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"


Products

1. DBL ASCORBIC ACID 500mg/5mL USP Injection

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
Prevention and treatment of ascorbic acid deficiency (i.e. scurvy) when oral therapy is contraindicated. As a supplement during periods of increases 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 methaemoglobinemia. The use ascorbic acid with desferrioxamine therapy to increase iron excretion remains unsubstantiated. Injectable ascorbic acid is administrated 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 Ampoule  Material Not recorded  Life Time 3 Years  Temperature Store below 25 degrees Celsius  Closure Not recorded  Conditions Protect from Light

Pack Size/Poison information

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

Components 1. -

Dosage Form Injection, solution
Route of Administration Subcutaneous
<table>
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<tr>
<th>Visual Identification</th>
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<tbody>
<tr>
<td>Intravenous</td>
<td></td>
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<tr>
<td>Intramuscular</td>
<td>Clear colourless solution</td>
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<table>
<thead>
<tr>
<th>Active Ingredients</th>
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<tbody>
<tr>
<td>ascorbic acid</td>
<td>100 mg/mL</td>
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