

Logotype ORSALIT

Drawing: little fish – 1x

Drawing: fruits – 1x

ORSALIT is an oral rehydration solution (ORS) with reduced osmolarity and composition in accordance with the recommendations of the European Society for Paediatric Gastroenterology, Hepatology and Nutrition (ESPGHAN). Using oral rehydration solutions is recommended by ESPGHAN and WHO / UNICEF* to supplement body fluids and mineral substances mainly during diarrhoea or vomiting.

ORSALIT provides effective rehydration as it uses the most effective mechanism of common absorption of water, sodium and glucose.

*World Health Organization / United Nations International Children's Emergency Fund

The following versions of ORSALIT are available for sale:

Pictogram ORSALIT (without flavour) intended for infants under the age of 6 months and for children prone to allergy.

Pictogram ORSALIT with raspberry flavour intended for children from 6 months of age.

Pictogram ORSALIT with banana flavour intended for children from 6 months of age.

Pictogram ORSALIT for adults with raspberry- lemon flavour.

Logotype ORSALIT nutris tasty oral rehydration solution with reduced salty taste. ORSALIT nutris is enriched with lactalbumin. Due to glucose, mineral salts and lactalbumin content ORSALIT nutris additionally serves a nutritional function. Lactalbumin is a protein contained in milk; provides the exogenous amino acids i.e. amino acids that are not produced by the human body and must be supplied with food. Thanks to its innovative formula the salty taste is hardly noticeable. ORSALIT nutris is intended for children from 6 months of age. ORSALIT nutris should not be used by persons with known allergy to cow's milk proteins.

Logotype ORSALIT DRINK is a ready for consumption oral rehydration solution with delicious, strawberry flavour. ORSALIT DRINK is available in the bottle of 200ml. The preparation is intended for children above 3 years of age.

Assessment of the degree of dehydration⁵

	None or mild dehydration	Moderate dehydration	Severe dehydration
Child body weight loss	<5%	5 - 10%	>10%
Child general condition	Calm, conscious	Restless, agitated*	Sleepy or unconscious, flaccid*
Eyeballs	Normal turgor	Sunken (dark circles under the eyes)	Very sunken (dark circles under the eyes)
Tears	Present	None	None
Amount of urine	Normal	Reduced, concentrated urine (dark)	Small amount or none
Mouth, tongue	Humid	Dry	Very dry
Thirst	Normal	Thirsty, drinks voraciously*	Drinks poorly or unable to drink unassisted*
Skin fold	Retracts immediately	Retracts slowly*	Retracts very slowly*

*The so-called “severe” symptoms of dehydration; in order to qualify a patient to a given category at least two of the conditions listed in the appropriate column must be identified, including one “severe”.

Figure 1: two hands and pressing the nail plate, instruction: press the nail plate until it gets pale

Figure 2: hand, instruction: blood returns longer than within 1.5s - a symptom of dehydration

Prolonged capillary refill time (>1.5 – 2s) is the most reliable in the assessment of moderate dehydration.

IMPORTANT INFORMATION

ORSALIT with banana flavour and ORSALIT with raspberry flavour are intended for children from 6 months of age. Infants under the age of 6 months and children prone to allergy should receive ORSALIT without flavour.

The product should be used under medical supervision. Do not use parenterally. ORSALIT is an incomplete foodstuff. It is not suitable for use as the sole source of nourishment. This product should not be used by people without risk of body dehydration.

INDICATIONS

ORSALIT is a food for special medical purposes for the dietary management of body dehydration, especially during diarrhoea or vomiting, and in situations associated with a risk of dehydration. ORSALIT supplements body fluids and mineral substances in case of water-electrolyte balance disturbances.

INGREDIENTS

ORSALIT: glucose monohydrate, sodium citrate, sodium chloride, potassium chloride.

ORSALIT with raspberry flavour and ORSALIT with banana flavour: glucose monohydrate, sodium citrate, sodium chloride, potassium chloride, flavour. ORSALIT with raspberry flavour and ORSALIT with banana flavour contain flavours, do not contain fruits.

