



6/12615566/0314

# 5% Dextrose In 0.9% Sodium Chloride

## Solution for infusion

### Composition

1000 mL of solution contain

Sodium chloride	9.0 g
Dextrose	50.0 g
(as dextrose monohydrate, 55.0 g)	

### Electrolytes

Sodium	154 mmol/L
Chloride	154 mmol/L

### Excipients

Water for injections

### Pharmaceutical form

Solution for infusion;  
Clear, colourless aqueous solution

Energy:	835 kJ/l $\triangle$ 200 kcal/L
Theoretical osmolarity:	586 mOsm/L
pH:	3.5 – 5.5

### Pharmacotherapeutic group

Solutions affecting the electrolyte balance  
ATC code: B05B B02 (Electrolytes with carbohydrates)

### Indications

- Fluid and electrolyte substitution in hypochloraemic alkalosis
- Chloride losses
- Hypotonic dehydration
- Isotonic dehydration
- Partial coverage of energy requirements
- Vehicle solution for compatible electrolyte concentrates and medicaments

### Dosage and method of administration

#### Dosage

##### Adults

The dose is adjusted according to the individual requirements of fluid, electrolyte and energy, thus the patient's age, weight, clinical and biological (acid-base balance) conditions and concomitant therapy should be taken into account.

##### Maximum daily dose:

40 ml/kg body weight (BW) per day, corresponding to 2 g dextrose/kg BW per day and 6 mmol of sodium / kg BW per day

##### Maximum infusion rate:

5 ml/kg BW per hour, corresponding to 0.25 g dextrose/kg BW per hour.

Partial coverage of energy requirements, i. e. substitution of the obligatory daily dextrose requirements, is only possible with the maximum dose stated above.

### Pediatric patients

The dose is adjusted according to the individual requirements of fluid, electrolytes and energy. Thus the patients age, weight, clinical and biological (acid-base balance) conditions and concomitant therapy should be taken into account.

When administering this solution the total daily fluid and dextrose requirements should be taken into account.

### Elderly patients

Basically the same dosage as for adults applies, but caution should be exercised in patients suffering from further diseases like cardiac insufficiency or renal insufficiency that may frequently be associated with advanced age.

### Other special patient groups

If the oxidative metabolism of glucose is impaired (e.g. in the early post-operative or post-traumatic period or in the presence of hypoxia or organ failure), the dosage should be adjusted to keep the blood glucose level close to normal values. Close monitoring of blood glucose levels is recommended in order to prevent hyperglycaemia. See also section Special warnings and precautions for use.

### Method of administration

#### Intravenous use

Hypertonic solutions should be administered in a large peripheral or central vein to diminish the risk of causing irritation.

### Contraindications

5% Dextrose In 0.9% Sodium Chloride must not be used in cases of

- hyperhydration
- hypertonic dehydration
- untreated hypokalaemia
- metabolic acidosis
- persistent hyperglycaemia not responding to insulin doses of up to 6 units/hour
- pulmonary or brain oedema
- decompensated cardiac insufficiency

### Special warnings and precautions for use

5% Dextrose In 0.9% Sodium Chloride should only be administered with caution in cases of

- hypernatraemia
- hyperchloraemia
- disorders where restriction of sodium intake is indicated, such as cardiac insufficiency, generalized oedema, pulmonary oedema, hypertension, eclampsia, severe renal insufficiency
- In patients with acute ischaemic stroke and hy-

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perglycaemia the glucose level should be corrected before application of this solution

**Please note:** If this solution is used as vehicle solution the safety information of the additive provided by the respective manufacturer have to be taken into account.

Clinical monitoring should include checks of the serum electrolytes (especially potassium), glucose level, the acid-base and water balance.

In post-operative and post-traumatic conditions and in conditions of impaired glucose tolerance: only administer with monitoring of blood glucose level.

The solution should not be administered through the same infusion equipment simultaneously, before or after an administration of blood because of the possibility of pseudo-agglutination.

#### **Interactions with other medicinal products and other forms of interaction**

##### **Corticosteroids**

Corticosteroids are associated with the retention of sodium and fluid.

#### **Fertility, pregnancy and lactation**

##### **Pregnancy**

There is a limited amount of data from the use of this 5% Dextrose In 0.9% Sodium Chloride in pregnant women. Animal studies relating to glucose and sodium chloride do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development.

Therefore caution should be exercised when prescribing to pregnant women, especially in the presence of eclampsia (see section Special warnings and precautions for use).

Careful monitoring of blood glucose is necessary.

##### **Lactation**

It is unknown whether 5% Dextrose In 0.9% Sodium Chloride or metabolites are excreted into breast-milk. As all active ingredients are present in human body, no negative effects are anticipated if used during lactation. Therefore, the solution can be used as indicated.

##### **Fertility**

Not relevant

#### **Effects on ability to drive and use machines**

5% Dextrose In 0.9% Sodium Chloride has no influence on the ability to drive and use machines.

#### **Undesirable effects**

Provided the solution is administered according to the directions given, adverse effects are not to be expected.

#### **Overdose**

##### **Symptoms**

Overdose may result in hyperhydration, with increased skin tension, venous congestion, oedema –

possibly also lung or brain oedema –, dilution of serum electrolytes, electrolyte imbalances, notably hypernatraemia, hyperchloraemia (see section Undesirable effects) and hypokalaemia, acid-base imbalances, hyperglycaemia, and hyperosmolarity of the serum (up to hyperglycaemic-hyperosmolar coma).

##### **Treatment**

Dependent on the severity of the disorders immediate stop of infusion, administration of diuretics with continuous monitoring of serum electrolytes, correction of electrolyte and acid-base imbalances, administration of insulin if necessary.

In severe cases of overdose dialysis may be necessary.

#### **Incompatibilities**

When mixing with other medicinal products possible incompatibilities should be considered. It should be remembered that the solution has an acid pH, which can cause precipitation in the mixture.

#### **Expiry date**

The product must not be used beyond the expiry date stated on the labelling.

##### **Shelf life after admixture of additives**

From a microbiological point of view, the product should be used immediately. If not used immediately, in-use storage times and conditions prior to use are the responsibility of the user and would normally not be longer than 24 hours at 2 to 8 °C, unless dilution has taken place in controlled and validated aseptic conditions.

#### **Special precautions for storage**

This medicinal product does not require any special storage conditions.

For storage conditions of the medicinal product after admixture of additives, see section above.

#### **Availability**

500 mL, 1000 mL

DR-XY12423

#### **Special precautions for disposal and other handling**

No special requirements for disposal.

The containers are for single use only. After use – discard container and any remaining contents.

Do not reconnect partially used containers.

Only to be used if the solution is clear and colourless and the container and its closure are undamaged.

#### **Caution**

Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

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