Public Summary

Summary for ARTG Entry: 48376 PHEBRA SODIUM BICARBONATE 8.4% w/v (8.4g/100mL) 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	23/05/1994
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 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 . PHEBRA SODIUM BICARBONATE 8.4% w/v (8.4g/100mL) injection BP 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
100mL x 10	Not scheduled. Not considered by committee
100mL x 5	Not scheduled. Not considered by committee
100mL x 1	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**

Other Ingredients (Excipients)
disodium edetate
water for injections

Public Summary