SUMMARY OF PRODUCT CHARACTERISTICS FOR ORASOL

1. Name of the medicinal product

Orasol

2. Qualitative and quantitative composition

Each sachet contains:

Dextrose Anhydrous	BP	75mmol/litre
Sodium	BP	75mmol/litre
Chloride	BP	65mmol/litre
Potassium	BP	20mmol/litre
Citrate	BP	10mmol/litre

3. Pharmaceutical form

Granules to be reconstituted for oral administration.

Description of the product:

Free flowing orange coloured granular powder with an orange flavor free from any visible impurities.

4. Clinical particulars

4.1 Therapeutic indications

For the treatment of acute diarrhoea and the treatment and prevention of dehydration by replacing fluids and electrolytes lost through diarrhoea.

4.2 Posology and method of administration

Prevention of dehydration (WHO - Treatment plan A)
Child under 24 months: 50 to 100 ml after each loose stool (approximately 500 ml daily)
Child from 2 to 10 years: 100 to 200 ml after each loose stool (approximately 1000 ml daily)
Child over 10 years and adult: 200 to 400 ml after each loose stool (approximately 2000 ml daily)

– Treatment of moderate dehydration (WHO - Treatment plan B)
Child and adult:
Over the first four hours:

Age	**under 4 months**	**4 to 11 months**	**12 to 23 months**	**2 to 4 years**	**5 to 14 years**	**15 years and over**
Weight	under 5 kg	5 to 7.9 kg	8 to 10.9 kg	11 to 15.9 kg	16 to 29.9 kg	30 kg and over
Orasol in ml	200 to 400	400 to 600	600 to 800	800 to 1200	1200 to 2200	2200 to 4000

– *Treatment of severe dehydration (WHO - Treatment plan C)*
In combination with IV therapy and only to a conscious patient:
Child and adult: 5 ml/kg per hour
After 3 hours (6 hours in infants), reassess and choose the appropriate plan *A*, *B* or *C*.

After four hours:
If there are no signs of dehydration: follow *Treatment plan A.*
If there are signs of moderate dehydration: repeat *Treatment plan B.*
If there are signs of severe dehydration: start IV therapy (*Treatment plan C*).

Duration

– As long as diarrhoea and signs of dehydration persist.

Infants under 1 year:

Should be instructed by a doctor

During the first 24 hours of illness Orasol should replace normal feeds in bottle fed babies, gradually resuming normal feeds as the baby gets better. In breast fed babies, firstly the recommended amount of Orasol should be given and then breast fed until satisfactory.

Reconstitution

The contents of each sachet should be dissolved in 1000 ml of fresh drinking water (adults and children). Freshly boiled and cooled water should be used for infants and when fresh water is not available. The solution should be made up immediately before use and used within 24 hours.

A doctor should be consulted if symptoms persist for longer than 24 – 48 hours.

4.3 Contraindications

Contraindicated in patients with phenylketonuria or those with hypersensitivity to any of the ingredients.

Oral treatment is inappropriate in such conditions as severe dehydration, which requires parenteral fluid therapy or intestinal obstruction.

4.4 Special warnings and precautions for use

Severe and persistent diarrhoea should be treated under medical supervision. If symptoms persist for more than 24 — 48 hours, medical advice should be sought. Inability to drink or retain fluids requires medical supervision.

Children

• Rehydration treatment should only be given to children under 1 year of age on medical advice.

• If a young child (particularly one under 6 months of age) has diarrhoea and/or vomiting advice should be sought from a pharmacist, doctor or other health care professional. If the diarrhoea and/or vomiting is severe the child should be seen by a doctor as soon as possible.

Renal Impairment

• Medical supervision is necessary in patients with renal disease, including anuria and prolonged oliguria.

Hepatic Impairment: Low potassium or Sodium diets: Diabetes

• Treatment should be supervised by a physician.

This product contains dextrose. Patients with rare-glucose-galactose malabsorption should not take this medicine.

4.5 Interaction with other medicinal products and other forms of interaction

None stated.

4.6. Pregnancy and lactation

May be used during pregnancy and lactation as there are no known adverse effects.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

None stated.

4.9 Overdose

If significant overdosage occurs, serum and electrolytes should be evaluated. Corrective measures should be carried out and levels monitored until a return to normal levels is achieved.

5. Pharmacological properties

5.1 Pharmacodynamic properties

The product consists of physiological salts and glucose, which are used synergistically in solution to aid rehydration. The pharmacodynamic effect is to counter the drop in the extracellular fluid volume and electrolytes in mild to moderate diarrhoea.

5.2 Pharmacokinetic properties

None relevant.

5.3 Preclinical safety data

None stated.

6. Pharmaceutical particulars

6.1 List of excipients

Orange Essence, Sunset Yellow Colour, Aerosil.

6.2 Incompatibilities

None stated.

6.3 Shelf life

36 Months shelf-life.

6.4 Special precautions for storage

Store below 30°C in a dry place.

6.5 Nature and contents of container

Foil - laminate sachets

6.6 Special precautions for disposal and other handling

None stated.

7. Manufacturer and Marketing Authorisation Holder

Biodeal Laboratories Limited,

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9. Date of first authorisation/renewal of the authorisation

September 1998.

10. Date of revision of the text

April 2018