B. Braun Melsungen AG · 34209 Melsungen, Germany

0.18% w/v Sodium Chloride and 4% w/v Glucose Intravenous Infusion BP

Solution for infusion
(Sodium chloride, Glucose)

Read all of this leaflet carefully before you start using this medicine because it contains important information for you.
- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

What is in this leaflet:

1. What 0.18% w/v sodium chloride and 4% w/v glucose is and what it is used for

0.18% w/v Sodium Chloride and 4% w/v Glucose is a solution for infusion. which will be given to you as an intravenous infusion (drip) by your doctor. It will be given to you if you are dehydrated and lose water (hypertonic dehydration).

You are given this medicine to provide you partially with carbohydrates if you are unable to eat and drink normally, especially if your energy needs are high or if you need restriction of fluid intake.

This solution may also be used to dissolve or dilute medicines that are to be given to you by an intravenous infusion (drip).

2. What you need to know before you use 0.18% w/v sodium chloride and 4% w/v glucose

Do not use 0.18% w/v Sodium Chloride and 4% w/v Glucose
- if you are allergic to sodium chloride or glucose or any of the other ingredients of this medicine (listed in section 6.)
- if you have an excessively high body fluid level (hyperhydration)
- if you are lacking water and salt (hypotonic dehydration)
- if you have a head trauma (first 24 hours)
- if you have severe kidney failure and no dialysis facilities are available
- if you have an abnormally high blood sugar level that only responds to high insulin doses or intolerance to glucose.

Paediatric population

This product should not be used in children except in paediatric specialist settings (such as renal, hepatic and cardiac units, high dependency units and intensive care units) under expert medical supervision.

Warnings and precautions

This medicine must not be used to treat fluid deficits without adequate administration of salts, since this may markedly reduce the salt concentration in your blood. A lack of salts can lead to problems with your heart and damage your brain.

This medicine shouldn't be used for routine rehydration or fluid maintenance therapy

Special care should be taken if you have an abnormally low level of sodium or potassium in the blood. An adequate supply of salts (in particular potassium and sodium) will then be ensured.

In diabetic patients, the amount of infused glucose has to be taken into account and insulin requirements may be modified.

You should normally not receive this medicine if you suffer or have recently suffered from stroke except your doctor considers it essential for your recovery.

Your levels of blood sugar, electrolytes (especially potassium) and acid-base and water balance will be checked to make sure that these are correct before and during infusion.

After major operations or severe injuries (post-traumatic and post-operative conditions or in the presence of tissue oxygen deficiency, abnormally high level of acid in the blood or organ failure) you may not be able to metabolise glucose properly (impaired glucose tolerance). Your blood sugar level will then be regularly monitored.

Please note:

If this solution is used to dilute or dissolve medicines that are to be given to you by a drip into your vein, your doctor will take into account the safety information of the additive.

Other medicines and 0.18% w/v Sodium Chloride and 4% w/v Glucose

Tell your doctor if you are using, have recently used or might use any other medicines.

Your doctor will adjust your dosage if you receive corticosteroids. Corticosteroids may cause an accumulation of sodium and fluid in your body.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor for advice before taking this medicine.

Pregnancy

Your doctor will decide carefully whether or not you should receive this solution if you are pregnant.

Thus special care will be taken if you have a specific disorder that may occur during pregnancy, called eclampsia, with the following symptoms: high blood pressure, cramps, swelling.

Blood sugar levels will be checked regularly.

Breast-feeding

This medicine can be given while you are breast-feeding.

Driving and using machines

0.18% w/v Sodium Chloride and 4% w/v Glucose has no influence on the ability to drive and to use machines.

3. How to use 0.18% w/v sodium chloride and 4% w/v glucose

Dosage

Adults, adolescents and children

The amount of the medicine that will be given to you will be determined by your doctor and will depend on your age, weight, clinical and biological (acid-base-balance) condition and concomitant therapy.

Elderly patients

In general the same dosage as for adults applies. However your doctor will take caution if you are suffering from other diseases often seen with advanced age.

