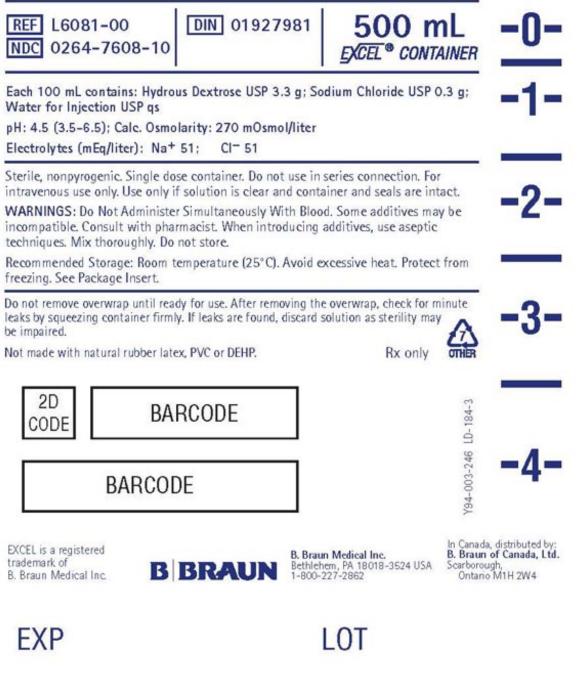
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Y94-003-246 LD-184-3





PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

5% Dextrose and 0.9% Sodium Chloride Injection USP

REF L6100 NDC 0264-7610-00 DIN 01924435 HK 22608

1000 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.9 g; Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 560 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 154; Cl⁻ 154

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

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Y94-003-253 LD-177-3 LOT

5% Dextrose and 0.9% Sodium Chloride Injection USP

REF L6100 NDC 0264-7610-00 DIN 01924435 HK 22608	1000 ml
Each 100 mL contains: Hydrou Sodium Chloride USP 0.9 g; W pH: 4.4 (3.5–6.5); Calc. Osmo hypertonic	ater for Injection USP qs
Electrolytes (mEq/liter): Na+	154; Cl ⁻ 154
Sterile, nonpyrogenic. Single dos series connection. For intravenou solution is clear and container a	us use only. Use only if
WARNINGS: Some additives ma with pharmacist. When introduc techniques. Mix thoroughly. Do n	ing additives, use aseptic
Recommended Storage: Room te excessive heat. Protect from free	
Do not remove overwrap until ready overwrap, check for minute leaks by leaks are found, discard solution as	squeezing container firmly.
Not made with natural rubber latex	, PVC or DEHP. Rx only
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PRINCIPAL DISPLAY PANEL - 500 mL Container Label

5% Dextrose and 0.9% Sodium Chloride Injection USP

REF L6101 NDC 0264-7610-10 DIN 01924435 HK 22608

500 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.9 g; Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 560 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 154; Cl⁻ 154

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect

from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute

leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

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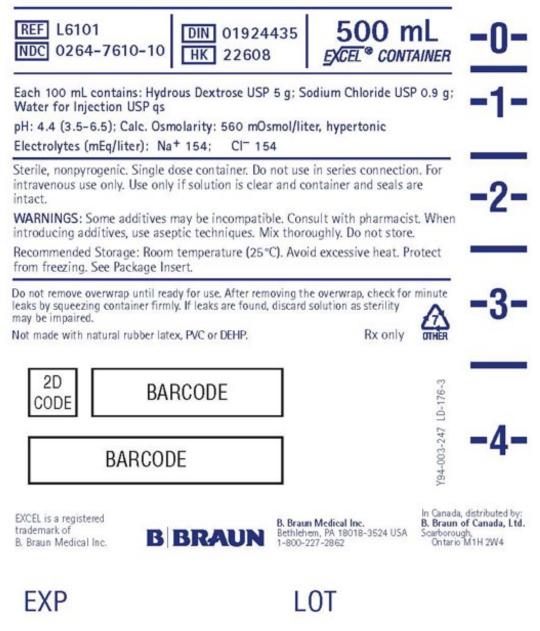
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Y94-003-247 LD-176-3



5% Dextrose and 0.9% Sodium Chloride Injection USP



L6101

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

5% Dextrose and 0.45% Sodium Chloride Injection USP

REF L6120 NDC 0264-7612-00 DIN 01927531 HK 22607

1000 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.45 g; Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 405 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 77; Cl⁻ 77

