

Each 14 g sachet contains:

0,44 g sodium chloride

0,38 g potassium chloride

0,42 g sodium bicarbonate

4,1 g glucose

8,1 g sucrose

Date of approval: 26 July 2023

PATIENT INFORMATION LEAFLET**SCHEDULING STATUS:** S0**REHIDRAT BLACKCURRANT powder****REHIDRAT ORANGE powder****REHIDRAT VANILLA powder****Glucose/Potassium chloride/Sodium bicarbonate/Sodium chloride/Sucrose/Glucose****Contains sugar: Each 14 g sachet contains 8,1 g sucrose and 4,1 g glucose.****Read all of this leaflet carefully because it contains important information for you.**

REHIDRAT is available without a doctor's prescription, for you to treat a mild illness.

Nevertheless, you still need to use REHIDRAT carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Do not share REHIDRAT with any other person.
- Ask your health care provider or pharmacist if you need more information or advice.
- You must see your doctor if your symptoms worsen or do not improve.

What is in this leaflet

1. What REHIDRAT is and what it is used for.
2. What you need to know before you use REHIDRAT.
3. How to use REHIDRAT.
4. Possible side effects.
5. How to store REHIDRAT.
6. Contents of the pack and other information.

1. What REHIDRAT is and what it is used for

REHIDRAT contains glucose and various salts which belong to a group of medicines called oral electrolytes, which act to replace lost fluids and salts. It can be used to relieve short term (acute) diarrhoea and vomiting and replace lost salts and fluids in your body, in order to prevent dehydration.

2. What you need to know before you use REHIDRAT

Do not take REHIDRAT

- If you or your child are hypersensitive (allergic) to glucose, potassium chloride, sodium bicarbonate, sodium chloride, sucrose or any of the other ingredients of REHIDRAT (see **What REHIDRAT contains**).
- If you or your child suffer from kidney problems, such as oliguria or anuria (producing little or no urine) partial or full blockage (obstruction) of your bowel and uncontrolled vomiting.
- If you or your child have severe diarrhoea or uncontrollable vomiting which is causing severe dehydration.
- If you or your child have an intolerance to some sugars, unless a doctor tells you to (see **What REHIDRAT contains**).
- If you or your child suffers from hemodynamic shock (weakness, dizziness or fatigue).

Warnings and precautions

Take special care with REHIDRAT

- If you or your child has difficulty taking REHIDRAT orally, or if you or your child is becoming weaker, dehydrated or has severe diarrhoea for 12 hours. You should contact a doctor or health care provider if this happens.
- If you or your child have kidney failure (reduced amount of urine, swelling of your legs, ankles or feet because of fluid retention).
- If you or your child have adrenal problems.

- If you or your child are dehydrated (losing more fluids than you can take in).
- If you or your child have muscle or heat cramps.
- If you or your child are taking water tablets (used to treat excessive fluid build-up in your body).
- If you or your child suffers from heart problems, high blood pressure, swelling of hands and feet, protein in your urine or water in your lungs (breathing problems, increased sweating, fatigue).
- If you or your child is diabetic. REHIDRAT contains sugar and the sugar content should be taken into account.
- If you or your child are taking in REHIDRAT too fast, it can cause vomiting. REHIDRAT should be given or taken in small and frequent amounts.

Other medicines and REHIDRAT

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.)

REHIDRAT with food and drink

See section 3.

Pregnancy, breastfeeding and fertility

Safety of REHIDRAT during pregnancy and lactation has not been established.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking REHIDRAT.

Driving and using machines

REHIDRAT is unlikely to impair your ability to drive a vehicle or use machines. Take special care before performing tasks requiring your attention, until you know how REHIDRAT will affect you.

REHIDRAT contains sucrose and glucose

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking REHIDRAT.

REHIDRAT contains sugar (sucrose and glucose) which may have an effect on the control of your blood sugar if you have diabetes mellitus.

3. How to use REHIDRAT

Do not share medicines prescribed for you or your child with any other person.

Always take REHIDRAT exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How to prepare:

The contents of one 14 g sachet should be dissolved into 250 mL of freshly boiled and cooled water. The solution must be freshly prepared every day. You should discard any unused solution after 1 hour or 24 hours if you store it in a refrigerator.

REHIDRAT should be taken in addition to, and in between, normal feeds/meals in small, frequent and slowly administered amounts.

