Oral Rehydration Salts and Zinc: Market and Supply Update

UNICEF Supply Division

October 2018
Oral Rehydration Salts and Zinc
Market and Supply Update – October 2018

This update provides information on supply and demand for oral rehydration salts and zinc for 2018-2019. Despite product availability, and it being a highly effective treatment, demand through UNICEF remains low. Countries should continue to improve access and scale-up use. UNICEF continues to advocate for countries to adopt World Health Organization treatment guidelines, use of oral rehydration salts and zinc, and product inclusion into national essential medicine lists.

1. Summary

- Oral rehydration salts (ORS) and zinc are cost-effective treatments for childhood diarrhoea. They reduce symptom severity and duration, and the risk of recurrence in the short-term.
- Globally, there are nearly 1.7 billion cases of childhood diarrhoeal disease annually, with an estimated 525,000 under-five children dying annually of the disease.¹
- An estimated 60 per cent of children suffering from diarrhoea do not receive treatment with ORS, and 95 per cent of children do not receive zinc.² Of those that do receive ORS and zinc treatment, compliance and adherence is a challenge. To improve compliance, manufacturers co-packaged ORS and zinc in accordance with World Health Organization (WHO) treatment protocol guidelines to improve treatment regimen adherence.
- UNICEF is supporting governments to scale-up the use of ORS and zinc by sourcing and promoting quality co-packaged ORS and zinc to facilitate access in countries requiring quality assured, secure, and stable programme supply. UNICEF recently expanded and diversified its supplier base to include manufacturers located in some high-burden countries, including two in Africa, to allow for quicker delivery times.

2. Background & Recent History

Diarrhoea is one of the leading causes of under-five child mortality globally, and is a leading cause of under-five child malnutrition. An estimated 525,000 children under the age of five die annually of diarrhoeal disease.³ Sixty per cent of these deaths occur in just 10 countries in Asia and Africa: Bangladesh, Democratic Republic of Congo, Ethiopia, India, Kenya, Niger, Nigeria, Pakistan, Tanzania, and Uganda.⁴ ORS and zinc are highly effective and affordable products that could prevent the deaths in up to 93 per cent of diarrhoea cases, compelling WHO to recommend using ORS and zinc collectively to ensure effective treatment.⁵ In 2005, WHO and UNICEF recommended a switch from standard ORS to an improved lower-osmolarity formulation, combined with the introduction of zinc supplementation for the treatment of diarrhoea in children (Figure 1).⁶

WHO recommends that diarrhoea treatment with ORS and zinc should be complemented by prevention interventions such as rotavirus vaccination,⁷ improved access to safe water, adequate sanitation, and good hygiene.⁸ Whereas ORS replaces the essential fluids and salts lost through diarrhoea, zinc supplementation decreases the duration and severity

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²The UN Commission on Life-Saving Commodities, Oral Rehydration Salts (ORS) - Product Profile, UN Foundation, New York, 2012.
³WHO, Diarrhoea Disease Fact Sheet N°330.
⁴Ibid.
⁷UNICEF, Rotavirus Vaccine, UNICEF, Copenhagen, August 2018.
⁸WHO, Diarrhoea Disease Fact Sheet N°330.
of episodes, and reduces the risk of recurrence in the short-term.\textsuperscript{9} WHO provides clear recommendations on the use of ORS together with zinc through the Integrated Community Case Management (iCCM) guidelines for the treatment of diarrhoea.\textsuperscript{10}

Figure 1 WHO’s Childhood Diarrhoea Treatment Protocol (less than 14 days AND no blood in stool)

![Diagram showing the treatment protocol for childhood diarrhoea](image)

Source: World Health Organization

WHO also included ORS and zinc in its \textit{Essential Medicines List (EML)}\textsuperscript{11} and \textit{Priority Medicines for Mothers and Children}\textsuperscript{12} and many high-burden countries have also included it in their national EMLs and treatment guidelines for childhood diarrhoea. The EML comprises a list of essential medicines that should be available in all functioning health systems. ORS and zinc are two of the 13 life-saving health commodities the UN Commission on Life Saving Commodities (UNCoLSC) had identified and targeted for scale-up and access.\textsuperscript{13}