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

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Y94-003-254 LD-108-3

5% Dextrose and 0.45% Sodium Chloride

Injection USP

REF L6120 NDC 0264-7612-00 DIN 01927531 HK 22607	1000 mL EXCEL [®] CONTAINER	<u>-0</u> - -1-
Each 100 mL contains: Hydrou Sodium Chloride USP 0.45 g; V pH: 4.4 (3.5–6.5); Calc. Osmol hypertonic Electrolytes (mEq/liter): Na ⁺	Water for Injection USP qs	-2-
Sterile, nonpyrogenic. Single dos series connection. For intravenou solution is clear and container ar	us use only. Use only if	-4-
WARNINGS: Some additives ma with pharmacist. When introduc techniques. Mix thoroughly. Do r	ing additives, use aseptic	-
Recommended Storage: Room te excessive heat. Protect from free		-5-
Do not remove overwrap until ready overwrap, check for minute leaks by leaks are found, discard solution as	squeezing container firmly. If	-6-
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LOT EXP

PRINCIPAL DISPLAY PANEL - 500 mL Container Label

5% Dextrose and 0.45% Sodium Chloride Injection USP

REF L6121 NDC 0264-7612-10 DIN 01927531 HK 22607

500 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.45 g; g; Water for Injection USP gs

Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 405 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 77; Cl⁻ 77

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect

from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute

leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

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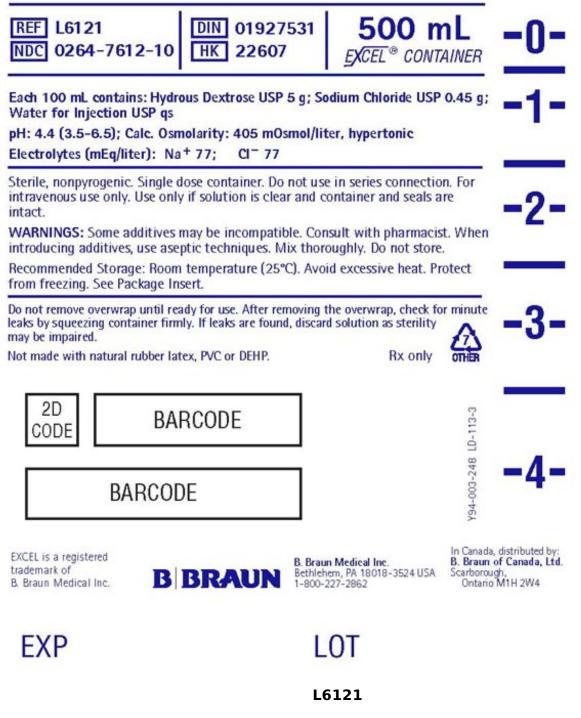
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Y94-003-248 LD-113-3



5% Dextrose and 0.45% Sodium Chloride Injection USP



PRINCIPAL DISPLAY PANEL - 250 mL Container Label

5% Dextrose and 0.45% Sodium Chloride Injection USP

REF L6122 NDC 0264-7612-20 DIN 01927531 HK 22607

250 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.45 g; Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 405 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 77; Cl⁻ 77

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

EXCEL is a registered trademark of B. Braun Medical Inc.

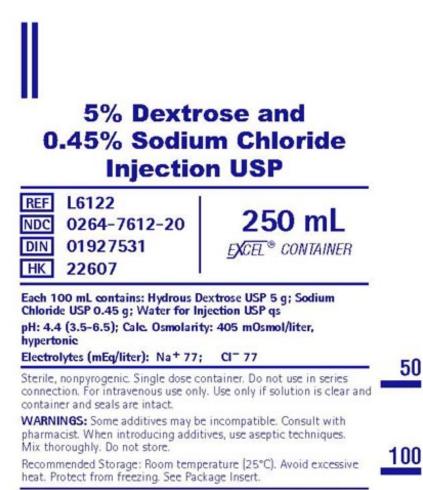
B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA 1-800-227-2862

In Canada, distributed by: **B. Braun of Canada, Ltd.** Scarborough, Ontario M1H 2W4

Y94-003-245 LD-114-3 FXP

LOT



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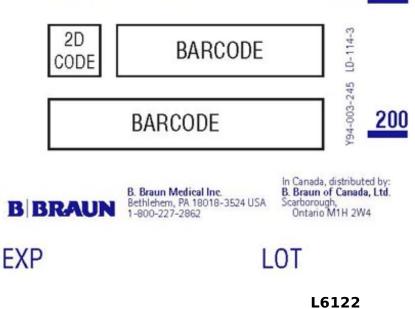
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Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Rx only

Not made with natural rubber latex, PVC or DEHP.

