

Oral Rehydration Salts

Contents of 5 sachets dissolved in 1 liter water will provide:

Sodium	75 mmol
Potassium	20 mmol
Chloride	65 mmol
Citrate	10 mmol
Glucose	75 mmol
Total Osmolarity	245 mmol

Hydrite[®] GRANULES FOR SOLUTION

FORMULATION

Each sachet contains:

Sodium chloride.....	520 mg
Trisodium citrate dihydrate.....	580 mg
Potassium chloride	300 mg
Glucose, anhydrous	2.7 g

PRODUCT DESCRIPTION

Hydrite Granules appears as off-white granules in a sachet available in natural, apple, banana and melon flavors.

WHAT IS IN THE MEDICINE?

This medicine conforms with the WHO/UNICEF reduced osmolarity glucose-based oral rehydration salts (ORS), the preferred method for treating diarrheal dehydration.

STRENGTH OF THE MEDICINE

Please see formulation

WHAT IS THE MEDICINE USED FOR?

This medicine is used in the treatment of children and adults with dehydration due to diarrhea (except those with severe dehydration).

This medicine replaces fluid and electrolytes (body salts) lost due to diarrhea and/or vomiting.

HOW MUCH AND HOW OFTEN SHOULD YOU USE THE MEDICINE?

The 2005 WHO Manual for the treatment of Diarrhea provides the following information on the assessment and treatment of dehydration:

I. HOW TO ASSESS THE DEGREE OF DEHYDRATION AND CHOOSE A TREATMENT PLAN

CLINICAL MARKERS	USE TREATMENT PLAN A (Can be treated at home)	USE TREATMENT PLAN B (Consult a doctor or health care worker)	PATIENT REQUIRES URGENT HOSPITALIZATION
	●NO DEHYDRATION ●Use ORS to prevent dehydration	●MILD TO MODERATE DEHYDRATION ●Use ORS to treat dehydration	●SEVERE DEHYDRATION ●Requires rapid intravenous rehydration
1. LOOK AT			
Condition	Well, alert	Restless, Irritable	Lethargic or unconscious
Eyes	Normal	Sunken	Sunken
Thirst	Not thirsty, drinks normally	Thirsty, drinks eagerly	Drinks poorly, or not able to drink
2. FEEL			
Skin Pinch	Goes back quickly	Goes back quickly (<2 seconds)	Goes back very slowly (>2 seconds)
3. DECIDE	The patient has NO SIGNS OF DEHYDRATION	If the patient has two or more signs, there is SOME DEHYDRATION	If the patient has two or more signs, there is SEVERE DEHYDRATION

II. HOW MUCH ORS SOLUTION TO USE BASED ON PATIENT ASSESSMENT AND TREATMENT PLAN

● TO PREVENT DEHYDRATION (TREATMENT PLAN A)

Direction: Dissolve the contents of one sachet in one glass of (200 mL) of clean drinking water.

Give as much fluid as the child or adult wants until diarrhea or vomiting stops or you may use the following guide according to the WHO:

Age Group	Amount of ORS Solution to Give After Every Watery Stool
Children under 2 years	1/4 to 1/2 glass (50 – 100 mL)
Children 2 – 10 years	1/2 to 1 glass (100 - 200 mL)
Older children & Adults	As much fluid as they want

- Give other suitable fluids including plain clean water, rice water, vegetable or chicken soup, green coconut water, yoghurt drink, weak tea (unsweetened), unsweetened fresh fruit juice. Do not use sports drink or foods with a lot of sugar.

CONTINUE USUAL FEEDING, AS TOLERATED. CONTINUE BREASTFEEDING.

● TO TREAT DEHYDRATION (TREATMENT PLAN B)

(To Replace Mild to Moderate Fluid Loss)

Direction: Dissolve contents of one sachet in every glass (200 mL) of drinking water.

Age Group	Approximate Weight (kg)	Amount of ORS Solution to Give Within the First 4 hours
Up to 4 months	Less than 6	1 – 2 glasses (200 – 400 mL)
4 – 12 months	6 - <10	2 - 3½ glasses (400 - 700 mL)
12 – 24 months	10 - <12	3½ - 4½ glasses (700 - 900 mL)
2 – 5 years	12 - 19	4½ - 7 glasses (900 - 1,400 mL)

Alternatively, one can **multiply the patient's weight (in kg) by 75 mL** to obtain the approximate volume (mL) of this reduced osmolarity ORS solution to be given in the **first 4 hours**.

