



Australian Government
Department of Health
 Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	19426	10% DEXTRAN 40 in 5% GLUCOSE 500mL injection bag FKB5053G
ARTG entry for	Medicine Registered	
Sponsor	Baxter Healthcare Pty Ltd	
Postal Address	PO Box 88, TOONGABBIE, NSW, 2146 Australia	
ARTG Start Date	30/09/1991	
Product Category	Medicine	
Status	Active	
Approval Area	Drug Safety Evaluation Branch	

Conditions

Conditions applicable to the relevant category and class of therapeutic goods as specified in the document "Conditions Applying to Therapeutic Goods Accepted for Registration or Listing as Goods Currently Supplied at the Commencement of the Therapeutic Goods Act 1989"

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 February 1992.

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 February 1992.

Products

1 . 10% Dextran 40 in 5% Glucose 500mL injection FKB5053G

Product Type	Single Medicine Product	Effective Date	3/07/2002
---------------------	-------------------------	-----------------------	-----------

Permitted Indications

No Permitted Indications included on Record

Indication Requirements

No Indication Requirements included on Record

Standard Indications

This product accepted for registration/listing as 'currently supplied' at the time of commencement of the Act. Indications held in ARTG paper records. (Old code)

Specific Indications

No Specific Indications included on Record

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Bag	Not recorded	Not recorded	Not recorded	Not recorded	Not recorded

Pack Size/Poison information

Pack Size	Poison Schedule
500mL x 15	Not scheduled. Not considered by committee

Components

1 . Medicine Component

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

Active Ingredients

dextran 40	100 g/L
glucose monohydrate	50 g/L

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

Other Ingredients (Excipients)

hydrochloric acid
sodium hydroxide
water for injections

© Commonwealth of Australia. This work is copyright. You are not permitted to re-transmit, distribute or commercialise the material without obtaining prior written approval from the Commonwealth. Further details can be found at <http://www.tga.gov.au/about/website-copyright.htm>.

Public Summary