

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*

903880190041

2F7144

NDC 0338-0190-04

1000 mL

DIN 00800007

Baxter Logo

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LOT
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| | | |
|--|--------------------------|-------------------------|
| TIS – U – SOL[®] Solution (Pentalyte Irrigation) Pour Bottle | 1000_{ML} | Qty 12 |
| NDC 0338 – 0190 – 04 | 2F7144 | |
| EXP | LOT # | |
|  | | |
| (01)50303380190046(17)080630(10)G012345 | | |

Carton Label

Carton Label

TIS-U-SOL[®] Solution
(Pentalyte Irrigation)
Pour Bottle

1000 mL

Qty
12

NDC 0338-0190-04
2F7144

EXP
LOT #

Bar Code
(01)50303380190046(17)080630(10)G012345

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:L YR4M0NH37, 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:L YR4M0NH37, 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: 059QF0K00R) | | | |
| 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 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) |