Professional information for REHIDRAT BLACKCURRANT, REHIDRAT ORANGE & REHIDRAT VANILLA

SCHEDULING STATUS

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1. NAME OF THE MEDICINE

REHIDRAT BLACKCURRANT powder

REHIDRAT ORANGE powder

REHIDRAT VANILLA powder

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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
Fructose	1
Total osmolarity	337

Excipient with known effect:

Contains sugar: Each 14 g sachet contains 8,1 g sucrose and 4,1 g glucose.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Powder.

A white to off-white powder.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Prevention and treatment of dehydration and electrolyte depletion associated with diarrhoea and gastro-enteritis.

4.2 Posology and method of administration

Posology:

Infants and children:

During the rehydration phase of therapy, care should be taken to 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:

Patients should be observed carefully to confirm adequate maintenance of hydration.

Frequent clinical observations should be made to ensure that adequate hydration is being maintained. The maximal dose of REHIDRAT should not be exceeded. If further fluid intake is required, water should be given freely.

Infants below 1 year of age:

Infants below 1 year of age should be given ½ to 1 cup (100 – 200 mL) of REHIDRAT for every bowel movement.

Children 1 to 5 years of age:

Children 1 to 5 years of age should be given at least one cup (200 mL) for every bowel movement.

Older children and adults:

Older children and adults should drink enough REHIDRAT to quench their thirst and replace the fluid lost in every stool.

If fluid volumes and body mass can be measured, the following doses can be used instead of those above and a nasogastric tube can be used to administer REHIDRAT:

Maintenance of hydration in patients unable to take usual feeds/meals:

Infants below 1 year of age:	120 mL /kg/day
Children 1 - 2 years of age:	100 mL/kg/day
Children 2 - 4 years of age:	85 mL/kg/day

Children 4 - 10 years of age: 70 mL/kg/day

Children over 10 years and adults: 2 to 3 litres/day

Rehydration in mild dehydration:

50 mL/kg body mass over the first 6 hours, followed by maintenance therapy.

Rehydration in moderate to severe dehydration:

100 mL/kg body mass over the first 6 hours, followed by maintenance therapy.

Patients with moderate to severe dehydration are preferably rehydrated via the intravenous route with specially formulated intravenous dextrose-electrolyte solutions.

Ongoing losses:

For every stool passed 10 to 20 mL/kg body mass should be given in addition to, and in between, normal feeds/meals.

Method of administration:

The contents of one 14 g sachet should be dissolved in 250 mL of freshly boiled and cooled water. The solution must be freshly prepared every day. Discard unused solution after 24 hours.
Oral rehydration solution should be administered using a method that the infant is familiar with e.g. baby bottle, cup or spoon.
Breastfeeding mothers may choose any of the aforementioned methods to administer the solution to their infants.
REHIDRAT should be given in addition to, and in between, normal feeds/meals in small, frequent and slowly administered amounts.

4.3 Contraindications

- Hypersensitivity to glucose, potassium chloride, sodium bicarbonate, sodium chloride, sucrose or to any of the inactive ingredients of REHIDRAT (see section 6.1).
- Patients with renal failure manifesting as oliguria or anuria, intestinal obstruction and paralytic ileus.
- Patients with severe diarrhoea where parenteral fluid therapy is required, such as severe dehydration or intractable vomiting, glucose-galactose malabsorption syndrome, and haemodynamic shock.

4.4 Special warnings and precautions for use

Contact a doctor, health professional, local clinic or hospital if:

- The infant cannot take fluid by mouth or is becoming weaker and dehydrated.
- Severe diarrhoea continues for 12 hours.

Care should be exercised when the formulation is given to patients with renal failure and diabetes insipidus.

Potassium should be given with caution to patients with renal or adrenal insufficiency, acute dehydration, muscle cramps or heat cramps as well as patients receiving angiotensin-converting enzyme inhibitors, and other potassium containing or potassium-sparing diuretics.

Sodium salts should be used with caution in patients with cardiac failure, hypertension, peripheral and pulmonary oedema, eclampsia/pre-eclampsia or aldosteronism. Sodium chloride solutions should not be used to induce emesis (see section 4.9).

Administration of oral sugar-electrolyte solutions to patients with sugar malabsorption may worsen the diarrhoea.

Glucose intolerance may occur in some patients with diarrhoea.

REHIDRAT should not be mixed or given with other oral electrolyte solutions. Salt or sugar should not be added to REHIDRAT.

When REHIDRAT is used alone or as a supplement to parenteral fluid therapy, care must be taken not to exceed the total water and electrolyte requirements.

