

## New formulation of Oral Rehydration Salts (ORS) with reduced osmolarity

### Background:

Two decades ago diarrhoea was responsible for around 5 million deaths annually. Through major public health efforts primarily aimed at preventing and treating dehydration this figure has decreased to around 2 million deaths. Prevention of dehydration is primarily achieved by ensuring that children with diarrhoea are provided with more fluids than usual, and/or increased frequency of breastfeeding, during the acute episode. The combination of increased home fluids and the use of Oral Rehydration Salts (ORS) for the treatment of dehydration have proven to be a very powerful intervention for the prevention of childhood deaths from diarrhoea.

### Purpose:

For more than 25 years UNICEF and WHO have recommended a single formulation of glucose-based ORS to prevent or treat dehydration from diarrhoea irrespective of the cause or age group affected. This product, which provides a solution containing 90 mEq/l of sodium with a total osmolarity of 311 mOsm/l, has proven effective and without apparent adverse effects in worldwide use. It has been well established, however, that ORS solution does not reduce stool output or duration of diarrhoea. For this reason the current ORS might have had less than optimal acceptance by mothers and health workers, preferring a treatment that causes diarrhoea to stop. During the past 20 years numerous studies have been undertaken to develop an 'improved' ORS. The goal was a product that would be at least as safe and effective as standard ORS for preventing or treating dehydration from all types of diarrhoea but which, in addition, would reduce stool output or have other important clinical benefits. One successful approach is based on reducing the osmolarity of ORS solution to avoid possible adverse effects of hypertonicity on net fluid absorption. This was done by reducing the solution's glucose and salt (NaCl) concentrations.

Studies to evaluate this approach were reviewed at a meeting in July 2001\*, and technical recommendations were made to WHO and UNICEF on the efficacy and safety of reduced osmolarity ORS in children with acute non-cholera diarrhoea, and in adults and children with cholera.

### Launch of new formulation:

At UNICEF Supply Division, a bid for Reduced Osmolarity ORS was launched in September 2003 and two manufacturers were approved for the supply of new ORS formulation. The new ORS is in stock at UNICEF Supply Division. Phase out of the old ORS and phase in of the new ORS is taking place and the old ORS will for a short period of time remain part of the New Emergency Health Kit, as a certain stock of these kits was packed before the introduction of the new ORS. For the moment, the price of new ORS is approximately 15 per cent lower than the old ORS formulation.



### Formulation:

Reduced osmolarity ORS	grams/litre	Reduced osmolarity ORS	mmol/litre
Sodium chloride	2.6	Sodium	75
Glucose, anhydrous	13.5	Chloride	65

Potassium chloride	1.5	Glucose, anhydrous	75
Trisodium citrate, dihydrate	2.9	Potassium	20
		Citrate	10
		Total Osmolarity	245

### Composition of standard and reduced osmolarity ORS solutions

	Standard ORS solution	Reduced Osmolarity ORS solutions		
	(mEq or mmol/l)	(mEq or mmol/l) (21)	(mEq or mmol/l) (6, 14, 22-27)	(mEq or mmol/l) (13, 15-18, 28-29)
Glucose	111	111	75-90	75
Sodium	90	50	60-70	75
Chloride	80	40	60-70	65
Potassium	20	20	20	20
Citrate	10	30	10	10
Osmolarity	311	251	210-260	245

### New item numbers:

The item numbers will change as follows, as the new formulation replaces the existing ORS:

Old formulation	New formulation
1561110 - ORS, 1L sachet/Box-100	1561120 - ORS, 1L sachet/Box-100
1561111 - ORS, 1 L sachet/CAR-1000	1561121 - ORS, 1 L sachet/CAR-1000

Programme Division and Supply Division have prepared detailed questions and answers (Q&A) on the new ORS and common technical issues, provided below .

### Questions and Answers:

- Why has a 'New' Oral Rehydration Salts (ORS) formula been developed?
- Why 'reduced osmolarity'?
- Is diarrhoea really that much of a problem for children?
- When will the new ORS be available?
- What do I do with the old ORS solution? Should I discard it and only use the new low osmolarity ORS solution?
- What about local production of the new ORS?
- How should the new ORS solution be given?
- Is there any risk associated with the use of this new ORS?

- What is the cost of the new ORS?

### **Frequently Asked Technical Questions:**

- What should we advise mothers to give at home to a child with diarrhoea, but who has no signs of dehydration?
- Should I continue to breastfeed my child with diarrhoea?
- Should we advise mothers to continue to feed a child who has diarrhoea?
- When should I take my child with diarrhoea to a health centre?
- What should I do in case of vomiting?
- What should I do in case of electrolyte disturbances in a child with diarrhoea?
- What should I do if intravenous therapy is not available for a severely dehydrated child?
- When should I suspect cholera in a child with diarrhoea?
- How can I assess for dehydration in a severely malnourished child?
- What should I do in case of convulsions in a child with diarrhoea?
- Should we give vitamin A to a child with diarrhoea?
- Should we give zinc supplementation to a child with diarrhoea?
- Can I give anti-diarrhoeal drugs to a child with diarrhoea?
- What antimicrobials can be used with ORS in the clinical management of diarrhoea?
- How can we protect our water?
- How important is hand washing?

For more details, please contact the Pharmaceutical & Micronutrients Team, UNICEF Supply Division, at [customer@unicef.org](mailto:customer@unicef.org).

\* Reduced osmolarity oral rehydration salts (ORS) formulation - [Report from a meeting of experts jointly organized by UNICEF and WHO. WHO/CAH/01.22; \(back to text\)](#)