

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rapolyte- Natural Powder for Oral Solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Sodium Chloride Ph. Eur.	0.35	g
Potassium Chloride Ph. Eur.	0.30	g
Sodium Citrate Ph. Eur.	0.60	g
Glucose Anhydrous Ph. Eur.	4.00	g

3 PHARMACEUTICAL FORM

Powder for oral solution.

White free-flowing crystalline powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the correction of fluid and electrolyte loss in the management of watery diarrhoea.

4.2 Posology and method of administration

The basic unit of dosage is the content of a single sachet reconstituted in 200ml of freshly boiled and cooled water. The solution must not be boiled after reconstitution.

The solution should not be administered to infants or young children except under direction of a physician.

Infants:

The solution is substituted for the milk feed.

Severe Diarrhoea:

On the first day the usual dose is 150ml of solution/kg body weight with no milk.

On each successive day there is a reduction of 30ml/kg in the volume of solution used and an increment of 30ml in the volume of milk.

Mild Diarrhoea:

Give 200ml of solution as required on both Day 1 and Day 2 of treatment. Thereafter give the solution as a 1:1 dilution with the milk feed.

Older Children and Adults:

Drink 50-100ml of solution/kg body weight every 4-6 hours.

4.3 Contraindications

Not applicable.

4.4 Special warnings and precautions for use

1. The solution should not be administered to infants or young children except under the direction of a physician after a diagnosis has been made.
2. The solution must not be reconstituted except with water and at the volume stated. Solutions of greater concentration may result in hypernatraemia. Those of greater dilution may result in inadequate replacement.
3. If nausea and vomiting are present with the diarrhoea, small but frequent amounts of Rapolyte-Natural should be drunk at first. In infants, this should be under medical supervision.
4. If there is no improvement within 24-48 hours, the physician should be consulted.
5. Patients with rare glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

Not applicable.

4.6 Pregnancy and lactation

This product should not be used during pregnancy unless considered essential by the physician.

4.7 Effects on ability to drive and use machines

Rapolyte- Natural does not produce effects on the ability to drive or use machines.

4.8 Undesirable effects

Not applicable.

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Rapolyte- Natural is an oral rehydration solution with the correct balance of sodium and glucose to facilitate fluid absorption. Addition of potassium addresses hypokalaemia during fluid and electrolyte loss.

5.2 Pharmacokinetic properties

Under conditions of diarrhoea, where gut absorption may be impaired, the uptake of glucose is not. There is an active transport mechanism, whereby addition of glucose to normal saline facilitates its absorption.

5.3 Preclinical safety data

Not Relevant.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Foil laminated sachets in a cardboard carton containing 4, 6, 10, 20 or 25 sachets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

For instructions on reconstitution, *see section 4.2, Posology and method of administration*.
The reconstituted solution will be clear with a saline odour and taste.

7 MARKETING AUTHORISATION HOLDER

Helsinn Birex Therapeutics Ltd.,
Damastown,
Mulhuddart,
Dublin 15.

8 MARKETING AUTHORISATION NUMBER

PA0915/011/005

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06 April 2001
Date of last renewal: 06 April 2006

10 DATE OF REVISION OF THE TEXT

January 2008