



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	120361	VOLUVEN 6% hydroxyethyl starch 130/0.4 500 mL solution for intravenous infusion 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	13/11/2006	
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 . VOLUVEN 6% hydroxyethyl starch 130/0.4 500 mL solution for intravenous infusion bag

Product Type	Single Medicine Product	Effective Date	26/05/2020
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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

Treatment of hypovolaemia due to acute blood loss when crystalloids alone are not considered sufficient. The use of Voluven is not a substitute for the appropriate use of packed red blood cells or fresh frozen plasma.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bag	Other composite material	3 Years	Store below 25 degrees Celsius	Not recorded	Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
10 x 500 mL	Not Scheduled after consideration by Committee
20 X 500 mL	Not Scheduled after consideration by Committee
15 X 500 mL	Not Scheduled after consideration by Committee

Components

1 . VOLUVEN 6% hydroxyethyl starch 130/0.4 500 mL solution for intravenous infusion bag

Dosage Form	Injection, solution
Route of Administration	Intravenous
Visual Identification	Clear solution.

Active Ingredients

hydroxyethyl starch 130/0.4	60 g/L
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Other Ingredients (Excipients)

hydrochloric acid
sodium chloride
sodium hydroxide
water for injections

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