EXCEL is a registered trademark of B. Braun Medical Inc.



PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

5% Dextrose and 0.33% Sodium Chloride Injection USP

REF L6140 NDC 0264-7614-00

1000 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.33 g; Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 365 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 56; Cl⁻ 56

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

EXCEL is a registered trademark of B. Braun Medical Inc.

B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA 1-800-227-2862

Y94-003-255 LD-115-3

5% Dextrose and 0.33% Sodium Chloride Injection USP

REF L6140 NDC 0264-7614-00	1000 mL EXCEL® CONTAINER
Each 100 mL contains: Hydroi Sodium Chloride USP 0.33 g;	
pH: 4.4 (3.5–6.5); Cale. Osmo hypertonic	olarity: 365 mOsmol/liter,
TOTAL DA DA DO BE MONTHERE WE WROT	1+ 56; CIT 56
Sterile, nonpyrogenic. Single do: series connection. For intraveno solution is clear and container a	us use only. Use only if
WARNINGS: Do Not Administer Some additives may be incompa pharmacist. When introducing a techniques. Mix thoroughly. Do	atible. Consult with additives, use aseptic
Recommended Storage: Room t excessive heat. Protect from fre	
Do not remove overwrap until read overwrap, check for minute leaks b leaks are found, discard solution as	y squeezing container firmly. If
Not made with natural rubber lates	k, PVC or DEHP. Rx only 7
EXCEL is a registered trademark of	B. Braun Medical Inc. OTHE
BARCODI	E m

		- 0 -	
BAR	CODE	Y94 003-255 1	
BBRAUN	B. Braun Medical Inc. Bethlehem, PA 18018-3524 USA 1-800-227-2862	-9-	

EXP LOT

PRINCIPAL DISPLAY PANEL - 500 mL Container Label

5% Dextrose and 0.33% Sodium Chloride Injection USP

REF L6141 NDC 0264-7614-10

500 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.33 g;

Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 365 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 56; Cl⁻ 56

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

EXCEL is a registered trademark of B. Braun Medical Inc.

B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA 1-800-227-2862

Y94-003-249 LD-174-3



5% Dextrose and 0.33% Sodium Chloride Injection USP

REF L6141 NDC 0264-7614-1	0	500 mL	-0-
Each 100 mL contains: Hy Water for Injection USP of pH: 4.4 (3.5–6.5); Cale. Of Electrolytes (mEq/liter):	s smolarity: 365 mOsmo		0.33 g; -1-
Sterile, nonpyrogenic. Singl intravenous use only. Use o WARNINGS: Do Not Admir incompatible. Consult with techniques. Mix thoroughly Recommended Storage: Roo freezing. See Package Inser	nly if solution is clear an hister Simultaneously Wi pharmacist. When intro 2 Do not store. om temperature (25°C).	nd container and seals are ith Blood. Some additives ducing additives, use asep	intact. may be tic
Do not remove overwrap until minute leaks by squeezing con sterility may be impaired. Not made with natural rubber	tainer firmly. If leaks are fo		→ -3-
2D CODE	BARCODE]	94-003-249 ID-174-3
BARC	ODE]	A94-003-24
EXCEL is a registered trademark of B. Braun Medical Inc.	2 PDAIIN	B. Braun Medical Inc. Bethlehem, PA 18018-3524 USA 1-800-227-2862	
EXP		LOT	

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

5% Dextrose and 0.20% Sodium Chloride Injection USP

REF L6160 NDC 0264-7616-00 DIN 01927558 HK 22606

1000 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.2 g; Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 320 mOsmol/liter

Electrolytes (mEq/liter): Na⁺ 34 ; Cl⁻ 34

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

EXCEL is a registered trademark of B. Braun Medical Inc.

