1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

1- Name of the Medicinal Product:

1.1 Product Name

Generic Name or International Non-Proprietary Name (INN)

Oral Rehydration Salts BP 20.5 gm

Brand Name

PINNACLE ORS

1.2 Dosage Strength

Each sachet contains (to produce 1000 ml)

Sodium Chloride BP…….2.6 gm

Potassium Chloride BP……..1.5 gm

Sodium Citrate BP…….2.9 gm

Anhydrous glucose BP……..13.5 gm

Excipients…….q.s.

1.3 Dosage Form

Powder

2- Quality and Quantitative Composition:

2.1 Qualitative Declaration

Each sachet contains (to produce 1000 ml)

Sodium Chloride BP…….2.6 gm

Potassium Chloride BP……..1.5 gm

Sodium Citrate BP…….2.9 gm

Anhydrous glucose BP……..13.5 gm

Excipients…….q.s.

2.2 Quantitative Declaration

Sr. No.	Ingredients	Spec.	mg/tab	Qty./Batch 63,200 in kg	Function
Sifting/Mixing					
1	Sodium Chloride	BP	2.600	164.320	Active
2	Potassium Chloride	BP	1.500	94.800	Active
3	Sodium Citrate	BP	2.900	183.280	Active
4	Dextrose Anhydrous	BP	13.595	859.204	Active
5	Colloidal Anhydrous Silica (Colloidal Silicon Dioxide)	BP	0.050	3.160	Glidant
6	Acesulfame Potassium	BP	0.020	1.264	Diluent
Average Net Content of Sachet			**20.67 gm ± 5%**		

Note: Active material was calculated on assay or Potency Basis.
BP = British Pharmacopoeia

3- Pharmaceutical Form:

White color free flowing powder.

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

Infants under 1 year:

Not to be given unless instructed by a doctor, in which case one to one and a half the usual 24 hour feed volume should be given.

During the first 24 hours of illness Replavite 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 Replavite should be given and then breast fed until satisfactory.

Children 1 to 12 years:

The contents of one sachet to be taken after each loose motion.

Adults, the elderly and children over 12 years:

The contents of one or two sachets to be taken after each loose motion.

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
ORS in ml	200 to 400	400 to 600	600 to 800	800 to 1200	1200 to 2200	2200 to 4000

Method of administration

Granules to be reconstituted for oral administration

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 warning 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 are 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.

Use with caution in patients with pre-existing blood disorders, gout, dental disease, liver disease or heart disease. This medication is classified as pregnancy category C and should be used during pregnancy or lactation only if clearly needed. These are not appropriate for patients with gastrointestinal obstruction, oliguric or anuric renal failure oral rehydration salts should be reconstituted only with water.

4.5 Interaction with other medicinal products and other forms of interaction

None stated

4.6 Fertility, 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 machine

None stated

4.8 Undesirable effects

None Stated

4.9 Overdose and treatment

If significant over dosage 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 Pharmacodynamics 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

This ORS composition has passed extensive clinical evaluations and stability tests. The pharmacokinetics and therapeutic values of the substances are as follows:

1. Glucose facilitates the absorption of sodium (and hence water) on a 1:1 molar basis in the small intestine;
2. Sodium and potassium are needed to replace the body losses of these essential ions during diarrhoea (and vomiting);

Citrate corrects the acidosis that occurs as a result of diarrhoea and dehydration.

5.3 Preclinical safety Data

None stated

6- Pharmaceutical Particulars :

6.1 List of excipients

Colloidal Anhydrous Silica

Acesulfame Potassium

6.2 Incompatibilities

None known

6.3 Shelf life

Powder having shelf-life of 36 Months.

The reconstituted solution should be discarded after 1 hour or 24 hours if stored in a refrigerator.

6.4 Special precautions for storage

Store below 30°C. Protect from light.

6.5 Nature and contents of container

3 Sachets packed in one carton along with its package insert. Such cartons packed in export worthy shipper.

Note: All pack may not be marketed.

7- Marketing Authorization Holder: Pinnacle Health Pharmaceutical & Store

8- Marketing Authorization Number(s): G/25/1749

Product license / registration Number (s)

9- Manufacturer Name:

-Name	**:**	**GLOBELA PHARMA PVT. LTD.**
- Address	**:**	Plot No. 357-358, Unit-I G.I.D.C., Sachin, Surat – 394 230, Gujarat, India.
- Phone	**:**	+91– 261–6158000
- E-mail	**:**	info@globelapharma.com

10- Date of first authorization/renewal of the Authorization: 13/10/2016

11- Date of revision of the text: