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

Exipients-Also contains ethanol

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Powder for oral solution
Product imported from UK:
White, homogeneous, granular powder with an odour and taste of blackcurrant

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

In the oral correction of fluid and electrolyte loss and 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 (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 and 20-40 mg/kg body weight for adults and children. A reasonable approximation is:

Infants – One to one and a half times the usual feed volume. For infants under 12 months, use only under medical advice.
Children – One sachet after every loose motion.
Adults including elderly – One or two sachets after every loose motion. More may be required initially to ensure early and full volume repletion.

4.3 Contraindications

There are no known contra-indications to Dioralyte.

4.4 Special warnings and precautions for use

Special labelling requirements.

1. The solution must not be reconstituted except with water at the volume stated.
2. Solutions of greater concentration may result in hypernatraemia. Those of greater dilution may result in inadequate replacement.
3. If there is no improvement within 24-36 hours the physician should be consulted.
4. For infants under 12 months use only on medical advice.
5. If nausea and vomiting are present with the diarrhoea, small but frequent amounts of dioralyte should be drunk at first.
6. 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 interaction

None.

4.6 Fertility, pregnancy and lactation

Dioralyte is not contra-indicated in pregnancy or lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

None stated.

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

Saccharin Sodium
Silicone Dioxide
Blackcurrant Flavour (containing ethanol)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

The shelf-life expiry date of this product is the date shown on the carton and sachet of the product on the market in the country of origin.

6.4 Special precautions for storage

Do not store above 25°C
The reconstituted solution should be used immediately but may be stored for up to 24 hours in a refrigerator at 2-8^{o}C

6.5 Nature and contents of container

Overlabelled sachet containing blackcurrant powder in an overlabelled outer carton
Pack size: 6 sachets

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

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 not be boiled after reconstitution.

7 PARALLEL PRODUCT AUTHORISATION HOLDER

G & A Licensing Limited
Ballymurray
Co. Roscommon
Ireland

8 PARALLEL PRODUCT AUTHORISATION NUMBER

PPA1447/72/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th June 2010.

10 DATE OF REVISION OF THE TEXT