IRISH MEDICINES BOARD ACTS 1995 AND 2006

MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007

(S.I. No.540 of 2007)

PA0915/011/002
Case No: 2045521

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

Helsinn Birex Therapeutics Ltd

Damastown, **Mulhuddart**, **Dublin 15**, **Ireland**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

Rapolyte -Orange Powder for Oral Solution

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **24/01/2008**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Rapolyte-Orange 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

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for solution
White free-flowing crystalline powder, with an orange odour.

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.

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

Fresh solution should be made daily. If nausea and vomiting are present with the diarrhoea, small but frequent amounts of Rapolyte-Orange should be drunk at first.
The solution should not be administered to young children (under 12 months) except under the direction of a physician after a diagnosis has been made.
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.
If there is no improvement within 24-48 hours, the physician should be consulted.
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-Orange 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-Orange 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

Orange flavour

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.
The reconstituted solution will be clear with an orange odour and taste.

7 MARKETING AUTHORISATION HOLDER

Helsinn Birex Therapeutics Ltd.
Damastown
Mulhuddart
Dublin 15

8 MARKETING AUTHORISATION NUMBER

PA 915/11/2

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