

PROFESSIONAL INFORMATION

SCHEDULING STATUS

S0

1 NAME OF THE MEDICINE

CRECHE GUARD RESTORE LOLLY

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 50ml lolly contains:

Sodium Citrate 0,13 g

Sodium Chloride 0,09 g

Potassium Chloride 0,075 g

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Clear colourless jelly-like liquid with smell and flavour of raspberries

4 CLINICAL PARTICULARS

4.1 Therapeutic indication

CRECHE GUARD RESTORE LOLLY is an oral nutrient solution to replace, refuel and replenish fluid loss in children.

4.2 Posology and method of administration

Children 3 years and older: Drink/suck one lolly every 3 hours (maximum of 9 lollies per day)

Can be consumed at room temperature or frozen.

4.3 Contraindications

Known hypersensitivity to any of the ingredients of CRECHE GUARD RESTORE LOLLY.

Cardiac failure, renal impairment or renal disease.

4.4 Special warnings and precautions for use

Use in children under the age of 3 must be under the supervision of a healthcare professional.

CRECHE GUARD RESTORE LOLLY contains sugar which may affect blood sugar levels in children with *Diabetes Mellitus*.

4.5 Interaction with other medicines and other forms of interaction

No interaction studies were performed.

4.6 Fertility, pregnancy and lactation

There is no data available on use during pregnancy or lactation.

4.7 Effects on ability to drive and use machines

The effects on ability to drive and use machines has not been studied.

4.8 Undesirable effects

No data available.

4.9 Overdose

Treatment is symptomatic and supportive.

5 PHARMACOLOGICAL PROPERTIES

5.1 PHARMACOLOGICAL CLASSIFICATION

Complementary Medicines: Health Supplement

D34.12 Multiple substance formulation

5.2 PHARMACOLOGICAL ACTION

CRECHE GUARD RESTORE LOLLY contains a mixture of potassium and sodium salts together with glucose which facilitates the absorption of sodium and potassium from the intestine. Water is drawn from the bowel by an osmotic effect. This helps correct any fluid and electrolyte loss from the body.

NUTRITIONAL INFO

	Per Sachet (50 ml)	Per 100 ml
Energetic Value	3,20 Kcal/13,60 KJ	6,40 Kcal/27,20 KJ
Carbohydrates - Glucose	0,80 g	1,60 g
K⁺	39,10 mg	78,20 mg
Na⁺	62,52 mg	131,04 mg
Cl⁻	88,63 mg	177,25 mg

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Carrageenan, citric acid, potassium sorbate, raspberry flavour, water (deionized).

Contains sugar: glucose 0,8 g/lolly

Contains sweetener: sucralose 0,012 g/lolly

6.2 Incompatibilities

Unknown

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store at or below 25 °C. Store in carton to protect from sunlight and moisture.

KEEP OUT OF THE REACH OF CHILDREN.

6.5 Nature and contents of container

Cardboard carton containing 5 x 50ml lollies.

6.6 Special precautions for disposal and other handling

No special requirements

7 HOLDER OF CERTIFICATE OF REGISTRATION

iNova Pharmaceuticals (Pty) Ltd, 15E Riley Road, Bedfordview, 2007

Tel: (011) 087 0000 www.inovapharma.co.za

8 REGISTRATION NUMBER

To be allocated

9 DATE OF PUBLICATION OF PROFESSIONAL INFORMATION

September 2020