

REHIDRAT BLACKCURRANT
REHIDRAT ORANGE
REHIDRAT VANILLA

SCHEDULING STATUS:

S0

PROPRIETARY NAMES (and dosage forms):

REHIDRAT BLACKCURRANT (Powder)

REHIDRAT ORANGE (Powder)

REHIDRAT VANILLA (Powder)

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:

	<u>mmol/l</u>
Sodium	50
Potassium	20
Chloride	50
Bicarbonate	20
Citrate	9
Glucose	92
Sucrose	96
Fructose	1
Total osmolarity	337

PHARMACOLOGICAL CLASSIFICATION:

A: 24 Mineral substitutes, electrolytes.

PHARMACOLOGICAL ACTION:

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

INDICATIONS:

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

CONTRA-INDICATIONS:

REHIDRAT is contra-indicated in patients with renal impairment manifesting as oliguria or anuria, intestinal obstruction, paralytic ileus and intractable vomiting.

Severe diarrhoea where parenteral fluid therapy is required. Patients with glucose-galactose malabsorption syndrome.

WARNINGS:

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.

DOSAGE AND DIRECTIONS FOR USE:

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.

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.

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 less than 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 should be given at least one cup (200 ml) for every bowel movement.

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 less than 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.

SIDE-EFFECTS AND SPECIAL PRECAUTIONS:

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.

The sugar content of REHIDRAT should be considered when treating diabetic patients.

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

Glucose intolerance may occur in some patients with diarrhoea.

Sodium salts should be used with caution in patients with cardiac failure, hypertension, peripheral and pulmonary oedema.

Potassium should be given with caution to patients with renal or adrenal insufficiency, acute dehydration or heat cramps as well as patients receiving potassium-sparing diuretics.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:

Overdosage of glucose may cause nausea and vomiting.

Overdosage of potassium may cause hyperkalaemia with paraesthesiae of the extremities, listlessness, mental confusion, weakness, paralysis, hypotension, cardiac arrhythmias, heart block and cardiac arrest.

Overdosage of sodium may cause hypernatraemia, symptoms of which may include restlessness, weakness, thirst, reduced salivation and lachrymation, swollen tongue, flushing of the skin, pyrexia, dizziness, headache, oliguria, hypotension, tachycardia, delirium, hyperpnoea and respiratory arrest.

Treatment is symptomatic and supportive.

IDENTIFICATION:

A white to off-white powder.

PRESENTATION:

Laminated foil sachet containing 14 g of powder.

STORAGE INSTRUCTIONS:

Store in a dry place below 30°C.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBERS:

Rehidrat Blackcurrant: Y/24/214

Rehidrat Orange: Y/24/181

Rehidrat Vanilla: N/24/103

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:

Johnson & Johnson (Pty) Ltd.

241 Main Road,

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