



Australian Government
Department of Health and Aged Care
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	16354	DBL ASCORBIC ACID 500mg/5mL injection USP ampoule
ARTG entry for	Medicine Registered	
Sponsor	Phebra Pty Ltd	
Postal Address	Locked Bag 3003, HUNTERS HILL, NSW, 2110 Australia	
ARTG Start Date	8/10/1991	
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 . DBL ASCORBIC ACID 500mg/5mL USP Injection

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

Prevention and treatment of ascorbic acid deficiency (i.e. scurvy) when oral therapy is contraindicated. As a supplement during periods of increased requirements, only if needs cannot be met from normal dietary sources and oral supplemental therapy is contraindicated, e.g. wound healing, burns, infections, trauma, post-operatively and in thyrotoxicosis. As an adjunct in the treatment of idiopathic methaemoglobinaemia. The use ascorbic acid with desferrioxamine therapy to increase iron excretion remains unsubstantiated. Injectable ascorbic acid is administered for the above indications where oral administration is not possible, or in which medication given by the oral route will not be sufficiently absorbed. INDICATIONS AS AT 8 January 2004: Prevention and treatment of ascorbic acid deficiency (i.e. scurvy) when oral therapy is contraindicated. As a supplement during periods of increased requirements, only if needs cannot be met from normal dietary sources and oral supplemental therapy is contraindicated, e.g. wound healing, burns, infections, trauma, post-operatively and in thyrotoxicosis. As an adjunct in the treatment of idiopathic methaemoglobinaemia. The use of ascorbic acid with desferrioxamine therapy to increase iron excretion remains unsubstantiated. Injectable ascorbic acid is administered for the above indications where oral administration is not possible, or in which medication given by the oral route will not be sufficiently absorbed.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Ampoule	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Protect from Light

Pack Size/Poison information

Pack Size	Poison Schedule
50x500mg/5mL	Not scheduled. Not considered by committee

Components

1 . -

Public Summary



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

Active Ingredients

ascorbic acid 100 mg/mL

Other Ingredients (Excipients)

benzyl alcohol
sodium bicarbonate
sodium chloride
thiourea
water for injections

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