



Australian Government
Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	131067	SODIUM BICARBONATE 8.4% w/v 840mg/10mL injection BP vial
ARTG entry for	Medicine Registered	
Sponsor	Phebra Pty Ltd	
Postal Address	Locked Bag 3003, HUNTERS HILL, NSW, 2110 Australia	
ARTG Start Date	2/02/2007	
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 . SODIUM BICARBONATE 8.4% w/v 840mg/10mL injection vial

Product Type	Single Medicine Product	Effective Date	22/02/2021
---------------------	-------------------------	-----------------------	------------

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

SODIUM BICARBONATE INJECTION is indicated as an alkalinising agent in the treatment of metabolic acidosis which may occur in many conditions including diabetes, starvation, hepatitis, cardiac arrest, shock, severe dehydration, renal insufficiency, severe diarrhoea, Addison's disease or administration of acidifying salts (e.g. excessive sodium chloride, calcium chloride, ammonium chloride).
SODIUM BICARBONATE INJECTION is also used to increase urinary pH in order to increase the solubility of certain weak acids (e.g. cystine, sulphonamides, uric acid) and in the treatment of certain intoxications (e.g. methanol, phenobarbitone, salicylates, lithium) to decrease renal absorption of the drug or to correct acidosis.

Warnings

See Product Information and Consumer Medicine Information for this product

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Vial	Glass Type I Clear	3 Years	Store below 30 degrees Celsius	Not recorded	Do not Freeze

Pack Size/Poison information

Pack Size	Poison Schedule
10mL vial, 10 per pack	Not scheduled. Not considered by committee

Components

1 . Medicine Component

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

Active Ingredients

sodium bicarbonate	84 mg/mL
--------------------	----------

Public Summary



Australian Government

Department of Health
Therapeutic Goods Administration

Other Ingredients (Excipients)

disodium edetate
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