B. Braun Medical Inc. Bethlehem, PA 18018-3524 USA 1-800-227-2862

In Canada, distributed by: **B. Braun of Canada, Ltd.** Scarborough, Ontario M1H 2W4

Y94-003-256 LD-172-3

5% Dextrose and 0.20% Sodium Chloride Injection USP

REF L6160 NDC 0264-7616-00 DIN 01927558 HK 22606	1000 mL EXCEL® CONTAINER	-0 -1
Each 100 mL contains: Hydrou Sodium Chloride USP 0.2 g; W pH: 4.4 (3.5–6.5); Calc. Osmo Electrolytes (mEq/liter): Na	ater for Injection USP qs larity: 320 mOsmol/liter	-2· -3·
Sterile, nonpyrogenic. Single dos series connection. For intravenou solution is clear and container an WARNINGS: Do Not Administer Some additives may be incompar pharmacist. When introducing an techniques. Mix thoroughly. Do r	us use only. Use only if nd seals are intact. Simultaneously With Blood. tible. Consult with dditives, use aseptic not store.	-4
Recommended Storage: Room te excessive heat. Protect from free Do not remove overwrap until ready overwrap, check for minute leaks by leaks are found, discard solution as	for use. After removing the squeezing container firmly. If sterility may be impaired.	-6
Not made with natural rubber latex, EXCEL is a registered trademark of E BARCODE	3. Braun Medical Inc. OTHER	-7

В	ARCODE	94-003-256
BRAUN	B. Braun Medical Inc.	Y9.



PRINCIPAL DISPLAY PANEL - 500 mL Container Label

5% Dextrose and 0.20% Sodium Chloride Injection USP

REF L6161 NDC 0264-7616-10 DIN 01927558 HK 22606

500 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.2 g; Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 320 mOsmol/liter

Electrolytes (mEq/liter): Na⁺ 34; Cl⁻ 34

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute

leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

EXCEL is a registered trademark of B. Braun Medical Inc.

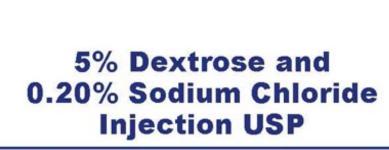
B. Braun Medical Inc.

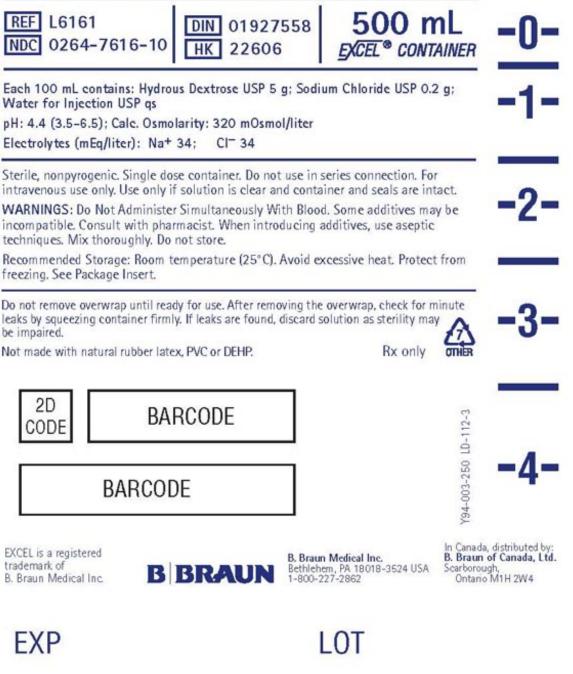
Bethlehem, PA 18018-3524 USA 1-800-227-2862

In Canada, distributed by: **B. Braun of Canada, Ltd.** Scarborough, Ontario M1H 2W4

Y94-003-250 LD-112-3

EXP LOT





L6161

PRINCIPAL DISPLAY PANEL - 250 mL Container Label

5% Dextrose and 0.20% Sodium Chloride Injection USP

REF L6162 NDC 0264-7616-20 DIN 01927558 HK 22606

250 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 5 g; Sodium Chloride USP 0.2 g; Water for Injection USP qs

pH: 4.4 (3.5-6.5); Calc. Osmolarity: 320 mOsmol/liter Electrolytes (mEq/liter): Na⁺ 34; Cl⁻ 34

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

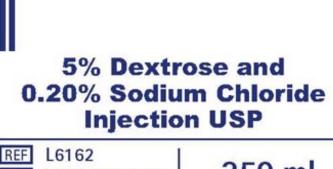
Rx only

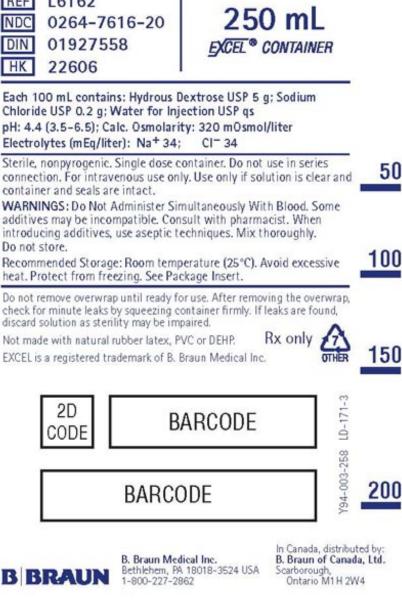
EXCEL is a registered trademark of B. Braun Medical Inc.

