| HALEWOOD LABORATORIES PVT. LTD. | |
|---|---|
| BRAND NAME: | **Tylife O** |
| GENERIC NAME: | Oral Rehydration Salts BP 21.0 gm |

## SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

### 1. Name of drug product

Tylife O

### 1.1 (Trade) name of product

Oral Rehydration Salts BP

### 1.2 Strength

Each sachet of 21 gm contains:

Glucose anhydrous BP 13.5 gm

Sodium chloride BP 2.6 gm

Potassium chloride BP 1.5gm

Sodium citrate BP 2.9 gm

Excipients Q.S.

### 1.3 Pharmaceutical Dosage Form

Powder for oral administration

### 2. QUALITATIVE & QUANTITATIVE COMPOSITION

### 2.1 Qualitative Declaration

Each sachet of 21 gm contains:

Glucose anhydrous BP 13.5 gm

Sodium chloride BP 2.6 gm

Potassium chloride BP 1.5gm

Sodium citrate BP 2.9 gm

Excipients Q.S.

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**2.2 Quantitative Declaration**

**Batch size: 40,000 pouches**

**Qualitative and Quantitative Formula for batch (40,000 pouches)**

| Sr. No. | Name of material | Label Claim (in gm) | Overages | Qty./ Sachet (in gm) | Qty/batch in kg | Function |
|---|---|---|---|---|---|---|
| 1 | Glucose (anhydrous) BP | 6.75 | 3.03% | 6.953 | 278.12 | Active |
| 2 | Sodium Chloride BP | 1.30 | --- | 1.30 | 52.00 | Active |
| 3 | Potassium Chloride BP | 0.75 | --- | 0.75 | 30.00 | Active |
| 4 | Sodium Citrate BP | 1.45 | --- | 1.45 | 58.00 | Active |
| 5 | Flavour Orange IHS | Q.S. | --- | Q.S. | 1.90 | Flavouring Agent |

## 3. PHARMACEUTICAL DOSAGE FORM

Powder for oral administration

## 4. CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

Oral replacement therapy of electrolyte and fluid loss in children and adults arising from dehydration associated with acute diarrhea.

### 4.2 Posology and Method of Administration

Reconstitution: Only with water and at the volume stated.

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**Adults and children:** The content of each sachet should be dissolved in approximately 500 ml of cool, fresh, clean drinking water. The resulting solution is both clear and colourless with an aroma of orange.

**Infants**: The water should be boiled then cooled before reconstitution as above.

The reconstituted cooled solution should be used immediately and the unused remainder discarded, or stored in a refrigerator for no longer than 24 hours. Do not boil after reconstitution. The product must only be used at the recommended dilution.

**Dosage:** Oral fluid replacement and maintenance therapy must be tailored to individual patient's needs. The volume of solution used will depend on the weight and age of the patient, using the basic principle of firstly rehydrating the patient by replacing lost fluid and thereafter maintaining fluid replacement in line with the volume of fluid lost from stools or vomiting plus normal daily requirements. As a basic guide, a daily intake of 150 ml/kg bodyweight for infants (under 2 years of age) or 20-40ml/kg for adults and children is needed.

**Replacement of fluid losses with ORS solution**

Infants (under 2 years of age): See special warnings and precautions for use. Reconstitute sachets according to directions and administer at 1-1.5 times usual feed volume. No milk (other than breast milk) or solids should be given during the first 24 hours. In breast-fed infants, ORS should be given before the feed. The re-introduction of normal feeding should only take place when symptoms of diarrhoea are abating and should be added gradually to make up the total daily fluid requirements.

Child 1–11 months: 1–1½times usual feed volume to be given

Child 1–11 years: 200 mL, to be given after every loose motion

Child 12–17 years: 200–400 mL, to be given after every loose motion, dose according to fluid loss

Adult: 200–400 mL, to be given after every loose motion, dose according to fluid loss.

In adults and children ORS can be given in amounts necessary to satisfy thirst. As with infants, solids should be avoided during the first day, but may be gradually resumed as necessary during day 2.

It is extremely difficult to over-hydrate by mouth, thus when there is normal renal function, it is better to give more ORS than less.

**4.3 Contraindications**

Hypersensitivity to any of the ingredients.

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

It is necessary for medical supervision in the presence of renal disease, including anuria or prolonged oliguaria, severe and persistent diarrhea and vomiting, inability to drink or retain oral fluids.

**4.4 Special Warnings and Precautions for Use**

Infants under the age of 2 years with severe diarrhoea/vomiting should be seen by a doctor as soon as possible.

If symptoms persist for longer than 24-48 hours, a doctor should be consulted.

The solution must be made up without adding extra sugar or salt. In treating diabetics with gastro-enteritis, the sugar content must be noted.

Solutions of greater concentration may result in hypernatraemia. Those of greater dilution may result in inadequate replacement.

**4.5 Interaction with Other Drugs, Other Forms of Interactions** None known.

**4.6 Fertility, pregnancy and lactation**

The dose is the same as adult dose. Breast feeding can be continued as normal. If vomiting is a problem then ORS solution should be taken in frequent small volumes.

ORS is not contraindicated in pregnancy or lactation but should be used on medical advice.

**4.7 Effects on ability to drive and operate machine** None known.

**4.8 Undesirable effects**

None.

**4.9 Overdose**

In oral electrolyte replacement therapy, toxicity is rare in previously healthy people. In subjects with renal impairment, hypernatraemia and hyperkalaemia might occur.

In the event of significant overdose serum electrolytes should be evaluated by means of full biochemical profile under hospital conditions and the physician should take the appropriate measures. This is particularly important in the very young and in cases of severe hepatic or renal failure.

**5. Pharmacological properties**

**5.1 Pharmacodynamic properties**

| | |
|---|---|
| Sodium Chloride | Salts/Electrolytes |
| Potassium Chloride | |
| Sodium Citrate | Acid Neutraliser |
| Glucose Anhydrous | Carbohydrate Electrolyte carrier |

**5.2 Pharmacokinetic properties**

The formulation is based upon the well accepted WHO oral rehydration solution (ORS).

Glucose has been shown to greatly enhance the absorption of salts and water. The concentration used in ORS is very effective and has been demonstrated as giving a twenty five-fold enhancement of absorption compared with isotonic saline.

The level of sodium in ORS reflects the stool concentration in most cases of severe diarrhoea. Also, as the solution is more palatable, patient compliance is increased.

Potassium and Chloride are included to replace these electrolytes lost in the stool.

Citrate combats metabolic acidosis.

**5.3 Pre-clinical safety data**

None stated.

**6. Pharmaceutical particulars**

**6.1 List of excipients**

 Flavour Orange

**6.2 Incompatibilities**

Not Applicable

**6.3 Shelf-Life**

36 months from the date of manufacture.

**6.3 Special Precautions for Storage**

Store in cool and dry place. Protect from light and moisture.

Keep medicine out of reach of children.

**6.4 Nature and Contents of Container**

10.5 gm powder packed in laminated sachet.

**7. Marketing authorisation holder**

**HALEWOOD LABORATORIES PVT.LTD.**

Plot No. 319, Phase – II, G.I.D.C., Vatva,

Ahmedabad – 382445.

**8. Marketing authorisation number(s)**

Not Applicable

**9. Date of first authorisation/renewal of the authorisation**

Not Applicable

**10. Date of revision of the text**

Not Applicable