

TIS-U-SOL- sodium chloride, potassium chloride, magnesium sulfate, sodium phosphate, and potassium phosphate irrigant
Baxter Healthcare Corporation

DESCRIPTION

Tis-U-Sol® Solution

(Pentalyte Irrigation)

Each 100 mL contains: 800 mg Sodium Chloride, USP, 40 mg Potassium Chloride, USP, 20 mg Magnesium Sulfate, Heptahydrate, USP, 8.75 mg Dibasic Sodium Phosphate, Heptahydrate, USP, 6.25 mg Monobasic Potassium Phosphate, NF. No antimicrobial agent has been added. pH 6.5 (4.0 to 7.0). Osmolarity 288 mOsmol/L (calc.). Sterile, nonpyrogenic. Pour Bottle.

INDICATIONS AND USAGE

Isotonic solution for irrigation only. Not for injection.

DOSAGE AND ADMINISTRATION

As directed by a physician.

Cautions: Warm in oven to not more than 50°C for a maximum of 60 days. Discard after 60 days of warming. Do not use unless solution is clear and seal is intact. Discard unused portion. Rx only.

HOW SUPPLIED

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

PRINCIPAL DISPLAY PANEL - PACKAGING LABELING

2F7144
NDC 0338-0190-04

1000 mL
DIN 00800007

Baxter

Not for Injection

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PL 325 plastic

Baxter Healthcare Corporation
Deerfield, IL 60015 USA

Made in USA

Distributed in Canada by

Baxter Corporation

Mississauga, ON L5N 0C2

LOT
EXP

07-09-68-118

Bar Code Position Only*

303380190041

2F7144

NDC 0338-0190-04

1000 mL

DIN 00800007

Baxter Logo

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TIS-U-SOL

sodium chloride, potassium chloride, magnesium sulfate, sodium phosphate, and potassium phosphate irrigant

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	Item Code (Source)	NDC:0338-0190
Route of Administration	IRRIGATION		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
SODIUM CHLORIDE (UNII: 451W47IQ8X) (SODIUM CATION - UNII:LYR4M0NH37, CHLORIDE ION - UNII:Q32ZN48698)	SODIUM CHLORIDE	800 mg in 100 mL
POTASSIUM CHLORIDE (UNII: 660YQ98I10) (POTASSIUM CATION - UNII:295O53K152, CHLORIDE ION - UNII:Q32ZN48698)	POTASSIUM CHLORIDE	40 mg in 100 mL
MAGNESIUM SULFATE HEPTAHYDRATE (UNII: SK47B8698T) (MAGNESIUM CATION - UNII:T6V3LHY838)	MAGNESIUM SULFATE HEPTAHYDRATE	20 mg in 100 mL
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE (UNII: 70WT22SF4B) (SODIUM CATION - UNII:LYR4M0NH37, PHOSPHATE ION - UNII:NK08V8K8HR)	SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	8.75 mg in 100 mL
POTASSIUM PHOSPHATE, MONOBASIC (UNII: 4J9FJ0HL51) (PHOSPHATE ION - UNII:NK08V8K8HR, POTASSIUM CATION - UNII:295O53K152)	POTASSIUM PHOSPHATE, MONOBASIC	6.25 mg in 100 mL

Inactive Ingredients

Ingredient Name	Strength
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0338-0190-04	12 in 1 CARTON	02/19/1982	
1		1000 mL in 1 BOTTLE, PLASTIC; Type 0: Not a		

1	Combination Product		
Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018508	02/19/1982	

Labeler - Baxter Healthcare Corporation (005083209)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		001728059	ANALYSIS(0338-0190) , MANUFACTURE(0338-0190) , LABEL(0338-0190) , PACK(0338-0190) , STERILIZE(0338-0190)

Establishment

Name	Address	ID/FEI	Business Operations
Baxter Healthcare Corporation		194684502	ANALYSIS(0338-0190)

Revised: 2/2014

Baxter Healthcare Corporation