The UNCoLSC, launched in 2012, sought to scale up the development and financing of several essential products in high-burden countries. UNICEF worked with the UNCoLSC to support the development, financing, and implementation of plans to scale-up the effective treatment of diarrhoea in high-burden countries. The initiative aimed to increase access to diarrhoea treatment through both the public and private sectors. UNICEF presents some of the actions it has undertaken to support the increase in access to diarrhoea treatment, which include introducing at scale the innovative co-packaged ORS and zinc through the public sector. UNICEF also highlights several challenges contributing to the limited local availability and uptake of ORS and zinc in many countries (Figure 2).

Despite ORS and zinc being readily available and affordable on the global market, and a treatment course costing approximately USD 0.50,\textsuperscript{14} many children (or caregivers) in developing countries do not have access to these products. Only 38 per cent of children suffering from diarrhoea are treated with ORS; and fewer than five per cent are treated with zinc.\textsuperscript{15}

\textsuperscript{9} Ibid.
\textsuperscript{13} The UN Commission on Life-Saving Commodities, \textit{Lifesaving Commodities} UN Foundation, New York, 2014.
\textsuperscript{14} The UNCoLSC, \textit{Oral Rehydration Salts (ORS) - Product Profile}.
\textsuperscript{15} Ibid.
Figure 2 Challenges Affecting ORS and Zinc Community Use and Local Availability

- **Awareness**
  - Poor general awareness and low access to ORS, including caregivers and health workers.
  - Poor awareness and low access to zinc.
  - Many communities poorly understand ORS and do not consider it medicine, as it can treat diarrhoea, but it is not a cure.

- **Products**
  - The taste of non-flavoured ORS is not appealing to children.
  - Flavoured ORS unavailable in the public sector.
  - The quantity of ORS produced with a 20.5g/1 litre sachet is considered too much, and of which a lot is wasted.

- **Access**
  - Manufacturers consider ORS/zinc to be of limited commercial value as they are low-priced and low-profit margin products.
  - Zinc availability is limited in many countries resulting in regular health facility stock-outs.

- **Utilization**
  - Inadequate ORS/zinc prescription accuracy.
  - Low patient ORS/zinc compliance with treatment prescription.

- **Considerations**

- **Actions Taken by UNICEF and Partners**
  - Governments encouraged to review and update their policy, legislation, and regulation of ORS and zinc, including switching zinc from a prescription only medicine to an over-the-counter medicine.
  - ORS and zinc included in WHO’s priority medicines for mothers and children.
  - Flavoured ORS formulations introduced into UNICEF’s Supply Catalogue.
  - UNICEF worked with manufacturers to introduce a 10.2g/0.5 litre sachet presentation for ORS treatment.
  - Wholesalers and distributors encouraged to include ORS and zinc in their supply chains.
  - UNICEF established long-term arrangements (LTAs) with multiple ORS/zinc certified manufacturers.
  - Co-packaged ORS and zinc field-tested to facilitate treatment prescription, administration, compliance, and adherence.
  - ORS/zinc user-friendly co-packaging developed in accordance with WHO treatment guidelines.

Source: UNICEF Supply Division

### 3. Products Available Through UNICEF

UNICEF describes the different products, their estimated warehouse stock prices, and the stock keeping units (SKU) offered through UNICEF’s Supply Catalogue (Table 1). Further information on the products available through UNICEF can be accessed [here](#).

