

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Electrolade (Lemon & Lime)

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each sachet contains 5.09 powder per/sachet

Sodium Chloride Ph.Eur.	0.236 g
Potassium Chloride Ph.Eur.	0.300 g
Sodium Bicarbonate Ph.Eur.	0.500 g
Anhydrous Dextrose Ph.Eur.	4.000 g

The reconstituted solution contains Sodium 50 mmol/L, Potassium 20 mmol/L, Chloride 40 mmol/L, Bicarbonate 30 mmol/L, Dextrose 111 mmol/L.

3 PHARMACEUTICAL FORM

Powder for oral solution.

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 diarrhoea.

4.2 Posology and method of administration

Reconstitution: Only with water and at the volume stated.

Adults and children: The content of each sachet should be dissolved in approximately 200 ml of cool, fresh, clean drinking water. The resulting solution is both clear and colourless and odourless.

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 patients 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 100-120 ml/kg for adults and children is needed.

Replacement of fluid losses with Electrolade 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, Electrolade 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.
Children:	One sachet after every loose motion, up to 12 sachets in 24 hours.
Adults:	1-2 sachets after every loose motion, up to 16 sachets in 24 hours.
	Elderly person: As for adults but care must be taken not to over-hydrate.

In adults and children Electrolade 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 Electrolade than less.

4.3 Contraindications

There are no absolute contra-indications to using Electrolade. However, it is necessary for medical supervision in the presence of renal disease, including anuria or prolonged oliguria, severe and persistent diarrhoea 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.

If there is no improvement within 24 hours to 48 hours the physician should be contacted.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

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

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

4.7 Effects on ability to drive and use machines

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. If these conditions occur, full biochemical profile under hospital conditions will be needed and the physician should take the appropriate measures.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium Chloride	}	Salts/Electrolytes
Potassium Chloride	}	

Sodium Bicarbonate	Acid Neutraliser
Dextrose Anhydrous	Carbohydrate Electrolyte carrier

5.2 Pharmacokinetic properties

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

Dextrose has been shown to greatly enhance the absorption of salts and water. The concentration used in Electrolade 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 Electrolade 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.

Bicarbonate combats metabolic acidosis.

Saccharin sodium is used as the sweetening agent, which also improves the general flavour.

5.3 Preclinical safety data

Not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Saccharin Sodium
Lemon & Lime Flavour

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years in the sealed sachet, not more than 24 hours after reconstitution.

6.4 Special precautions for storage

Electrolade should be stored in a dry place below 25°C.

6.5 Nature and contents of container

The powder is available in cartons containing 4, 6 or 20 individual sachets of powder and in Multiflavour pack of Banana, Orange, Blackcurrant and Lemon/Lime.

6.6 Special precautions for disposal

Keep this medicine out of the reach and sight of children. This medicine must not be used after the date (Exp) printed on the pack. Return any left over medicine to your pharmacist.

7 MARKETING AUTHORISATION HOLDER

Actavis Group PTC ehf
Reykjavíkurvegi 76-78
220 Hafnarfjörður
Iceland.

8 MARKETING AUTHORISATION NUMBER(S)

PL30306/0145

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

14th April 2003

10 DATE OF REVISION OF THE TEXT

11 DOSIMETRY (IF APPLICABLE)

12 INSTRUCTIONS FOR PREPARATION OF RADIOPHARMACEUTICALS (IF APPLICABLE)