Rapid intake of REHIDRAT may result in vomiting. REHIDRAT should be given in small and frequent amounts.

Patients should stop use and consult a physician if symptoms persist or worsen, or if any new symptoms occur.

REHIDRAT contains sugar (sucrose) and glucose. Patients with rare hereditary conditions such as fructose intolerance, glucose-galactose malabsorption or sucrase isomaltase insufficiency should not take REHIDRAT. REHIDRAT may have an effect on the glycaemic control of patients with diabetes mellitus.

4.5 Interaction with other medicines and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

There are no adequate and well controlled studies for the combination of glucose, potassium chloride, sodium bicarbonate, sodium chloride in pregnant or breastfeeding women.

Safety during pregnancy and lactation has not been established.

4.7 Effects on ability to drive and use machines

The effect of REHIDRAT on the ability to drive a vehicle and use machines have not been studied. REHIDRAT is not expected to have any effect on the ability to drive a vehicle or operate machines.

4.8 Undesirable effects

No adverse events were identified for the combination of glucose, potassium chloride, sodium bicarbonate, sodium chloride and sucrose from the review of post marketing safety data.

Reporting of suspected adverse reactions:

Reporting suspected adverse reactions after authorisation of REHIDRAT is important. It allows continued monitoring of the benefit/risk balance of REHIDRAT. Health care providers are asked to report any suspected adverse reactions to SAHPRA via the "**6.04 Adverse Drug Reactions Reporting Form**", found online under SAHPRA's publications:
https://www.sahpra.org.za/Publications/Index/8.
For further information, please contact the Johnson & Johnson call centre on 0860 410032 (landline).

4.9 Overdose

No overdose-associated adverse events for glucose, potassium chloride, sodium bicarbonate, sodium chloride and sucrose have been reported in literature or post marketing safety data.

The information presented below describes potential overdose symptoms where REHIDRAT is

improperly formulated with water or ingested in large amounts without being diluted with water.

Glucose:

Overdosage of glucose may cause nausea and vomiting.

Potassium chloride:

Overdosage of potassium may cause hyperkalaemia with vomiting, paraesthesia of the extremities, cyanosis, poor peripheral pulses, listlessness, mental confusion, weakness/hypotonia, paralysis, unconsciousness, hypotension, abnormal electrocardiography findings and cardiac dysrhythmias, heart block and cardiac arrest.

Sodium bicarbonate:

Overdosage of sodium bicarbonate may lead to hypokalaemia, hypernatremia, hypochloraemia and metabolic alkalosis. Symptoms include nausea and vomiting, abdominal pain, diarrhoea, abdominal bloating and gas, mood changes, tiredness/lethargy/drowsiness and weakness, dizziness, agitation, respiratory depression/hypoventilation and irregular heart beat/abnormal electrocardiographic changes. Muscle hypertonicity, twitching, and tetany may develop, especially in hypocalcaemic patients.

Sodium chloride:

Overdosage of sodium may cause hypernatraemia, symptoms of which may include nausea, vomiting, diarrhoea, restlessness, or agitation, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypotension or hypertension, tachycardia, drowsiness/lethargy, muscle twitching, delirium/altered

mental status, seizures/convulsions, coma, and, hyperpnoea or tachypnoea and respiratory arrest.

Sodium chloride solutions should not be used to induce emesis.

Treatment is symptomatic and supportive.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Category and class: A 24 Mineral substitutes, electrolytes.

Pharmacotherapeutic group: Oral rehydration salt formulations.

ATC code: A07CA

REHIDRAT powder is a glucose-electrolyte mixture which, when mixed with water as directed, replenishes electrolytes and fluids.

5.2 Pharmacokinetic properties

Absorption:

Glucose:

Glucose is rapidly absorbed from the gastrointestinal tract, It is actively absorbed against a concentration gradient in the small intestine via the sodium dependent glucose transporter (SGLT1) into the enterocyte cytoplasm, and then transported out of the enterocyte into the intracellular space by glucose transporter2 (GLUT-2).

Following oral administration of 25 mg/mL glucose solution, bioavailability was reported to be 0,65 in a group of healthy elderly subjects and 0,70 in a group of healthy young subjects, with no significant difference between the two groups; approximately 30 % to 35 % of the orally taken glucose did not reach the plasma. In hypoglycemic patients, maximum plasma concentration is achieved approximately 40 minutes after oral doses.

Potassium chloride:

Potassium chloride is readily absorbed from the gastrointestinal tract via passive diffusion. Apparent potassium absorption was 85 %, which did not significantly change over the wide range of intakes.

