

Technical Bulletin No. 23 (August 2017)

## Product update for Therapeutic Milks, F-75 and F-100

As part of ongoing efforts to promote quality care and treatment for children with severe acute malnutrition (SAM) with medical complications through safe preparation of F-75 and F-100 therapeutic milk (TM), improvements have been made to the packaging and reconstitution method of therapeutic milk. The change in packaging of TM from sachets to canister does not indicate a change in the protocol for treatment of SAM. There is however, a change when reconstituting dry TM powder into liquid form.

### Purpose

This bulletin describes improvements to F-75 and F-100 supplied by UNICEF. The improvements are designed to:

1. Align the production of TM to industry standards for the production of specialized milks to provide better quality assurance during manufacturing
2. Reduce the risk of contamination and incorrect dosing during preparation and storage of therapeutic milk at the end user level

The changes to the packaging and reconstitution process for F-75 and F-100 are described below.

### Background

F-75 and F-100 (TM) are used for treatment of children with SAM with medical complications in an inpatient setting. Both products require reconstitution with clean safe drinking water before use. They are to be administered by trained health care staff.

F-75 and F-100 sachets were previously designed to be reconstituted in their entirety at one time with 1 sachet added to 500ml of water making up around 600 ml of TM. Observations of end users preparing TMs showed an inconsistency in following the label instructions on the sachet. For example, it was observed that health workers were using measuring implements such as scoops or spoons not developed for use with TM, posing risks of incorrect dosing. In addition, as there was no effective way to close the sachet, the remaining unused powder was often left exposed to the environment in the opened sachet, posing hygiene risks to the milk powders.

Over the last 10 years, industry standards and best practices in both the production of specialised milks and the instructions given for the preparation in inpatient settings have been adapted to better address food safety risks. The improvement to the therapeutic milk products procured by UNICEF

represent greater alignment with these updated Codex<sup>1</sup> and WHO standards<sup>2</sup>, and best industry practices.

## What has changed?



### Improved manufacturing Process

The supply of TM will be from manufacturers who can fully meet the current Codex Alimentarius standards for hygienic production of milk formulas for infants. As a result of the improvements in production standards, there is lower risk of contamination during production and in addition, the products have a milkier texture with less separation once water is added to the TM powders, as milk rather than whey powder is now the main dairy ingredient. The nutritional composition is still based on WHO's 1999 manual "Management of severe malnutrition: a manual for physicians and other senior health workers"<sup>3</sup> and all nutrient levels remain the same as the previously supplied products.

### Packaging and pack size

F-75 and F-100 Therapeutic Milks will now be supplied in a new packaging format of 400g canisters<sup>4</sup> as per table 1 below. The new packaging allows for longer shelf life of TM once the packaging is opened: 4 weeks for canisters compared to 24 hours for sachets. For indicative prices please see the UNICEF Supply Division catalogue.<sup>5</sup>

Table 1

Material Number	Short description	Gross Weight and Volume of each carton	Image
S0000236	Each canister contains 400g of F-75 Therapeutic milk powder.  There are 24 canister in a Carton	13.7 - 14.0 kg 0.035 - 0.046 m <sup>3</sup>	
S0000237	Each canister contains 400g of F-100 Therapeutic milk powder.  There are 24 canister in a Carton	13.7 - 14.0 kg 0.035 - 0.046 m <sup>3</sup>	

Note: These items are not stocked in UNICEF Supply Division Warehouse, they are delivered directly from the supplier to the consignee. Please allow 30 to 90 days for order processing, production, sampling/testing and preparation for shipment. The minimum order quantity is one carton containing 24 canisters.

<sup>1</sup> Code of hygienic practice for powdered formulae for infants and young children CAC/RCP 66 2008

<sup>2</sup> How to Prepare Powdered Infant Formula in Care Settings, *World Health Organization*, 2007

<sup>3</sup> <http://apps.who.int/iris/bitstream/10665/41999/1/a57361.pdf>

<sup>4</sup> The canisters for supply as of 2017 are a metal canister with a plastic lid.

<sup>5</sup> [https://supply.unicef.org/unicef\\_b2c/app/displayApp/\(cpgsize=5&layout=7.0-12\\_1\\_66\\_68\\_115\\_2&uiarea=2&care=511ADD71123C6AD9E1000009E710FC1&cpgnum=1\)/.do?rf=y](https://supply.unicef.org/unicef_b2c/app/displayApp/(cpgsize=5&layout=7.0-12_1_66_68_115_2&uiarea=2&care=511ADD71123C6AD9E1000009E710FC1&cpgnum=1)/.do?rf=y)

## Scoop to measure and prepare different volumes of TM feeds

Each canister comes with a specifically developed scoop that allows smaller amounts of therapeutic milk to be prepared (as small as 28ml). F-75 comes with a white branded scoop and F-100 comes with a blue branded scoop. Having an opportunity to safely prepare smaller amounts of freshly made up milk reduces wastage and minimizes the risk of contaminated feeds being given to children. Specific scoops and amounts of water preparation are outlined in table 2.