**Table 1: ORS / Zinc Products Procured by UNICEF**

<table>
<thead>
<tr>
<th>UNICEF Catalogue Number</th>
<th>Material</th>
<th>SKU</th>
<th>SKU Guide Price</th>
</tr>
</thead>
<tbody>
<tr>
<td>S1561120</td>
<td>ORS low osm. sachet 20.5g/11</td>
<td>Carton of 100</td>
<td>USD 7.10 carton</td>
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<tr>
<td>S1561121</td>
<td>ORS low osm. sachet 20.5g/11</td>
<td>Carton of 1000</td>
<td>USD 70.18 carton</td>
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<tr>
<td>S1561140</td>
<td>ORS low osm. sachet 10.2g/0.5l</td>
<td>Carton of 1000</td>
<td>USD 54.89 carton</td>
</tr>
<tr>
<td>S1561130</td>
<td>ORS low osm. orange flavour sachet 20.5g/11</td>
<td>Carton of 100</td>
<td>USD 9.46 carton</td>
</tr>
<tr>
<td>S1561131</td>
<td>ORS low osm. orange flavour sachet 20.5g/11</td>
<td>Carton of 1000</td>
<td>USD 94.63 carton</td>
</tr>
<tr>
<td>S1561132</td>
<td>ORS low osm. orange flavour sachet 10.2g/0.5l</td>
<td>Carton of 1000</td>
<td>USD 76.45 carton</td>
</tr>
<tr>
<td>S1580020</td>
<td>Zinc 20mg tablets</td>
<td>Carton of 100</td>
<td>USD 1.80 carton</td>
</tr>
<tr>
<td>S1580021</td>
<td>ORS flav. 4x10.2g/0.5l+Zinc 20mg 10 tabs</td>
<td>Co-pack</td>
<td>USD 0.54 pack</td>
</tr>
<tr>
<td>S1580022</td>
<td>ORS flav. 2x20.5g/11+Zinc 20mg 10 tabs</td>
<td>Co-pack</td>
<td>USD 0.58 pack</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

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Until 2012, UNICEF procured non-flavoured ORS in sachets for reconstitution in one litre of water, and zinc in 20mg dispersible tablets. In 2012, UNICEF expanded the ORS and zinc product offerings to meet the needs of end-users by introducing orange flavoured ORS, as well as ORS sachets for reconstitution with 500ml of water. The improved taste of the newer products is encouraging up-take and will lead to reducing wastage.

### 3.1 ORS / Zinc Co-Packaging

WHO added zinc supplementation for the treatment of childhood diarrhoea to its Essential Medicines List in 2005 to encourage countries to include zinc in their programmes through their national medicines lists and health budgets. UNICEF has supplied 20mg zinc tablets since 2006. However, despite zinc being readily available through UNICEF, the general lack of knowledge and awareness, including by caregivers and health workers, impacts and limits the demand for zinc in many countries. As such, children often do not receive the optimum recommended treatment for childhood diarrhoea. To address this, UNICEF worked with its manufacturers to develop a co-packaged ORS and zinc product (Figure 3), based on WHO’s guidelines (Figure 1), and introduced two ORS and zinc co-packaged products into its Supply Catalogue in 2014, as presented above (Table 1).

*Figure 3 Co-Packaged ORS and Zinc*

In many countries, ORS is an over-the-counter medicine (OTC), while zinc is a prescription only medicine (POM). To ensure that OTC classification was retained for co-packaged ORS and zinc, UNICEF, together with UNCoLSC’s Pneumonia and Diarrhoea Working Group, advocated for zinc reclassification from POM to OTC. Many countries have implemented the change, enabling manufacturers to distribute and market co-packaged ORS and zinc as an OTC product. Providing ORS and zinc as co-packaged products will ensure that caregivers dispense, and patients adhere to, the current recommended treatment for childhood diarrhoea. Co-packaged ORS and zinc availability through the public sector is a priority for UNICEF and WHO, and since its introduction into UNICEF’s Supply Catalogue in 2014, sixteen countries have introduced this product for public sector distribution. UNICEF has to date procured 15.4 million ORS and zinc co-packs.

### 3.2 Supply

ORS and zinc are high turnover items, which UNICEF procures mainly for its various child health programmes and for use in emergencies. From 2005 until 2013, UNICEF procured on average approximately 51 million ORS sachets per year, primarily of 20.5g/l, with quantities ranging annually from 30 million to 80 million sachets, with the high-end of the range typically driven by emergency response requirements. From 2014, following the introduction into its catalogue of the co-packaged ORS and zinc, UNICEF’s procurement of ORS has increased to reach an annual average of 95 million sachets, ranging from 76 million to 116 million sachets per year (Figure 4). The noted fluctuations in quantities reflects the sporadic nature of national country requests in response to local programme needs for ORS and zinc procurement.

