FINAL PACKAGE INSERT [1]

SCHEDULING STATUS

S3

PROPRIETARY NAME AND DOSAGE FORM

REHYDRATION SOLUTION FRESENIUS Infusion

COMPOSITION

	Each 200 ml contains:	**Each 1 000 ml contains:**
Sodium chloride	0,9 g	4,5 g
Dextrose monohydrate	11 g	55 g
Equivalent to/or		
Dextrose anhydrous	10 g	50 g
Water for injections ad	200 ml	1 000 ml

PHARMACOLOGICAL CLASSIFICATION

A 24 Mineral substitutes, electrolytes

PHARMACOLOGICAL ACTION

General principles of IV fluid therapy

1. To provide daily maintenance needs.
2. To repair deficits developed prior to treatment.
3. To replace any concurrent abnormal losses in excess of maintenance needs.

[1] Notification of Regulation 9 compliance only

When fluid losses prior to therapy have not exceeded intake, only daily maintenance needs must be fulfilled. When past maintenance needs have not been met or when fluid losses have exceeded intake, repair of past losses is required in addition to daily maintenance. When, during treatment, excessive fluids are lost via sweating, diarrhoea, vomiting, gastrointestinal suction, or drainage, additive replacement therapy is required.

Daily maintenance:

The average adult patient with normal renal function excretes about 1 000 – 1 500 ml of water per day as urine. The daily extrarenal water losses consist of faecal loss of 100 – 300 ml, and insensible loss of 850 – 1 500 ml, 60 per cent via the skin and 40 per cent via the lungs. Faecal loss is greatly increased by diarrhoea. Insensible loss is affected by rate and depth of respiration, fever, room temperature, humidity, and particularly by sweating, which may increase the loss to 100 ml per square metre of body surface per hour.

Depending on intake, the normal adult excretes daily in the urine about 2,5 g of sodium, about 2,3 g of potassium, and about 4,2 g of chloride. Extrarenal loss of electrolytes in the stool and sweat may vary greatly, depending on diarrhoea, sweating, and the extent of adaptation to warm temperature or salt depletion.

Thus, daily maintenance therapy in the average adult patient with normal renal function, without regard to replacement of any past deficits or concurrent abnormal losses, should provide the following:

1. Fluid: 2 600 ml
2. Sodium: about 110 mmol
3. Potassium: about 60 mmol
4. Protein or protein hydrolysate: 50 g
5. Carbohydrate: at least 100 g to minimise fasting ketosis.

Most patients require many more calories.

The parenteral solutions available for this purpose include carbohydrate in water solutions; carbohydrate in sodium chloride solutions; isotonic sodium chloride solutions; potassium solutions; multiple electrolyte solutions; vitamin solutions.

Used in proper combination, these solutions are adequate for 80 percent of the patients requiring maintenance fluid therapy. The dosage criterion for most of these solutions is body weight.

Solution	% Laevulose	% Dextrose	millimoles			Calories/ (joules)	Approx pH
			Na^+	K^+	Cl^-		
GSH Maintenance	2,5	2,5	26	26	5,2	200 (836,8)	4,5
GSH Replacement	2,5	2,5	103	15	118	200 (836,8)	4,5

However, some investigations find that the body surface provides a better index of electrolyte requirements, especially in children.

The GSH solutions are a group of multiple electrolyte solutions, some designed for daily water and electrolyte maintenance and others for the replacement of losses.

GSH maintenance solution with 2,5 % dextrose and 2,5 % laevulose, when administered in accordance with water needs, provides electrolytes in an amount to meet the usual daily needs without exceeding the body's tolerance for electrolytes when there is adequate kidney function. It is designed to provide the usual daily needs in infants and children. The solution provides more water in relation to electrolytes than the replacement solution and should be used in adults when there is excessive water loss or an inability to concentrate urine.

The replacement solution has essentially the same composition as plasma except that the concentration of potassium is doubled. The replacement solution is useful for the replacement of intravascular, interstitial and transcellular fluid losses caused by diarrhoea, loss of plasma, etc.

