Australian Government

Department of Health
Therapeutic Goods Administration

Public Summary

Summary for ARTG Entry:	27482	Gastrolyte Fruit Flavour oral powder sachet

ARTG entry for	Medicine Registered
Sponsor	Sanofi-Aventis Healthcare Pty Ltd T/A Sanofi Consumer Healthcare
Postal Address	PO Box 403, VIRGINIA, QLD, 4014 Australia
ARTG Start Date	21/10/1991
Product Category	Medicine
Status	Active
Approval Area	Non-Prescription Medicines

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 . Gastrolyte Fruit Flavour oral powder sachet

Product Type	Single Medicine Product	**Effective Date**	26/02/2009

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

Oral correction of fluid and electrolyte loss in infants, children and adults. The product has been formulated to treat fluid and electrolyte loss associated with acute dehydration in infantile diarrhoea, but is also appropriate for the treatment of older children and adults. Gastrolyte is also indicated for the correction of dehydration due to traveller's gastroenteritis and vigorous and prolonged exercise.

Warnings

No Warnings included on Record

Additional Product information

Container information

Type	Material	Life Time	Temperature	Closure	Conditions
Sachet	Not recorded	3 Years	Store below 25 degrees Celsius	Not recorded	Store in a Dry Place

Pack Size/Poison information

Pack Size	Poison Schedule
10 x 4.9g sachets	Not scheduled. Not considered by committee

Components

1 . Medicine Component

Dosage Form	Powder, oral
Route of Administration	Oral
Visual Identification	A fine white to off-white homogeneous powder, free from visible contamination

Active Ingredients

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glucose monohydrate	**3.56 g**
potassium chloride	**.3 g**
sodium acid citrate	**.53 g**
sodium chloride	**.47 g**

Other Ingredients (Excipients)

aspartame

colloidal anhydrous silica

Flavour

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