UNICEF prepositions a significant proportion of the ORS and zinc it procures in its warehouse in Copenhagen for emergency response preparedness to cover the needs of 250,000 children. Small quantities for local programme needs can be shipped from the warehouse in Copenhagen. However, most quantities for ongoing programme needs are shipped directly from UNICEF manufacturers. Sometimes emergency response requirements can generate demand volumes that substantially exceed the contingency stock levels, and the direct deliveries from international manufacturers, in such cases, supply can sometimes be subject to significant lead-times. Therefore, having manufacturers located in strategic programme countries can potentially improve local and regional emergency response capacity, both in terms of supply availability and timely delivery. As such, UNICEF established supply arrangements with new ORS and zinc manufacturers located in some high-burden programme countries, i.e. Bangladesh, Kenya, and
Nigeria. This expanded UNICEF’s number of approved Good Manufacturing Practice (GMP) manufacturers for ORS and zinc from two to five, including two in Africa, and will improve access to quality assured products and allow for quicker delivery times.

Figure 4 ORS and Zinc Supply through UNICEF 2005-2017

Source: UNICEF Supply Division

UNICEF selects manufacturers competitively from among its approved GMP manufacturers via tenders. UNICEF awards manufacturers LTAs with successful bids to supply products, usually over a two or three-year period. Table 2 lists UNICEF’s most recent ORS, zinc, and ORS / zinc co-packaged tender awards.

Table 2 UNICEF Current ORS / Zinc Product LTA for 2017-2019 – Continued next page
## ORS

<table>
<thead>
<tr>
<th>Supplier</th>
<th>Duration</th>
<th>Start</th>
<th>End</th>
<th>Description</th>
<th>Material</th>
</tr>
</thead>
<tbody>
<tr>
<td>CHI (Nigeria)</td>
<td>2 years</td>
<td>09/05/2017</td>
<td>08/05/2019</td>
<td>ORS low osm. Flav.20.5g/1l CAR/100</td>
<td>S1561130</td>
</tr>
<tr>
<td>Eskayef (Bangladesh)</td>
<td>2 years</td>
<td>09/05/2017</td>
<td>08/05/2019</td>
<td>ORS low osm. Flav.20.5g/1l CAR/100</td>
<td>S1561131</td>
</tr>
<tr>
<td>FDC (India)</td>
<td>2 years</td>
<td>24/05/2017</td>
<td>23/05/2019</td>
<td>ORS low osm. 20.5g/1l CAR/100</td>
<td>S1561120</td>
</tr>
<tr>
<td>KBI (Germany)</td>
<td>2 years</td>
<td>24/05/2017</td>
<td>23/05/2019</td>
<td>ORS low osm. 20.5g/1l CAR/100</td>
<td>S1561121</td>
</tr>
<tr>
<td>Renata (Bangladesh)</td>
<td>2 years</td>
<td>24/05/2017</td>
<td>23/05/2019</td>
<td>ORS low osm. Flav.20.5g/1l CAR/100</td>
<td>S1561130</td>
</tr>
<tr>
<td>Universal Corp. (Kenya)</td>
<td>2 years</td>
<td>24/05/2017</td>
<td>23/05/2019</td>
<td>ORS low osm. 20.5g/1l CAR/100</td>
<td>S1561120</td>
</tr>
</tbody>
</table>

Source: UNICEF Supply Division

### 4. Way Forward

- UNICEF will continue to actively seek and encourage potential GMP compliant ORS/Zinc manufacturers, especially in programmatically strategic countries.
- UNICEF will continue to maintain good supply security to promote access to co-packaged ORS and Zinc.
- UNICEF will continue to advocate for the use of ORS and Zinc as a cost-effective treatment for childhood diarrhoea in integrated community case management (iCCM), especially in UNICEF programme countries.

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Other UNICEF information notes are found at: [http://www.unicef.org/supply/index_54214.html](http://www.unicef.org/supply/index_54214.html)