SUMMARY OF PRODUCTS CHARACTERISTICS

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

OSMOLYTE
Oral Rehydration Salts BP

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains (27.9 gm);

Sodium Chloride BP	: 3.5 gm
Potassium Chloride BP	: 1.5 gm
Sodium Citrate BP	: 2.9 gm
Anhydrous Glucose BP	: 20 gm
Excipients	: Q.S.
Colour	: Sunset Yellow

For excipients, see 6.1.

3. PHARMACEUTICAL FORM

Powder
For oral administration.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

For the treatment of diarrhoea and fluid loss due to diarrhoea in infants, children and adults.

4.2 Posology and method of administration

Dissolve the contents of one sachet in 1Litre of previously boiled and cooled water. The solution should be given hourly in quantities sufficient to provide for the loss of fluid, or as directed by a doctor. In cases of children with acute diarrhoea the solution must be used as indicated by thirst. Any unused solution must be discarded after 24 hours. Do not exceed 27.9 g (or 1L of solution) per 24 hours.

Method of Administration
Oral

4.3 Contraindications

- Should not be given to patients with glucose-galactose malabsorption syndrome or with anuria.
- Care should be taken when given to patients with renal failure and diabetes insipidus.
- Hypersensitivity to any of the components.

- Cardiac failure, patients with very severe vomiting, diarrhoea and dehydration requiring fluid therapy.

- It should not be used when there is peripheral or pulmonary oedema or toxaemia of pregnancy.

4.4 Special warnings and precautions for use

- It is very important to dissolve oral rehydration salts in water of the correct volume. A weak solution will not contain optimum glucose and electrolyte concentration and a strong solution may give rise to electrolyte imbalance.
- Diarrhoea can have very serious consequences in children under 3 years old. Immediate medical advice should be sought.
- In other age groups, if symptoms persist for more than 24 - 48 hours, consult your doctor.
- If nausea and vomiting are present with the diarrhoea, small and frequent amounts of oral rehydration salts should be drunk first. In infants, immediate medical assistance should be obtained.
- Keep out of the reach of children.
- Use within one hour of reconstitution, or within 24 hours if stored in a refrigerator.
- 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.
- The solution must not be reconstituted except with water at the volume stated.
- Solutions of greater concentration may result in hypernatraemia. Those of greater dilution may result in inadequate replacement.

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Pregnancy and lactation

Can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

None known

4.8 Undesirable effects

None known

4.9 Overdose

OSMOLYTE overload is managed by sodium, potassium and water restriction plus measures to increase renal sodium, potassium and water loss such as “loop diuretics”
e.g. Frusemide.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Oral rehydration salt formulations

ATC code: A07CA

The reconstituted solution contains a mixture of sodium and potassium salts along with glucose, which facilitates the absorption of sodium and potassium from the intestine. Water is drawn from the bowel by the osmotic effect. As well as "drying- up" the stools, the dehydration and loss of electrolytes caused by the diarrhoea is corrected by the water and electrolytes absorbed.

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

Not applicable

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Name of Material	Specification
Flavoured orange dry	IHS
Colour sunset yellow supra	IHS
Aspartame	BP
Colloidal Anhydrous Silica	BP

6.2 Incompatibilities

NA

6.3 Shelf life

36 Months

6.4 Special precautions for storage

Store in a dry place below 30°C. Store solution in a refrigerator and discard any unused solution after 24 hours.
KEEP OUT OF REACH OF CHILDREN.

6.5 Nature and contents of container

1x 3 sachet packed in Box.

6.6 Instructions for use and handling

No special requirements.

7. MARKETING AUTHORISATION HOLDER

Ahmedabad
Gujarat, India.
E-mail: info@sagalabs.com
URL: www.sagalabs.com

8. NUMBER(S) IN THE NATIONAL REGISTER OF FINISHED PHARMACEUTICAL PRODUCTS

06963/08400/NMR/2020

9. DATE OF FIRSHT AUTHORISATION/RENEWAL OF THE AUTHORISATION

27/12/2021

10. DATE OF REVISION OF THE TEXT

01 April 2026