B. Braun Medical Inc. Bethlehem, PA 18018-3524 USA 1-800-227-2862

In Canada, distributed by: **B. Braun of Canada, Ltd.** Scarborough, Ontario M1H 2W4

Y94-003-258 LD-171-3





EXP

L6162

LOT

PRINCIPAL DISPLAY PANEL - 1000 mL Container Label

10% Dextrose and 0.45% Sodium Chloride Injection USP

REF L6220 NDC 0264-7622-00

1000 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 10 g; Sodium Chloride USP 0.45 g; Water for Injection USP qs

pH: 4.3 (3.5-6.5); Calc. Osmolarity: 660 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 77; CF 77

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found, discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

EXCEL is a registered trademark of B. Braun Medical Inc.

B. Braun Medical Inc.

Bethlehem, PA 18018-3524 USA 1-800-227-2862

Y94-003-257 LD-170-3

EXP LOT

10% Dextrose and 0.45% Sodium Chloride Injection USP

REF L6220 NDC 0264-7622-00	1000 r EXCEL® CONT.	
Each 100 mL contains: Hydro Sodium Chloride USP 0.45 g; pH: 4.3 (3.5-6.5); Calc. Osm	Water for Injection	USP qs =2=
hypertonic Electrolytes (mEq/liter): N	a ⁺ 77; Cl ⁻ 77	-3-
Sterile, nonpyrogenic. Single do series connection. For intraveno solution is clear and container	ous use only. Use onl	
WARNINGS: Some additives m with pharmacist. When introdu techniques. Mix thoroughly. Do	cing additives, use a	Second Seco
Recommended Storage: Room excessive heat. Protect from fre		
Do not remove overwrap until ready overwrap, check for minute leaks by leaks are found, discard solution as	squeezing container fir	mly. If 🛛 🗖 🗖
Not made with natural rubber latex,	PVC or DEHP. Rx only	
EXCEL is a registered trademark of E	8. Braun Medical Inc.	OTHER -7-
BARCOD)E	

		D-17	-8-
BA	RCODE	Y94-003-257	
BBRAUN	B. Braun Medical Inc. Bethlehem, PA 18018-3524 USA 1-800-227-2862		<mark>-9-</mark>

I OT EXP

PRINCIPAL DISPLAY PANEL - 250 mL Container Label

10% Dextrose and 0.20% Sodium Chloride Injection USP

REF L6232 NDC 0264-7623-20

250 mL EXCEL[®] CONTAINER

Each 100 mL contains: Hydrous Dextrose USP 10 g; Sodium Chloride USP 0.2 g; Water for Injection USP qs

pH: 4.3 (3.5-6.5); Calc. Osmolarity: 575 mOsmol/liter, hypertonic

Electrolytes (mEq/liter): Na⁺ 34; Cl⁻ 34

Sterile, nonpyrogenic. Single dose container. Do not use in series connection. For intravenous use only. Use only if solution is clear and container and seals are intact.

WARNINGS: Do Not Administer Simultaneously With Blood. Some additives may be incompatible. Consult with pharmacist. When introducing additives, use aseptic techniques. Mix thoroughly. Do not store.

Recommended Storage: Room temperature (25°C). Avoid excessive heat. Protect from freezing. See Package Insert.

Do not remove overwrap until ready for use. After removing the overwrap, check for minute leaks by squeezing container firmly. If leaks are found,

discard solution as sterility may be impaired.

Not made with natural rubber latex, PVC or DEHP.

Rx only

EXCEL is a registered trademark of B. Braun Medical Inc.

B. Braun Medical Inc.

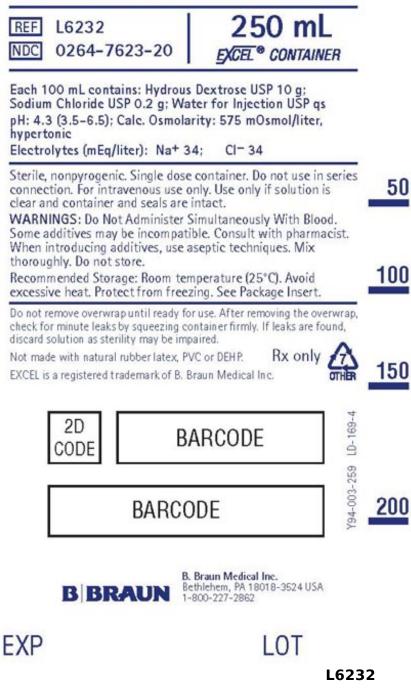
Bethlehem, PA 18018-3524 USA 1-800-227-2862

Y94-003-259 LD-169-4

EXP LOT



10% Dextrose and 0.20% Sodium Chloride Injection USP



DEXTROSE AND SODIUM CHLORIDE

dextrose and sodium chloride injection, solution

C:0264-7605 Strengt 2.5 g in 100 mL 0.45 g in 100 mL
2.5 g in 100 mL 0.45 g in 100 mL
2.5 g in 100 mL 0.45 g in 100 mL
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2017
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Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0264-7608
Route of Administration	INTRAVENOUS		
Active Ingredient/Active	Moiety		
			_

Ingradiant Nama

Basis of Strongth

				Stren	gth	Strengt
	EXTROSE, UNSP NII:5SL0G7R0OK)	PECIFIED FORM (UNII: IY9XDZ 35W2) (ANHYDROUS DE	EXTROSE -	DEXTROSE, UNSPECIFIED	FORM	3.3 g in 100 ml
	DDIUM CHLORIE HLORIDE ION - UN	DE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0 III:Q32ZN48698)	0NH37,		ORIDE	0.3 g in 100 ml
lr	nactive Ingre	edients				
		Ingredient Name			Strength	ı
w	ATER (UNII: 0590	QF0KO0R)				
P	ackaging					
#		Package Description		ing Start ate		ting End ate
1	NDC:0264- 7608-00	12 in 1 CASE	02/24/1988	3		
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product				
2	NDC:0264- 7608-10	24 in 1 CASE	02/24/1988	3		
		500 mL in 1 CONTAINER; Type 0: Not a Combination Product				
2						
2						
	larketing	Information				
	larketing Marketing Category	Information Application Number or Monograph Citation		ing Start ate		ting End ate

DEXTROSE AND SODIUM CHLORIDE

dextrose and sodium chloride injection, solution

Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Code	(Source)	NDC:0	264-7610
Route of Administration	INTRAVENOUS				
	Malaka				
Active Ingredient/Active	мојету				
Ingi	redient Name		Basis o Strengt	-	Strength
DEXTROSE, UNSPECIFIED FORM UNII:5SL0G7R0OK)	(UNII: IY9XDZ35W2) (ANHYDROUS	DEXTROSE -	DEXTROSE, UNSPECIFIED FC	ORM	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W47 CHLORIDE ION - UNII:Q32ZN48698)	(IQ8X) (SODIUM CATION - UNII:LYR4	M0NH37,	SODIUM CHLOR	IDE	0.9 g in 100 mL
Inactive Ingredients					
mactive myreulents					

		Ingredient Name		Strength
W	ATER (UNII: 0590	QF0KO0R)		
Pa	ackaging			
#	ltem Code	Package Description	Marketi Da	Marketing End Date
1	NDC:0264- 7610-00	12 in 1 CASE	02/24/1988	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0264- 7610-10	24 in 1 CASE	02/24/1988	
2		500 mL in 1 CONTAINER; Type 0: Not a Combination Product		
3	NDC:0264- 7610-20	24 in 1 CASE	02/24/1988	07/31/2014
3		250 mL in 1 CONTAINER; Type 0: Not a Combination Product		
Μ	larketing	Information		
	Marketing Category	Application Number or Monograph Citation	Marketiı Da	Marketing End Date
NC	A A	NDA019631	02/24/1988	

