SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dioralyte Relief Raspberry

Dioralyte Relief Blackcurrant & Raspberry

Dioralyte Relief Raspberry & Blackcurrant

Dioralyte Double Action Raspberry

(See section 6.5 for pack details)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients per sachet:

Pre-cooked Rice Powder	6g
Sodium Citrate PhEur	580mg
Sodium Chloride PhEur	350mg
Potassium Chloride PhEur	300mg

3 PHARMACEUTICAL FORM

Sachet containing powder for mixing with water prior to administration.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Oral correction of fluid and electrolyte loss in infants aged 3 months upwards, children and adults.

Treatment of watery diarrhoea of various aetiologies including gastroenteritis in all age groups from 3 months upwards.

Dioralyte Relief is particularly recommended in the case of too loose or frequent stools where it enables over-loose stools to revert to normal.

4.2 Posology and method of administration

Posology

Adults and children:

5 sachets per day for 3 to 4 days following a loose motion.

Infants from 3 months to one year under medical advice:

In the event of diarrhoea and depending on the extent of dehydration (loss of weight assessed at less than 10%) 150 to 200 ml/kg/24 hours of preparation may be given.

- half the volume is to be given during the first 8 hours, and the other half during the next 16 hours.

- in the event of vomiting accompanying the diarrhoea, the amount administered can be divided up (5 to 10 ml every 5 minutes) and this may be gradually increased until the infant can drink normally.

Method of Administration

Pour the contents of one sachet into a large glass of drinking water (200ml). Mix well and drink the whole glassful. For infants and where drinking water is not available, the water should be freshly boiled and cooled. The solution should be made up immediately before use.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients listed in section 6.1.

Dioralyte Relief should not be used in patients with phenylketonuria. However, there may be a number of conditions where treatment with Dioralyte Relief may be inappropriate, e.g. intestinal obstruction requiring surgical intervention, cases of severe renal or hepatic impairment.

4.4 Special warnings and precautions for use

For oral administration only. Dioralyte Relief should not be reconstituted in diluents other than water.

Each sachet should always be dissolved in 200ml water.

Dioralyte Relief should not be administered to infants under 3 months and for those aged 3 months to 1 year, administered under medical advice.

Infants under the age of 2 with diarrhoea should be seen by the physician as soon as possible.

If diarrhoea persists unremittingly for longer than 36 hours the patient should be reassessed by the physician.

No specific precautions are necessary in the elderly. However, care should be taken when administering Dioralyte Relief solution in conditions where normal electrolyte balance may be disturbed (such as severe vomiting or diarrhoea). Dioralyte Relief should not be used for self-treatment by patients on low potassium or sodium diets.

The use of Dioralyte Relief in patients with the following conditions should be supervised by a physician:

• On low potassium or low sodium diets.

This medicine contains 190 mg sodium (main component of cooking/table salt) in each sachet, equivalent to 10 % of the WHO recommended maximum daily dietary intake of 2g of sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, Pregnancy and lactation

Dioralyte Relief is not contraindicated in pregnancy or lactation but should be used on medical advice.

Pregnancy

There is limited data available on the use of Dioralyte Relief in pregnant women. However, no conclusions can be drawn whether Dioralyte Relief is safe for use during pregnancy or not. Dioralyte Relief should be used during pregnancy only if the potential benefits to the mother outweigh the potential risks, including those to the fetus.

Lactation

There is limited data available on the presence of Dioralyte Relief in human milk, milk production, or the effects on the breastfed infant. However, no conclusions can be drawn whether Dioralyte Relief is safe for use during breastfeeding or not. Dioralyte Relief should be used during breastfeeding only if the potential benefits to the mother outweigh the potential risks, including those to the breastfed child.

4.7 Effects on ability to drive and use machines

Dioralyte Relief could not be expected to affect the ability to drive or use machines.

4.8 Undesirable effects

The information below lists reported adverse reactions, ranked using the following frequency classification:

Very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); very rare (<1/10,000), not known (cannot be estimated from the available data).

Immune system disorders

Not known: Hypersensitivity

Reporting of suspected adverse reactions

Reporting suspected adverse reaction after authorisation of the medicinal product is important. It allows continued monitoring of the benefit / risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse

reactions via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

In the event of significant overdose, serum electrolytes should be evaluated as soon as possible, appropriate steps taken to correct any abnormalities and levels monitored until return to normal levels is established. This is particularly important in the very young and in cases of severe hepatic or renal failure.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Dioralyte Relief contains a balanced amount of electrolytes, starch and proteins in water. Oral rehydration therapy with Dioralyte Relief enables a dehydrated subject to be rehydrated rapidly. The presence of pre-cooked rice in the formulation enables watery stools to return to normal more rapidly.

The advantages of Dioralyte Relief are bound with its composition.

- *Water:* the appropriate amount is essential to correct dehydration.
- *Starch:* low osmotic capacity (unlike pure glucose) thus preventing any additional loss of fluid through the stools. Rice starch contains 20% amylose and 80% amylopectin.
- *Proteins:* specific nutritional properties.
- *Electrolytes:* essential for restoring the ionic equilibrium. The role of citrate is to correct the acidosis that occurs as a result of diarrhoea. Citrate also enhances the absorption of Na^+ and is more stable than bicarbonate.

5.2 Pharmacokinetic properties

Content of electrolytes in the reconstituted preparation:

Na^+	60 mmol/l
$C1^-$	50 mmol/l
K^+	20mmol/l

Citrate	10 mmol/l (or 30 meq/l)
Osmolarity	140 mosml/l

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Raspberry Flavour Givaudan 611417E

Hypromellose

Aspartame

Ethanol 96%

Purified Water

6.2 Incompatibilities

None known.

6.3 Shelf life

A shelf life of 36 months is given for unopened sachets of the product when stored under the conditions given in section 6.4. Once reconstituted, any solution should be used within one hour, or within 24 hours if stored in a refrigerator.

6.4 Special precautions for storage

Store in a dry place under 25°C.

6.5 Nature and contents of container

Carton containing paper/PVDC sachets of Dioralyte Relief Raspberry powder. Dioralyte Relief Raspberry is available in packs of 6 or 20 sachets.

Dioralyte Relief Blackcurrant & Raspberry is available as a pack of 6 sachets containing:

4 sachets blackcurrant flavour*, 2 sachets raspberry flavour

Dioralyte Relief Raspberry & Blackcurrant is available as a pack of 6 sachets containing:

4 sachets raspberry flavour, 2 sachets blackcurrant flavour*

(*, blackcurrant formulation PL 04425/0273).

6.6 Special precautions for disposal

See section 4.2 for instructions on reconstitution.

7 MARKETING AUTHORISATION HOLDER

Phoenix Labs Unlimited Company,

Suite 12, Bunkilla Plaza,

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Clonee,

Co. Meath,

Ireland.

8 MARKETING AUTHORISATION NUMBER(S)

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3 March 2009

10 DATE OF REVISION OF THE TEXT

30/06/2023