Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Dioralyte Blackcurrant Powder for Oral Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains:

Sodium chloride Ph. Eur. 0.47 g
Potassium Chloride Ph. Eur. 0.30 g
Glucose Ph. Eur. 3.56 g
Disodium Hydrogen Citrate B.P. 0.53 g

Excipients: also includes ethanol, less than 100 mg per dose.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution
White, homogeneous, granular powder with an odour and taste of blackcurrant.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Dioralyte is indicated for use in infants, children and adults for the oral correction of fluid and electrolyte loss of gastrointestinal origins and in the management of watery diarrhoea.

4.2 Posology and method of administration

The contents of each sachet should be dissolved in 200ml (approximately 7 fluid ounces) of drinking water. Use fresh drinking water for adults and children. For infants where drinking water is unavailable the water should be freshly boiled and cooled. The solution should be made up immediately before use. If refrigerated, the solution may be stored for up to 24 hours, otherwise any solution remaining an hour after reconstitution should be discarded.
The solution must not be boiled after reconstitution.

Daily intake may be based on a volume of 150ml/kg body weight for infants up to the age of 24 months and 20-40 ml/kg body weight for adults and children. A reasonable approximation is:

Infants under 24 months	Use only under medical advice. One to one and a half times the usual 24 hour feed volume.
Children over 24 months	One sachet after every loose stool.
Adults including elderly	One or two sachets after every loose stool.

More may be required initially to ensure early and full volume repletion.
If diarrhoea persists for longer than 24 to 36 hours the patient should be seen by a doctor.
Do not exceed the maximum daily dose of 14 sachets.
The product should not be used for more than 5 days.

<u>Special population</u>
No specific dose adjustment for the use of Dioralyte in elderly patients is recommended.
For patients with renal or hepatic impairment see section 4.4.

4.3 Contraindications

Hypersensitivity to the active substances or to any of the excipients.

4.4 Special warnings and precautions for use

Dioralyte should not be used for treatment in infants below the age of 24 months without medical supervision.

Dioralyte should not be used for self-treatment by patients with:

- Chronic or persistent diarrhoea
- Liver or kidney disease
- Diabetes
- On low potassium or sodium diets
- Intestinal obstruction The use of Dioralyte in patients with these conditions should be supervised by a doctor. The solution must not be reconstituted except with water at the volume stated.A weaker solution than recommended will not contain the optimal glucose and electrolyte concentration and a stronger solution than recommended may give rise to electrolyte imbalance. If there is no improvement within 24-36 hours the physician should be consulted.If nausea and vomiting are present with the diarrhoea, small but frequent amounts of dioralyte should be drunk at first. For use in the elderly no specific precautions are necessary. However, care should be taken when administering glucose-electrolyte solutions in cases of severe renal or hepatic impairment or other conditions where the normal electrolyte balance may be distributed.

4.5 Interaction with other medicinal products and other forms of interactions

None.

4.6 Fertility, pregnancy and lactation

Medical supervision is recommended for use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None stated.

Reporting of suspected adverse reactions
Reporting of suspected adverse reactions 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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

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 is an oral rehydration therapy. The combination of electrolytes stimulates water and electrolyte absorption from the gastro-intestinal tract and therefore prevents dehydration in diarrhoea.

5.2 Pharmacokinetic properties

Sodium and glucose are actively transported via the membrane into the enterocytes. Sodium is then extruded into the intercellular spaces and the resulting osmotic gradient causes water and electrolytes to be drawn from the gut and then into the circulation.

5.3 Preclinical safety data

None.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colloidal Anhydrous Silica
Saccharin Sodium
Blackcurrant flavour
(containing ethanol)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years.

6.4 Special precautions for storage

Store below 25°C. Store in the original package in order to protect from moisture. The reconstituted solution should be used immediately but may be stored for up to 24 hours in a refrigerator at 2-8°C.

6.5 Nature and contents of container

Foil/polyethylene laminates sachets containing powder for reconstitution, packed in outer cartons.
Pack sizes: 3, 6, 7, 10, 14, 20, 30 Sachets.
Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

The solution should be prepared immediately before use.
The contents of each sachet should be dissolved in 200ml (approximately 7 fluid ounces) of drinking/cooled boiled water where relevant. Dioralyte should only be prepared with water and to the volume stated. The solution must be boiled after reconstitution.

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare France SAS T/A Sanofi
82 Avenue Raspail
94250 Gentilly
France

8 MARKETING AUTHORISATION NUMBER

PA23180/006/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 3rd June 1992

Date of last renewal: 3rd June 2007

10 DATE OF REVISION OF THE TEXT

October 2021