DEXTROSE AND SOD					
dextrose and sodium chloride	e injection, solution				
Product Information					
Product Type	HUMAN PRESCRIPTION DRUG	Item Code	e (Source)	NDC:	0264-7612
Route of Administration	INTRAVENOUS				
Active Ingredient/Active	Moiety				
Ing	redient Name		Basis of Strength		Strength
DEXTROSE, UNSPECIFIED FORM UNII:5SL0G7R0OK)	I (UNII: IY9XDZ 35W2) (ANHYDROUS	DEXTROSE -	DEXTROSE, UNSPECIFIED FO	RM	5 g in 100 mL
SODIUM CHLORIDE (UNII: 451W4) CHLORIDE ION - UNII:Q32ZN48698)		M0NH37,	SODIUM CHLORI	DE	0.45 g in 100 mL
Inactive Ingredients					
Ing	redient Name		Sti	rengt	:h
WATER (UNII: 059QF0K00R)					

	ackaging			
#	ltem Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0264- 7612-00	12 in 1 CASE	02/24/1988	
1		1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		
2	NDC:0264- 7612-10	24 in 1 CASE	02/24/1988	
2		500 mL in 1 CONTAINER; Type 0: Not a Product	Combination	
3	NDC:0264- 7612-20	24 in 1 CASE	02/24/1988	
3		250 mL in 1 CONTAINER; Type 0: Not a Product	Combination	
M	arketing	Information		
M	l arketing Marketing Category		ograph Marketing Start Date	Marketing End Date

DEXTROSE	AND SOD	IUM CHLORIDE				
dextrose and soc	dium chloride	injection, solution				
Product Infor	mation					
Product Type		HUMAN PRESCRIPTION DRUG	Item Code	e (Source)	NDC:	0264-7614
Route of Admini	stration	INTRAVENOUS				
Active Ingredi	ent/Active	Moiety				
Active ingrea		redient Name		Basis (Streng		Strength
DEXTROSE, UNSPI UNII:5SL0G7R0OK)	ECIFIED FORM	I (UNII: IY9XDZ 35W2) (ANHYDROUS I	DEXTROSE -	DEXTROSE, UNSPECIFIED	FORM	5 g in 100 mL
SODIUM CHLORID CHLORIDE ION - UNI		7IQ8X) (SODIUM CATION - UNII:LYR4	MONH37,	SODIUM CHLO	RIDE	0.33 g in 100 mL
Inactive Ingre						
	-	redient Name		S	Strengt	th
WATER (UNII: 059Q	FOKOOR)					
Packaging						
# Item Code	Pa	ckage Description		ting Start Pate		eting End Date
1 NDC:0264- 7614-00	12 in 1 CASE		02/24/198	8		

Marketing Marketing Category	Information Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
Marketing	Information		
2	500 mL in 1 CONTAINER; Type 0: Not a Combination Product	n	
2 NDC:0264- 7614-10	24 in 1 CASE	02/24/1988	
	1000 mL in 1 CONTAINER; Type 0: Not a Combination Product		

DEXTROSE AND SODIUM CHLORIDE dextrose and sodium chloride injection, solution **Product Information Product Type** HUMAN PRESCRIPTION DRUG Item Code (Source) NDC:0264-7616 **INTRAVENOUS Route of Administration Active Ingredient/Active Moiety Basis of Ingredient Name** Strength Strength DEXTROSE, UNSPECIFIED FORM (UNII: IY9XDZ 35W2) (ANHYDROUS DEXTROSE -DEXTROSE, 5 g UNII:5SL0G7R0OK) UNSPECIFIED FORM in 100 mL SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, 0.2 g SODIUM CHLORIDE in 100 mL CHLORIDE ION - UNII:Q32ZN48698) **Inactive Ingredients Ingredient Name** Strength WATER (UNII: 059QF0K00R) Packaging **Marketing Start Marketing End** Item Code **Package Description** # Date Date 1 NDC:0264-12 in 1 CASE 02/24/1988 7616-00 1000 mL in 1 CONTAINER; Type 0: Not a 1 **Combination Product** NDC:0264-2 24 in 1 CASE 02/24/1988 7616-10 500 mL in 1 CONTAINER; Type 0: Not a Combination 2 Product NDC:0264-

