

Product Information Sheet

1. TRADE NAME OF THE FOOD SUPPLEMENT

ORSALIT DRINK

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition: water, glucose monohydrate, sodium citrate, sodium chloride, potassium chloride, citric acid; sodium benzoate, potassium sorbate, sucralose, strawberry flavour.

Quantitative composition:

No.	Ingredients:	In one bottle (200 ml)
1.	Water	200 ml
2.	Glucose monohydrate	3.2 g
2.	Sodium citrate	0.59 g
3.	Sodium chloride	0.35 g
4.	Potassium chloride	0.3 g
5.	Citric acid	0.25 g
6.	Sodium benzoate	0.1 g
7.	Potassium sorbate	0.1 g
8.	Sucralose	0.03 g
9.	Strawberry flavour	0.025 ml

Preparation osmolarity: 231 mOsm/l.

3. PHARMACEUTICAL FORM

Colourless liquid

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

ORSALIT DRINK is a dietary 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.

The preparation is intended for children over 3 years of age.

4.2 Posology and method of administration

ORSALIT DRINK is a ready for consumption oral rehydration solution with composition in accordance with the recommendations of the ESPGHAN*.



*European Society for Paediatric Gastroenterology, Hepatology and Nutrition
Posology

The posology depends on the degree of dehydration and the medical recommendations. During the first 3-4 hours it is recommended to:

- **in mild dehydration** (child is calm and conscious, normal eyeballs turgor, tears present, mouth and tongue humid, normal thirst) administer 30-50 ml per kilogram of body weight;
- **in moderate dehydration** (child is restless and agitated, sunken eyeballs, no tears, mouth and tongue dry, thirst - drinks voraciously) administer 50-100 ml per kilogram of body weight.

At a later stage of rehydration it is recommended to administer 5-10 ml per kilogram of body weight after each diarrhoeal stool or vomiting.

4.3 Contra-indications

Bowel obstruction or hemodynamic shock. The product can be used by diabetics, but it is necessary to monitor blood sugar level.

4.4 Special warnings and special precautions for use

This product should not be used by people without risk of body dehydration. The product should be used under medical supervision.

4.5 Interaction with other medicaments and other forms of interaction

Not tested.

4.6 Pregnancy and lactation

No data available.

4.7 Effects on ability to drive and use machines

Not tested.

4.8 Undesirable effects

No data available.

4.9 Overdose

No data available.



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5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

No data available.

5.2 Pharmacokinetic properties

No data available.

5.3 Preclinical safety data

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acidity regulator – citric acid; preservatives – sodium benzoate, potassium sorbate; sweetening agent – sucralose; strawberry flavour.

6.2 Incompatibilities

No data available.

6.3 Shelf life

24 months

6.4 Special precautions for storage

Before opening, store the product at room temperature (15-25°C).

After opening, store in a refrigerator. Use within 48 hours.

Keep out of reach and sight of young children.

6.5 Nature and contents of container

Four bottles of 200 ml each in unitary packaging.

6.6 Instructions for use / handling

The preparation is ready for consumption. Shake before use.

7. MANUFACTURER AND MARKETING AUTHORISATION HOLDER

Manufacturer:

IBSS BIOMED S.A.

Al. Sosnowa 8

30-224 Krakow, Poland



Tel.: + 48 12 37 69 200

Fax: +48 12 37 69 205

e-mail: bdu@biomed.pl

Marketing Authorisation Holder:

U.G.A. Nutraceuticals S.r.l.

Via L. Da Vinci

129/C - 06024

Gubbio (PG) Italy

8. MARKETING AUTHORISATION NUMBER

No: GIS-ŻP-SP-4230-00648/BR/14

9. DATE OF FIRST AUTHORISATION / RENEWAL OF AUTHORISATION

Date of first authorization: 23/05/2014

10. DATE OF (PARTIAL) REVISION OF THE TEXT

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