SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Dioralyte Natural

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Glucose	3.56g
Sodium chloride	0.47g
Potassium chloride	0.30g
Disodium hydrogen citrate	0.53g

Excipient with known effect: Each sachet contains approximately 300 mg of sodium.

For a full list of excipients see, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for reconstitution with 200ml water.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

For treatment of fluid and electrolyte loss associated with acute diarrhoea.

4.2 Posology and method of administration

Route of administration: Oral

RECONSTITUTION

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

A basic principle of treatment of diarrhoea is to replace lost fluid and electrolytes and then to maintain sufficient fluid intake to replace fluid loss from stools. The amount of reconstituted Dioralyte administered should be adapted to the age and weight of the patient and the stage and severity of the condition.

Severe dehydration may need to be corrected by parenteral fluids initially, followed by oral maintenance if indicated. If the loss of fluid in the diarrhoea is excessive, medical advice should be sought.

Daily intake may be based on a volume of 150ml/kg body weight for infants up to the age of 2 and 20-40ml/kg body weight for adults and children.

A reasonable approximation is:

Infants up to the age of 2:

One to one and a half times the usual 24 hour feed volume.

Children:

One sachet dissolved in 200ml of water after every loose motion.

Adults (including the elderly):

One or two sachets after every loose motion. Each sachet should be dissolved in 200ml of water.

More may be required initially to ensure early and full volume repletion.

In the initial stages of treatment of diarrhoea all foods, including cow's or artificial milk, should be stopped. However breast milk need not be withheld. In breast fed infants it is suggested that the infant is given the same volume of Dioralyte as the bottle fed baby and then put to the breast until satisfied. Expression of residual milk from the breasts may be necessary during this period. After 24-48 hours, when symptoms have subsided, the normal diet should be resumed but this should be gradual to avoid exacerbation of the condition.

When vomiting is present with the diarrhoea it is advisable that small amounts of Dioralyte be taken frequently. However, it is important that the whole of the required volume of Dioralyte be taken. Where the kidneys are functioning normally, it is difficult to over-hydrate by mouth and where there is doubt about the dosage, more rather than less should be taken. If no improvement is seen within 24-48 hours it is recommended that the patient be seen by a physician.

4.3 Contraindications

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

There are no known contraindications to Dioralyte. However, there may be a number of conditions where treatment with Dioralyte will be inappropriate e.g. intestinal obstruction requiring surgical intervention.

4.4 Special warnings and precautions for use

For oral administration only. Dioralyte should not be reconstituted in diluents other than water. Each Sachet should always be dissolved in 200ml of water. 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 diarrhoea persists for longer than 24-48 hours the patient should be seen by a physician. Dioralyte should not be used for the self treatment of chronic or persistent diarrhoea except under medical supervision. Dioralyte shall not be used for treatment in infants below the age of 24 months without medical supervision. Infants under the age of 2 years with diarrhoea should be seen by a physician as soon as possible. No specific precautions are necessary in the elderly.

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

- with chronic or persistent diarrhea.
- with liver or kidney disease.
- with diabetes.
- on low potassium or sodium diets.
- with an intestinal obstruction.

The use of Dioralyte in patients with these conditions should be supervised by a physician.

If nausea and vomiting are present with the diarrhoea, small but frequent amounts should be drunk at first.

Excipients

This medicinal product contains approximately 300 mg sodium per sachet, equivalent to 15% of the WHO recommended maximum daily intake of 2 g sodium for an adult.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6 Fertility, Pregnancy and lactation

Dioralyte is not contra-indicated in pregnancy or lactation.

Medical supervision is recommended for use during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

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

4.8 Undesirable effects

None stated

Reporting of suspected adverse reactions

Reporting 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 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 an 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 of 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 GI tract and therefore prevents or reverses 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

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin sodium

Silicon dioxide

6.2 Incompatibilities

None stated.

6.3 Shelf life

Foil/Laminate sachets 36 months

6.4 Special precautions for storage

Store below 25°C. Store in the original package in order to protect from moisture.

6.5 Nature and contents of container

Foil/Laminate sachets containing powder for reconstitution with 200mL water.

6.6 Special precautions for disposal

The contents of each sachet should be dissolved in 200mL (approximately 7 fluid ounces) of drinking water.

7 MARKETING AUTHORISATION HOLDER

Opella Healthcare UK Limited, trading as Sanofi,
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8 MARKETING AUTHORISATION NUMBER(S)

PL 53886/0017

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