

# **New formulation of Oral Rehydration Salts (ORS) with reduced osmolarity- February 2004**

## **“New ORS” Q&A**

### **1. Why has a “New” Oral Rehydration Salts (ORS) formula been developed?**

Two decades ago, diarrhoea was responsible for about 5 million deaths annually. Through programs that distribute and promote ORS and home treatments for dehydration as well as preventive interventions, deaths have decreased to about 2 million. In spite of this success, there remains criticism from health workers and mothers that the original ORS solution did not stop diarrhoea or reduce the duration of the episode. This is why, during the past 20 years, research has been undertaken to develop an “improved” ORS that would be safe and effective for treating or preventing dehydration in all types of diarrhoea, and would also have other clinical benefits when compared with standard ORS.

The study results clearly describe the advantages of this new reduced osmolarity ORS solution in treating children with acute diarrhoea:

1. It reduces stool output or stool volume by about 25% when compared to the original WHO-UNICEF ORS solution,
2. It reduces vomiting by almost 30%,
3. It reduces the need for unscheduled IV therapy by more than 30%.

This last advantage is particularly important because this means less hospitalisation, and therefore less risk of hospital acquired infections, less disruption of breastfeeding, decreased use of needles (which remains a strong advantage especially in high HIV prevalence contexts), less cost, and in areas where IV therapy is not readily available less risk of dying of diarrhoea.

### **2. Why “reduced osmolarity”?**

Studies have shown that the efficacy of ORS for treatment of children with acute diarrhoea is improved by reducing its sodium concentration to 75 mEq/l, its glucose concentration to 75 mmol/l, and its total osmolarity to 245 mOsm/l. This compares to the original solution which contained 90 mEq/l of sodium with a total osmolarity of 311 mOsm/l. There has been a concern that the original solution, which is slightly “hyperosmolar” when compared with plasma, may risk hypernatraemia (high plasma sodium concentration) or an increase in stool output, especially in infants and young children.

### **3. Is diarrhoea really that much of a problem for children?**

The recently published “Lancet Series” on child survival estimates that there are almost 11 million deaths occurring each year in children under the age of five. The vast majority of these deaths occur in low income and least developed countries, particularly those in South Asia and Africa. Although use of ORS or increased fluids, use of clean water and improved hygiene, and increased breastfeeding practices have contributed substantially to a dramatic global reduction in mortality from diarrhoeal disease, there are still approximately 2 million deaths each year as a result of diarrhoea. The Lancet papers also estimate that use of Oral Rehydration Therapy by itself could prevent more than 5% of under-five deaths that occur, and therefore its wide availability and proper use is a key to improved child survival.

### **4. When will the new ORS be available?**

Supply Division normally keeps 1-2 months stock of ORS in the warehouse in Copenhagen, and it is suggested that there should be an overlap of the two formulations for a period of about two months. The new ORS was made available from UNICEF Supply Division in February 2004.

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The shelf-life of the product is 3 years, without any particular storage precautions. Because there is less sodium and glucose in the new product, the package will be made a bit smaller later in 2004, however the initial supplies have identical package size as compared to the old ORS. The new product will be clearly labelled as "New Formula" with an expiration date clearly marked.

## 5. What do I do with the old ORS solution? Should I discard it and only use the new low osmolarity ORS solution?

You should not hesitate to continue using the standard WHO UNICEF ORS (90 mEq/l of sodium with a total osmolarity of 311 mOsm/l solution), which is highly effective in the treatment of dehydration. However, because of its added advantages, WHO and UNICEF now recommend that countries use and manufacture reduced osmolarity ORS.

Countries should take this opportunity to review amounts of existing stocks of ORS. If any outdated stocks are found, these should be discarded. Any existing stocks that have not reached their expiry date should be used up first, on a "First In – First Out" basis.

## 6. What about local production of the new ORS?

For local production, the manufacture of the new reduced osmolarity ORS can normally be undertaken without any change in equipment or new investment in factories where the standard WHO UNICEF ORS has been produced previously. UNICEF has, in the past, had a large input into establishing local manufacturing of ORS, however these activities are no longer routinely undertaken or supported from central level. Despite this, "local manufacturers" of ORS need to be informed of the new formulation.

Although this single ORS formulation is *recommended*, WHO and UNICEF have previously published criteria, which remain unchanged, for *acceptable* ORS formulations. These criteria are listed below; they specify the desired characteristics of the solution after it has been prepared according to the instructions on the packet:

<b>The total substance concentration:</b>	(including that contributed by glucose) should be within the range of <b>200-310 mmol/l</b>
<b>The individual substance concentration:</b>	
<b>Glucose</b>	should at least equal that of sodium but <b>should not exceed 111 mmol/l</b>
<b>Sodium</b>	should be within the range of <b>60-90 mEq/l</b>
<b>Potassium</b>	should be within the range of <b>15-25 mEq/l</b>
<b>Citrate</b>	should be within the range of <b>8-12 mmol/l</b>
<b>Chloride</b>	should be within the range of <b>50-80 mEq/l</b>

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## **7. How should the new ORS solution be given?**

The new ORS is to be mixed and given in the same manner as the original solution. The new ORS packet is still to be mixed in **1 litre of clean water**. A family member should be taught to prepare and give ORS solution. The solution should be given to infants and young children using a clean spoon or cup. Feeding bottles should *not* be used. For babies, a dropper or syringe (without the needle) can be used to put small amounts of solution into the mouth. Children under 2 years of age should be offered a teaspoonful every 1-2 minutes; older children (and adults) may take frequent sips directly from the cup. Remember that breastfeeding should be continued for infants and young children.

## **8. Is there any risk associated with the use of this new ORS?**

Some studies have reported a slightly increased risk of hyponatraemia (low plasma sodium concentration) in patients who have received this new ORS solution. However, this decrease, which was very limited, was not associated with any clinical signs. WHO is planning to monitor this very carefully by doing what we call "post-marketing" studies: in areas where the new ORS will first be introduced, they will monitor the incidence/prevalence of hyponatraemia, biochemically as well as clinically.

## **9. What is the cost of the new ORS?**

Because of the reduced amount of sodium and glucose, and smaller packaging, the new ORS solution will cost slightly less than that which was previously used (by about 15%).

UNICEF country programmes should advocate for free distribution of the ORS for children whenever possible, in order to increase the availability and accessibility for the poorest and those most at risk.