The preparations contain sugar. Do not contain milk protein and lactose. Gluten-free.

Nutritional value	In 100 g of the product in sachets	In 100 ml of the product ready for consumption	Osmolarity [mOsm/l]
energetic value (energy)	1586 kJ/373 kcal	38 kJ/9 kcal	-
fat	0 g	0 g	-
of which			
— saturates	0 g	0 g	-
carbohydrate	93.30 g	2.26 g	-
of which			
— sugars (glucose)	70.03 g	1.62 g	90
protein	0 g	0 g	-
salt	7.23 g	0.18 g	*
minerals			
citrate	7.84 g	0.19 g	10
chloride	7.34 g	0.18 g	50
sodium	5.71 g	0.14 g	60
potassium	3.25 g	0.08 g	20

* included in osmolarity of chlorides and sodium

Osmolarity of the solution: 230 (mOsm/l).

ORSALIT is an oral rehydration solution with reduced osmolarity and sodium content in accordance with ESPGHAN recommendations.

METHOD OF PREPARATION

Shake well before opening the sachet. Lack of powdery consistency does not affect the quality of the product. Dissolve the content of one sachet in 200ml of warm, boiled water. In order to measure the appropriate amount of water use the measure included in the package. The solution should not be sweetened. ORSALIT may be administered with a straw. Cool down before administration. If vomiting occurs the solution should be administered frequently in small portions (with a teaspoon).

DOSAGE

The dosage depends on recommendations. Usually oral rehydration solution



the degree of dehydration and the medical it is recommended to administer 50-100ml of per kg of body weight during the first 4 hours

and additionally 5-10ml per kg of body weight after each diarrhoeal stool or vomiting. At a later stage of rehydration 5-10ml of oral rehydration solution should be administered per kg of body weight after each diarrhoeal stool or vomiting.

Example of ORSALIT dosage		
A person receiving ORSALIT	REHYDRATION PHASE (the first 3-4 hours of rehydration)	REHYDRATION MAINTENANCE PHASE (subsequent stages of rehydration)
Body weight up to 4kg (age: up to 4 months)	1 sachet dissolved according to the recommendation (200ml) Administer during 3-4 hours	1 sachet dissolved according to the recommendation (200ml) Administer 100ml after each diarrhoeal stool or vomiting
Body weight 4-8kg (age: up to 6 months)	2 sachets dissolved according to the recommendation (400ml) Administer during 3-4 hours	
Body weight 8 - 12kg (age: 6 months - 1 year)	3 sachets dissolved according to the recommendation (600ml) Administer during 3-4 hours	
Body weight 12 - 15kg (age: 1 - 2 years)	4 sachets dissolved according to the recommendation (800ml) Administer during 3-4 hours	1 sachet dissolved according to the recommendation (200ml) Administer after each diarrhoeal stool or vomiting
Body weight over 15kg (age: over 2 years)	6 sachets dissolved according to the recommendation (1200ml) Administer during 3-4 hours	

Applying the dosage scheme presented above the body weight should be considered firstly.

Prevention (before dehydration occurs) – use as in the rehydration maintenance phase.

Usage and dosage of ORSALIT rehydration solution has been based on the recommendations of ESPGHAN, WHO / UNICEF.

The quantity, daily dose and duration of consumption of ORSALIT required to obtain the beneficial effect depend on the age, body weight and rehydration phase.

CONTRAINDICATIONS

ORSALIT should not be used in case of bowel obstruction or hemodynamic shock. The product can be used by diabetics, but it is necessary to monitor blood sugar level.

STORAGE

Store in a dry place at room temperature, keep out of reach of young children.

PACKAGE CONTENTS

ORSALIT - 10 sachets – 4.80g each. Net weight 48g.

ORSALIT with banana flavour - 10 sachets – 4.84g each. Net weight 48.4g.

ORSALIT with raspberry flavour - 10 sachets- 4.87g each. Net weight 48.7g.

Plastic container for water measuring and two straws.

MANUFACTURER

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