

Oral Rehydration Salts

HydroAid™ Granules for Solution REHYDRATION SOLUTION

FORMULATION:

Each sachet contains:
 Glucose anhydrous.....2.7 g
 Sodium chloride.....526.5 mg
 Trisodium citrate anhydrous.....516.2 mg
 Potassium Chloride.....298 mg

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

Glucose75 mmol
 Sodium.....75 mmol
 Chloride.....65 mmol
 Potassium20 mmol
 Citrate10 mmol

PRODUCT DESCRIPTION

Reformulated Hydrite is an ORS which appears as off-white granules in a sachet. It comes in natural, apple and banana flavor.

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 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:

1. 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
		<ul style="list-style-type: none"> ● NO DEHYDRATION ● Use ORS to prevent dehydration 	<ul style="list-style-type: none"> ● MILD TO MODERATE DEHYDRATION ● Use ORS to treat dehydration
1. LOOK AT			
Condition	Well, alert	*Restless, Irritable*	*Lethargic or unconscious; floppy*
Eyes	Normal	Sunken	Very sunken and dry
Tears	Present	Absent	Absent
Mouth and Tongue	Moist	Dry	Very dry
Thirst	Not thirsty, drinks normally	*Thirsty, drinks eagerly*	*Drinks poorly, or not able to drink*
2. FEEL			
Skin Pinch	Goes back quickly	*Goes back slowly*	*Goes back very slowly* (>2 seconds)
3. DECIDE			
	The patient has NO SIGNS OF DEHYDRATION	If the patient has two or more signs, including at least one of the signs with double asterisk marks (*sign*), there is SOME DEHYDRATION	If the patient has two or more signs, including at least one of the signs with double asterisk marks (*sign*), 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 (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 (am), vegetable or chicken soup, green coconut water (*buko* water), yoghurt drink, weak tea (unsweetened), unsweetened fresh fruit juice.

**CONTINUE USUAL FEEDING, AS TOLERATED.
 CONTINUE BREASTFEEDING.**

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● **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
Less than 4 months	Less than 5	1 – 2 glasses (200 – 400 mL)
4 – 11 months	5 – 7.9	2 – 3 glasses (400 – 600 mL)
12 – 23 months	8 – 10.9	3 – 4 glasses (600 – 800 mL)
2 – 4 years	11 – 15.9	4 – 6 glasses (800 – 1,200 mL)
5 – 14 years	16 – 29.9	6 – 11 glasses (1,200 – 2,200 mL)
15 years or older	30 or more	11 - 20 glasses (2,200 – 4,000 mL)

Alternatively, one can multiply the patient's weight (in kg) by 75 mL to obtain the approximate volume (mL) of this reduced osmolality 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

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 IF YOU HAVE USED 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 osmolality 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 osmolality ORS granules in sachet should be made into solution immediately before use. If not refrigerated, discard any remaining solution an hour after constitution. If refrigerated, the constituted solution can be kept for **24 hours** after which it should no longer be used.
- Use only cool clean drinking water to constitute this product. The constituted solution should never be boiled.
- This product gives a cloudy solution when constituted. 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.

ADVERSE DRUG REACTION REPORTING STATEMENT

For suspected adverse drug reaction, seek medical attention immediately and report to the FDA at www.fda.gov.ph. By reporting undesirable effects, you can help provide more information on the safety of this medicine.

AVAILABILITY

Oral Rehydration Salts (HydroAid™)aluminum sachet in box of 20s (apple, grape and strawberry flavor)

Date of First Authorization: Nov 2018

Registration Number(s):

Oral Rehydration Salts [HydroAid™ (Strawberry Flavor)] - DRHR-1870

Oral Rehydration Salts [HydroAid™ (Grape Flavor)] -DRHR-1871

Oral Rehydration Salts [HydroAid™ (Apple Flavor)] -DRHR-1872

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Manufactured by

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