



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry: 213304 lonolyte sodium chloride, sodium acetate trihydrate, potassium chloride, magnesium chloride, Injection for intravenous infusion 1000 mL Freeflex bag

ARTG entry for Medicine Registered
Sponsor Fresenius Kabi Australia Pty Ltd
Postal Address Level 2, 2 Woodland Way, Mount Kuring-gai, NSW, 2080 Australia
ARTG Start Date 9/05/2014
Product Category Medicine
Status Active
Approval Area Drug Safety Evaluation Branch

Conditions

Conditions applicable to all therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Standard Conditions Applying to Registered or Listed Therapeutic Goods Under Section 28 of the Therapeutic Goods Act 1989" effective 1 July 1995.

Products

1. lonolyte sodium chloride, sodium acetate trihydrate, potassium chloride, magnesium chloride, Injection for intravenous infusion 1000 mL Freeflex bag

Product Type	Single Medicine Product	Effective Date	22/01/2021
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Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

No Standard Indications included on Record

Specific Indications

lonolyte is indicated for:- mild metabolic acidosis,- as a source of water and electrolytes

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bag	Plastic	36 Months	Store below 30 degrees Celsius	Neither child resistant closure nor restricted flow insert	Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
1000mL x 10 bags	Not scheduled. Not considered by committee

Components

1. lonolyte sodium chloride, sodium acetate trihydrate, potassium chloride, magnesium chloride, Injection for intravenous infusion 1000 mL Freeflex bag

Dosage Form Injection, intravenous infusion
Route of Administration Intravenous Infusion
Visual Identification lonolyte solution for infusion is a clear and colourless solution.

Active Ingredients

magnesium chloride hexahydrate .3 g/L

Public Summary



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potassium chloride	.3 g/L
sodium acetate trihydrate	4.63 g/L
sodium chloride	6.02 g/L

Other Ingredients (Excipients)

hydrochloric acid
sodium hydroxide
water for injections

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Public Summary