Approximately 90 % of potassium was absorbed following administration of 40 mEq potassium chloride liquid formulation. Mean peak plasma concentrations of potassium following oral administration of liquid potassium chloride formulations (50 and 64 mEq doses) were 5,8 and 4,9 mEq/L, respectively, corresponding to a 19 to 38 % increase from normal levels. The time taken to reach maximum serum concentration (T_{max}) after a single oral administration of liquid potassium chloride formulation ranged from 1,0 h to 1,5 h.

Sodium bicarbonate:

In healthy subjects, bicarbonate exhibited net movement across jejunal and ileal mucosa against an electrochemical gradient. Bicarbonate absorption is hypothesized to be mediated by active hydrogen secretion, and related to the transport of other electrolytes, specifically chloride, sodium and hydrogen, via the chloride/bicarbonate transporter and sodium/hydrogen transporter.

Sodium chloride:

Absorption of sodium and chloride primarily occurs in the small intestine. Apparent sodium absorption was approximately 98 % across a wide intake range with mean positive metabolic balance of + 0,47 g/day for sodium.

Sucrose:

Sucrose is hydrolysed in the small intestine by the enzyme sucrase to glucose and fructose which are then absorbed.

Distribution:

Glucose:

The volume of distribution of an orally administered glucose solution (25 mg/mL) was found to be 0,0078 mL (range 0,0049 – 0,0125 mL) in young healthy subjects and 0,0186 mL (range 0,0152 – 0,0204 mL) in elderly subjects.

Potassium chloride:

Approximately 98 % (3420 mEq) of potassium is found intracellularly in muscle tissue, liver, and red blood cells; 2,0 % (80 mEq) is distributed in the extracellular fluid. Plasma protein binding of K+ is negligible.

Sodium bicarbonate:

Clinical studies on the distribution kinetics of oral formulations of sodium bicarbonate in healthy subjects are limited. However, a study using intravenous formulations showed that the “initial equilibrium” volume of distribution of excess buffer base ranged from 15 % to 32 % in healthy subjects infused with an intravenous formulation of sodium bicarbonate, with an average value of 21,0 % of body weight.

Sodium chloride:

Majority of absorbed sodium and chloride are found extracellularly: in plasma (at concentrations of 140 mmol/L for sodium and 104 mmol/L for chloride), interstitial fluid (145 mmol/L for sodium and 115 mmol/L for chloride), and plasma water (150 mmol/L for sodium and 111 mmol/L for chloride).

Intracellularly, both sodium and chloride have normal concentrations of 3 mmol/L, including in muscle tissues.

Sucrose:

There is limited data on the distribution of oral sucrose in man.

However, the volume of distribution of intravenously administered sucrose in four normal subjects was found to be between 7,8 and 14,3 L (16,2 % to 19,1 % body weight).

Metabolism:

Glucose:

Glucose is metabolised via pyruvic or lactic acid to carbon dioxide and water with the release of energy.

Potassium chloride:

There is no information available regarding the metabolism of potassium chloride in humans.

Sodium bicarbonate:

There is no information available regarding the metabolism of sodium bicarbonate in humans.

Sodium chloride:

There is no information available regarding the metabolism of sodium chloride in humans.

Sucrose:

Sucrose is hydrolysed in the small intestine by sucrase to glucose and fructose. Hydrolysis products of sucrose are metabolised through different pathways in the body. Glucose elicits a glycaemic and insulinemic response that stimulates its uptake into cells while fructose is mainly metabolised in the liver via an insulin-dependent pathway not regulated by energy supply. Fructose may be converted into trioses that can be used for the de novo synthesis of triglycerides and cholesterol.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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).

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Rehidrat Blackcurrant: 36 months.

Rehidrat Orange: 24 months.

Rehidrat Vanilla: 24 months.

The reconstituted solution should be discarded after 1 hour or 24 hours if stored in a refrigerator.

6.4 Special precautions for storage

Store in a dry place at or below 30 ºC.

6.5 Nature and contents of container

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.

6.6 Special precautions for disposal and other handling

No special requirements.

7. HOLDER OF CERTIFICATE OF REGISTRATION

Johnson & Johnson (Pty) Ltd.

241 Main Road,

Retreat

7945

South Africa

8. REGISTRATION NUMBERS

Rehidrat Blackcurrant:	Y/24/214
Rehidrat Orange:	Y/24/181
Rehidrat Vanilla:	N/24/103

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1 October 1991.

10. DATE OF REVISION OF THE TEXT

26 July 2023.

Export Registration Details

Botswana:

Rehidrat Blackcurrant:	B9311635
Rehidrat Orange:	R9700121
Rehidrat Vanilla:	B9311630