- Continue breastfeeding even during the initial rehydration period
- **After 4 hours**, reassess the patient using the assessment chart and select the appropriate Treatment Plan.

If there are no signs of dehydration, shift to Treatment Plan A.

If signs indicating some dehydration are still present, repeat Treatment Plan B and continue to reassess the patient frequently.

If signs of **severe dehydration** have appeared, **bring the patient to the hospital immediately for urgent intravenous rehydration**. For this to happen is unusual, however, occurring only in children who drink ORS solution poorly and pass large watery stools frequently during the rehydration period.

- When rehydration is complete, skin pinch is normal, thirst subsides, urine is passed, and the patient is no longer irritable.

CONTINUE USUAL FEEDING, AS TOLERATED, AFTER THE INITIAL 4-HOUR REHYDRATION PERIOD

- **GIVE ZINC SUPPLEMENTS. (For Both Treatment Plans A and B)**

Age Group	Recommended Oral Zinc Dose (take for 10 - 14 days even when diarrhea has already stopped)
Children up to 6 months	10 mg once a day
Children 6 - 59 months	20 mg once a day

WHEN SHOULD YOU NOT TAKE THIS MEDICINE?

- If you are allergic to any component of the product or if you have glucose malabsorption

UNDESIRABLE EFFECTS

There are no expected undesirable effects if the recommended dilution, volume of ORS solution to be administered and dosing are followed.

WHAT OTHER MEDICINE OR FOODS SHOULD BE AVOIDED WHILE TAKING THIS MEDICINE?

This medicine is not expected to interact with food or medicines.

WHAT SHOULD YOU DO IF YOU MISS A DOSE?

Just take the next dose if still needed to help replace fluids and electrolytes lost due to diarrhea and/or vomiting.

HOW SHOULD YOU KEEP THE MEDICINE?

Keep the product out of reach and sight of children.

Store at temperatures not exceeding 30°C.

SIGNS AND SYMPTOMS OF OVERDOSAGE

There is no information regarding overdosage of this product.

WHAT TO DO WHEN YOU HAVE TAKEN MORE THAN THE RECOMMENDED DOSAGE?

If you have taken more than the recommended dosage, consult a doctor.

CARE THAT SHOULD BE TAKEN WHEN TAKING THIS MEDICINE

- Follow directions for dilution and the recommended amount of this reduced osmolarity ORS solution according to weight and the recommended amount of this reduced osmolarity ORS solution according to weight and/or age of patient and intended use (prevention or treatment of dehydration) (see Tables) to avoid underdosing or overdosing.
- Oral rehydration salts may be used in severe dehydration only if intravenous fluid is not available.
- This reduced osmolarity ORS granules in sachet should be made into solution immediately before use. If not refrigerated, discard any remaining solution 4 hours after reconstitution. If refrigerated, the reconstituted solution can be kept for 24 hours after which it should no longer be used.
- Use only cool clean drinking water to reconstitute this product. The reconstituted solution should never be boiled.
- This product gives a cloudy solution when reconstituted. Shake or stir well before feeding.
- Do not use more than the recommended dose unless recommended by a doctor.
- Do not use after the expiry date on the label

WHEN SHOULD YOU CONSULT YOUR DOCTOR?

- If any undesirable effect occurs or dehydration worsens.

Consult a doctor if the patient:

- Passes many stools
- Is very thirsty
- Has sunken eyes
- Seems not to be getting better after 3 days
- Has fever
- Does not eat or drink normally
- Is having difficulty in breathing or is breathing fast
- Has trouble or pain in swallowing food, vomiting with blood or has bloody or black stools.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov/ph AND Unilab at (+632) 858-1000 or productsafety@unilab.com.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY

Oral Rehydration Salts (Hydrite[®]) aluminum sachet in box of 100s (banana, natural, apple, and melon flavor)

Date of Revision: February 26, 2015

DATE OF FIRST AUTHORIZATION / REG. NO.:

- Banana: November 5, 2007 / DRHR-758
- Natural: January 24, 2017 / DRHR-557
- Melon: October 26, 2017 / DRHR-1810
- Apple: January 24, 2017 / DRHR-759

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