### **Important Note on scoops:**

*While the weight of the TM powder is around the same from all the suppliers, there may be slight variations in the volume that the scoop holds, due to different bulk density of the powder from different suppliers, therefore it is important to use the scoop provided with each canister, and place it back in the canister without any cleaning or contact with prepared milk or water. The scoop should be discarded together with the empty canister once the canister is finished.*

*The “red scoops” used with the previously supplied therapeutic milk sachets must not be used with the canisters. For the improved TM, there will be white scoops for F75 and blue scoops for F100.*

## Labelling

The labels have been standardized: black and white for F-75 and blue and white for F-100. The label will be available in combinations of the following languages: English/French and English/Arabic.

## Transport, storage and Inventory management

TM in its original packaging should be transported and stored under cool dry conditions at temperatures not exceeding 30°C. The cartons containing TM canisters will have better stacking capabilities for storage and transport.

Please note that the weight and volumes of the TM 400g canisters in cartons of 24 is different from the TM sachets in cartons and may be different from each supplier. For more detailed logistics information, please go to:

[https://intranet.unicef.org/denmark/do/danresourcelibrary.nsf/0/3C98E96A0A7EA852C12575ED0040D455/\\$FILE/Therapeutic%20milk\\_logistics%20info.pdf](https://intranet.unicef.org/denmark/do/danresourcelibrary.nsf/0/3C98E96A0A7EA852C12575ED0040D455/$FILE/Therapeutic%20milk_logistics%20info.pdf)

## New reconstitution process of F-75 and F-100

To reduce contamination risk, therapeutic milk should always be prepared with safe drinking water that has been boiled and left to cool for not less than 3-5 mins (so the temperature of the water is no cooler than 70°C) in accordance with WHO guidance.<sup>6</sup> The prepared milk should then be left to cool to feeding temperature before giving it to the patient. The vitamin levels have been adjusted in the products supplied to account for any nutrient losses during the preparation with hot water.

The reconstitution of TM powder to milk for smaller amounts has been simplified; both F-75 and F-100 in canisters now use increments of 25ml of added water per scoop of TM powder. See details in table 2 and 3.

Table 2

<b>F-75</b>		
<b>Level scoop<sup>7</sup></b>	<b>Quantity of water (ml)</b>	<b>Approximate Feed volume (ml)</b>
1	25	≈ 28
2	50	≈56
4	100	≈112
8	200	≈224
10	250	≈280
20	500	≈560
Whole canister of 400g <sup>8</sup>	2200	≈2480
24 canisters (9.6 kg net weight)	≈52.8 litres	≈59.5 litres

<sup>6</sup> [http://www.who.int/foodsafety/publications/micro/pif\\_guidelines.pdf](http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf)

<sup>7</sup> Scoops measure around 4.6g. Powder weight per scoop may vary depending on how tightly packed or full the powder is within the scoop.

<sup>8</sup> Approximately 88 scoops

## F100

Level scoop <sup>9</sup>	Quantity of water* (ml)	Approximate Feed volume (ml)
1	25	≈29
2	50	≈58
4	100	≈117
8	200	≈234
10	250	≈290
20	500	≈580
Whole canister of 400g <sup>10</sup>	1850ml	≈2158
24 canisters 9.6kg (net weight)	44 litres	≈52 litres

\*An additional 30% dilution rate can be applied for the management of SAM in infants < 6 months. When managing infants <6 months of age refer to Guideline: updates on the management of severe acute malnutrition in infants and children.  
[http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328\\_eng.pdf](http://apps.who.int/iris/bitstream/10665/95584/1/9789241506328_eng.pdf).

For more information contact: UNICEF Supply Division: [sd.nutritionssupplies@unicef.org](mailto:sd.nutritionssupplies@unicef.org) or for Nutrition Program related enquiries: [nutrition@unicef.org](mailto:nutrition@unicef.org)

### References

How to Prepare Powdered Infant Formula in Care Settings. World Health Organization, 2007  
[http://www.who.int/foodsafety/publications/micro/PIF\\_Care\\_en.pdf](http://www.who.int/foodsafety/publications/micro/PIF_Care_en.pdf)

Safe preparation, storage and handling of powdered infant formula Guidelines. World Health Organization in collaboration with Food and Agriculture Organization of the United Nations, 2007  
[http://www.who.int/foodsafety/publications/micro/pif\\_guidelines.pdf](http://www.who.int/foodsafety/publications/micro/pif_guidelines.pdf)

---

<sup>9</sup> Scoop measures approximately 5.4g. Powder weight per scoop may vary depending on how tightly packed or full the powder is within the scoop.

<sup>10</sup> Approximately 74 scoops