INDICATIONS

One or more of the GSH multiple electrolyte solutions are indicated in most patients requiring fluid and electrolyte therapy. The solutions are designed to facilitate treatment of the patient in accordance with the basic principles of fluid therapy.

GSH maintenance solution:

1. Daily water and electrolytes maintenance.
2. Sweating.
3. Water depletion due to reduction in water intake.
4. Potassium deficit resulting from chronic pyloric obstruction, ulcerative colitis, burns (healing phase), prolonged infusion of potassium-free solutions, vomiting, and diarrhoea.
5. Mild metabolic acidosis.

GSH replacement solution:

1. Mild diarrhoea.
2. Excessive water intake or sodium depletion, hyponatraemia.
3. Diabetic acidosis.
4. Metabolic acidosis.
5. Postoperative water retention resulting in hyponatraemia.
6. Replacement or maintenance of extracellular fluid volume preoperatively or postoperatively.

CONTRAINDICATIONS

1. Patients with severe renal disease, adrenal insufficiency or hypoparathyroidism.
2. Patients with diabetes insipidus. GSH maintenance solution can be used to supply electrolytes but the greater portion of water requirements should be supplied with carbohydrate and water solutions.
3. Hyperkalaemia.

WARNINGS AND SPECIAL PRECAUTIONS

1. Marked losses of sodium should be replaced with replacement solution, 0,9 % sodium chloride, or 5 % sodium chloride.
2. In hyponatraemia without marked oedema, replacement solution, 0,9 % sodium chloride, or 5 % sodium chloride should be used.
3. Establish renal function using 5 % dextrose in 0,2 % sodium chloride before giving potassium-containing solutions.
4. GSH Multiple Electrolyte Solutions do not supply calcium or magnesium to correct calcium or magnesium deficiency.
5. Sodium content may cause oedema in salt-retaining patients.
6. Supplementary doses of potassium may be required to correct potassium deficit.
7. Use with caution in patients with hypertension, heart failure, peripheral or pulmonary oedema, pre-eclampsia or other conditions associated with sodium retention.

DOSAGE AND DIRECTIONS FOR USE

Dose – Maintenance Solution is given on the basis of water requirements. About 1 300 ml per square metre of body surface per 24 h, supplies the minimal maintenance needs of water and electrolytes. The dose can be safely increased to 3 000 ml per square metre per 24 h to cover abnormal maintenance needs. For example, a man having a height of 1,7 m,

and weighing 68 kg has a body surface area of 1,8 square metres. The recommended dose would therefore be a minimum of 2 340 ml to a maximum of 5 400 ml per day.

It is interesting to note however, that professor D.A.K. Black in his “Essentials of Fluid Balance” states the following: ‘great many intravenous solutions for fluid therapy have been described There is no “dose” of such preparations. The amount to be given has to be assessed from the initial clinical and biochemical observations, and reassessed from time to time by further observations, of which those concerning general well-being, the state of the circulation and the amount of urine formed are perhaps the most important’.

Replacement solution is given on the basis of the loss being replaced. About 1 – 2 L is the usual adult dose.

Rate – Solutions are given at a rate of 120 – 240 ml per square metre of body surface area per hour.

The rate for a 68 kg patient is about 210 ml per h.

Replacement solution can be given as rapidly as 1L in ½ hour, however, a slower rate is recommended.

Route – All solutions should be given intravenously.

SIDE EFFECTS

See “Warnings and special precautions”.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

Not applicable.

IDENTIFICATION

A clear, colourless to light straw coloured solution, sterile and pyrogen-free, of the above ingredients in water for injections.

PRESENTATIONS

1 000 ml – 1's and 12's in freeflex bags

STORAGE INSTRUCTIONS

Store at or below 25 °C.

KEEP OUT OF REACH OF CHILDREN

REGISTRATION NUMBER

F/24/64

NAME AND BUSINESS ADDRESS OF THE HOLDER OF CERTIFICATE OF REGISTRATION

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