Infants and children:

Ensure an adequate intake of REHIDRAT to replace the loss of water and electrolytes (see recommended daily dose in **Maintenance therapy** section below).

Maintenance therapy:

Do not exceed the maximum dose. If you feel that you or your child needs additional fluid, water can be given or taken.

Infants below 1 year of age:

Give ½ to 1 cup (100 – 200 mL) of REHIDRAT for every bowel movement.

Children 1 to 5 years of age:

Give at least one cup (200 mL) for every bowel movement.

Older children and adults:

Drink enough REHIDRAT to quench your thirst and replace the fluid lost in every stool.

If you have the impression that the effect of REHIDRAT is too strong or too weak, tell your doctor or pharmacist.

If you take more REHIDRAT than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

Take this leaflet and the remaining REHIDRAT with you so the doctor will know what you have taken.

If you forget to take a dose of REHIDRAT

If you have missed your dose by only a few hours, take the missed dose as soon as you remember. If it is almost time for your next dose, skip the missed dose and take REHIDRAT at the next regularly scheduled time.

Do not take a double dose to make up for the forgotten individual doses.

4. Possible side effects

REHIDRAT can have side effects.

Not all side effects reported for REHIDRAT are included in this leaflet.

Should your or your child's general health worsen or if you experience any untoward effects while taking REHIDRAT, please consult your health care provider for advice.

If any of the following happens, stop taking REHIDRAT and tell your doctor immediately or go to the casualty department at your nearest hospital:

- swelling of your hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing;
- rash or itching;
- fainting.

These are all very serious side effects. If you or your child have them, you may have had a serious allergic reaction to REHIDRAT. You may need urgent medical attention or hospitalisation.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist. You can also report side effects to SAHPRA via the “**6.04 Adverse Drug Reactions Reporting Form**”, found online under SAHPRA's publications:

<http://www.sahpra.org.za/Publications/Index/8>.

By reporting side effects, you can help provide more information on the safety of REHIDRAT.

For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).

5. **How to store REHIDRAT**

- Store in a dry place at or below 30 °C.
- Store all medicines out of reach of children.
- Do not use after the expiry date printed on the sachet.
- Return all unused medicine to your pharmacist.
- Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. **Contents of the pack and other information**

What REHIDRAT contains

Each 14 g sachet contains:

Sodium chloride	0,44 g
Potassium chloride	0,38 g
Sodium bicarbonate	0,42 g
Glucose	4,1 g
Sucrose	8,1 g

When reconstituted with 250 mL water REHIDRAT contains:

	mmol/L
Sodium	50
Potassium	20
Chloride	50
Bicarbonate	20
Citrate	9
Glucose	92
Sucrose	96

Each 14 g sachet contains:

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0,38 g potassium chloride

0,42 g sodium bicarbonate

4,1 g glucose

8,1 g sucrose

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Fructose	1
Total osmolarity	337

The other ingredients are:

Rehidrat Blackcurrant: Citric acid (E330), flavourant (Blackberry Flavour and Blackcurrant Flavour).

Rehidrat Orange: Citric acid (E330), flavourant (Flavour Orange).

Rehidrat Vanilla: Citric acid (E330), flavourant (Flavour Vanilla and Flavour Milk Cream).

What REHIDRAT looks like and contents of the pack

A white to off-white powder.

1, 6 or 20 laminated foil sachets containing 14 g of powder each.

The pack sizes of 6 and 20 sachets are packed in an outer carton.

Holder of certificate of registration

Johnson & Johnson (Pty) Ltd.

241 Main Road

Retreat

7945

South Africa

This leaflet was last revised in

26 July 2023.

Registration numbers

Rehidrat Blackcurrent: Y/24/214

Rehidrat Orange: Y/24/181

Rehidrat Vanilla: N/24/103

Access to the corresponding Professional Information

The latest electronic Professional Information may be found at the SAHPRA website:

<https://www.sahpra.org.za/pi-pil-repository/>.

Alternatively, you may contact Johnson & Johnson (Pty) Ltd. directly at:

Consumer Contact Centre:

0860 410032 (South Africa Only)

SMS jnj & comment to +27 83 293 3273

Email: jnjza@its.jnj.com

Export Registration Details

Botswana:

Rehidrat Blackcurrant: B9311635

Rehidrat Orange: R9700121

Rehidrat Vanilla: B9311630