02/24/1988

24 in 1 CASE

Product

250 mL in 1 CONTAINER; Type 0: Not a Combination

3

3

7616-20

marketing	Informat	ion				
Marketing Category	Applica	tion Number or Monograph Citation		ing Start ate	Mark	ceting End Date
NDA	NDA019631		02/24/1988	3		
lexuose and so		e injection, solution				
Product Infor	mation					
Product Type		HUMAN PRESCRIPTION DRUG	Item Code	e (Source)	NDC	:0264-7622
Route of Admin	istration	INTRAVENOUS				
Active Ingred	ient/Active	Moiety				
	Ingi	redient Name		Basis (Streng		Strength
DEXTROSE, UNSP UNII:5SL0G7R0OK)	ECIFIED FORM	I (UNII: IY9XDZ 35W2) (ANHYDROUS	DEXTROSE -	DEXTROSE, UNSPECIFIED I	FORM	10 g in 100 mL
Sodium Chlorid Chloride Ion - UN		7IQ8X) (SODIUM CATION - UNII:LYR4	MONH37,	SODIUM CHLO	RIDE	0.45 g
	. ,			000101101120		in 100 mL
	. ,					in 100 mL
Inactive Ingre						IN 100 mL
Inactive Ingre	edients	redient Name			Streng	
-	edients Ing					
-	edients Ing					
WATER (UNII: 059C	edients Ing					
WATER (UNII: 0590	edients Ing QFOKOOR)				itreng	
WATER (UNII: 0590 Packaging # Item Code	edients Ing QFOKOOR)	redient Name		ing Start ate	itreng	th ceting End
WATER (UNII: 0590 Packaging # Item Code 1 NDC:0264- 7622-00	edients Ing DFOKOOR) Pa 12 in 1 CASE	redient Name ackage Description ONTAINER; Type 0: Not a	D	ing Start ate	itreng	th ceting End
WATER (UNII: 0590 Packaging # Item Code 1 NDC:0264- 7622-00 1	edients Ing DFOKOOR) Pa 12 in 1 CASE 1000 mL in 1 C	redient Name ackage Description ONTAINER; Type 0: Not a	D	ing Start ate	itreng	th ceting End
WATER (UNII: 0590 Packaging # Item Code 1 NDC:0264- 7622-00 1	edients Ing FOKOOR) Pa 12 in 1 CASE 1000 mL in 1 C Combination Pr	redient Name Ackage Description	D	ing Start ate	itreng	th ceting End
1 NDC:0264- 7622-00	edients ing FOKOOR) Pa 12 in 1 CASE 1000 mL in 1 C Combination Pr Informat	redient Name Ackage Description	02/24/198	ing Start ate	itreng Mark	th ceting End

DEXTROSE AND SODIUM CHLORIDE

dextrose and sodium chloride injection, solution

	roduct Info	rmation					
Pr	oduct Type		HUMAN PRESCRIPTION DRUG	Item Code	e (Source)	NDC:	0264-7623
Ro	oute of Admin	istration	INTRAVENOUS				
Ac	tive Ingred	lient/Active	Moiety				
Ingr			redient Name		Basis Streng		Strengt
	XTROSE, UNSF II:5SL0G7R0OK)	PECIFIED FORM	(UNII: IY9XDZ 35W2) (ANHYDROU	S DEXTROSE -	DEXTROSE, UNSPECIFIED	FORM	10 g in 100 mL
		DE (UNII: 451W47 III:Q32ZN48698)	Q8X) (SODIUM CATION - UNII:LYR4M0NH37, SODIU			ORIDE	0.2 g in 100 mL
In	active Ingr	edients					
			redient Name		9	Strengt	th
	ATER (UNII: 059)		redient Name		5	Strengt	th
	ATER (UNII: 059)		redient Name		2	Strengt	th
W	ATER (UNII: 059) ACKAging		redient Name		2	Strengt	th
w <i>i</i> Pa		QF0KO0R)	redient Name ckage Description		ing Start ate	Marko	th eting End Date
w# Pa #	ackaging	QF0KO0R)			ing Start ate	Marko	eting End
w# Pa #	ackaging Item Code NDC:0264-	QF0KO0R) Pa 24 in 1 CASE	ckage Description NTAINER; Type 0: Not a	D	ing Start ate	Marko	eting End
w/ Pa #	ackaging Item Code NDC:0264-	QF0KO0R) Pa 24 in 1 CASE 250 mL in 1 CO	ckage Description NTAINER; Type 0: Not a	D	ing Start ate	Marko	eting End
W/ Pa # 1	Item Code NDC:0264- 7623-20	QF0KO0R) Pa 24 in 1 CASE 250 mL in 1 CO	ckage Description NTAINER; Type 0: Not a oduct	D	ing Start ate	Marko	eting End
w/ Pa # 1	Item Code NDC:0264- 7623-20	QF0KO0R) Pa 24 in 1 CASE 250 mL in 1 CO Combination Pr Informat	ckage Description NTAINER; Type 0: Not a oduct	n Market	ing Start ate	Marko	eting End

Labeler - B. Braun Medical Inc. (002397347)

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B. Braun Medical Inc.