SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal Product
MAXALYTE (Oral Rehydration Salts BP 20.5 gm)

2. Qualitative and quantitative composition

Sr. No	Ingredients Chemical Name	Specification	Qty. Required / Sachet (gm)	Function
1	Anhydrous Glucose	BP	13.500	Active
2	Sodium Chloride	BP	2.600	Active
3	Sodium Citrate	BP	2.900	Active
4	Potassium Chloride	BP	1.500	Active
5	Flavour Orange Powder	HIS	0.100	Flavoring agent

3. Pharmaceutical form
Oral Rehydration
Description: White to off white coloured crystalline powder.

4. Clinical particulars
4.1 Therapeutic indications
Oral rehydration salt is indicated for the treatment of acute diarrhea and the treatment and prevention of dehydration by replacing fluids and electrolytes lost through diarrhoea.

4.2 Posology and method of administration
Adults, the elderly and children over 12 years:
The contents of one or two sachets to be taken after each loose motion.

Children 1 to 12 years:
The contents of one sachet to be taken after each loose motion.

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 Relative should be given and then breast fed until satisfactory.

Reconstitution
The contents of each sachet should be dissolved in 200 ml (7 fluid ounces) 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 one hour. If refrigerated the solution can be kept for up to 24 hours. A doctor should be consulted if symptoms persist for longer than 24 – 48 hours.

Method of administration
For oral use

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

Sodium Bicarbonate
Increases excretion of lithium, resulting in a reduced plasma-lithium concentration.

Potassium Chloride
ACE inhibitors (hyperkalemia); cyclosporine (increased risk of hyperkalemia).
Potassium sparing diuretics where hyperkalemia may result. No known interactions to other actives.

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 machines
No studies on the effects on the ability to drive and use machines have been performed.

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 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 diarrhea is corrected by the water and electrolytes absorbed.

Pharmacotherapeutic group: Electrolytes with Carbohydrates
ATC Code: A07CA

5.2 Pharmacokinetic properties
Glucose
After oral administration glucose is completely absorbed by a sodium dependent uptake mechanism exhibiting saturation kinetics. Blood levels return to normal within two hours of ingestion.

Potassium Chloride
No specific control mechanisms limit absorption of potassium, which is usually complete. Potassium is excreted largely by the kidneys, though 10% is excreted by the colonic mucosa. Potassium excretion is reduced in patients with renal impairment and in the elderly, so extreme caution should be used in treating such patients with potassium salts.

Sodium Bicarbonate
Kinetics are determined by the physiological state of the patient at the time.

Sodium Chloride
Readily absorbed from the gastrointestinal tract. Gut absorption, particularly in the jejunum is enhanced by the addition of glucose. Under conditions of sodium balance, the excretion of sodium in the urine will match intake.

5.3 Pre-clinical safety data
Not Applicable

6. Pharmaceutical particulars

6.1 List of excipient
Flavour Orange Powder

6.2 Incompatibilities
Not applicable.

6.3 Shelf life
36 Months

6.4 Special precautions for storage
Store below 30°C. Protect from light & moisture.

6.5 Nature and contents of container
20.5 gm powder packed in aluminum foil sachet. Such 25 sachets' are packed in carton along with an insert.

6.6 Special precautions for disposal <and other handling>
Not Applicable

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES:

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8. Marketing authorization number
TAN 21 HM 0092

9. Date of first <registration>/renewal of the <registration>
29/03/2021

10. Date of revision of text:
March, 2021