Other special patient groups

If you have an impaired glucose tolerance (e.g. after surgery, severe injury, organ failure, tissue oxygen deficiency etc.), the dosage should be adjusted to keep the blood glucose level close to normal values.

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If you received more 0.18% w/v Sodium Chloride and 4% w/v Glucose than you should

It is unlikely that this occurs because your doctor will determine your daily doses.

Symptoms

An overdose may lead to excess fluid in the body (hyperhydration), electrolyte imbalances (especially hypokalaemia and hyponatraemia), acid-base imbalances, and high blood sugar (hyperglycaemia). Severe hyponatraemia could lead to death.
Clinical symptoms of overdose may occur as nausea, vomiting, spasms, increased skin tension, venous congestion (heaviness and swelling of legs) and, tissue swelling (possibly with water on the lungs or swelling of the brain) and thirst.
If you develop such symptoms, inform your doctor immediately.

Treatment

The therapy to normalise your condition will be determined by your doctor. If you have any further questions on the use of this product, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

The following side effects may be serious. If any of the following side effects occur, tell your doctor immediately, he will stop giving you this medicine:

- electrolyte imbalances (low blood sodium concentration)
- local reactions at the administration site, including local pain, vein irritation and inflammation of the vein

Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet.

You can also report side effects directly via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971;
Fax: +353 1 6762517. Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store 0.18% w/v sodium chloride and 4% w/v glucose

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the container and carton labels. The expiry date refers to the last day of that month.

This medicinal product does not require any special storage conditions.

This medicine must only to be used if the solution is clear and colourless up to faintly strawcoloured and the container and its closure are undamaged.

This medicine is for single use only. After use discard container and any unused medicine.

Containers once opened must be used immediately and must not be stored for later use.

6. Contents of the pack and other information

What 0.18% w/v Sodium Chloride and 4% w/v Glucose contains

The active substances are:

sodium chloride and glucose

- 1000 ml of solution contain

Sodium chloride	1.8 g
Glucose monohydrate	44.0 g
equivalent to glucose	40.0 g
Energy	668 kJ/l ≙ 160 kcal/l
Theoretical osmolarity:	282 mOsm/l
Acidity (titration to pH 7.4):	< 0.5 mmol/l
pH:	3.5 – 5.5

The other ingredient is:

Water for injections

What 0.18% w/v Sodium Chloride and 4% w/v Glucose looks like and contents of the pack

It is a clear, colourless, to faintly straw-coloured aqueous solution of sodium chloride and glucose in water.

It is supplied in
plastic bottles, contents: 500 ml and 1000 ml
available in packs of 10 x 500 ml, 10 x 1000 ml

Not all pack-sizes may be marketed.

Marketing authorisation holder and manufacturer

Marketing Authorisation Holder

B. Braun Medical Limited,
3, Naas Road Industrial Park,
Dublin 12, Republic of Ireland

Manufacturer

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen, Germany
or
B. Braun Medical, S. A.
Carretera de Terrassa 121
08191 Rubí, Barcelona, Spain

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The following information is intended for healthcare professionals only:

Posology:

The dose has to be adjusted 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 dose is 40 ml/kg body weight per day. The maximum infusion rate is restricted to 5 ml per kg body weight per hour.

Method of administration:

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.

Special warnings and precautions:

0.18 % w/v Sodium Chloride and 4 % w/v Glucose Intravenous Infusion BP, Solution for Infusion should not be used for fluid substitution, especially rehydration therapy, without adequate electrolyte administration, because this could lead to markedly decreased serum electrolyte values, notably severe hyponatraemia, with potentially detrimental effects on the patient, e.g. brain damage or heart affections. Especially children, elderly patients and patients in poor general condition are at risk.

Paediatric population

This product should not be used in children except in paediatric specialist settings (such as renal, hepatic and cardiac units, high dependency units and intensive care units) under expert medical supervision.

Intravenous fluid therapy should be closely monitored in the paediatric population as they may have impaired ability to regulate fluids and electrolytes. Adequate urine flow must be ensured and careful monitoring of fluid balance, plasma and urinary electrolyte concentrations are essential.
The infusion of hypotonic fluids together with the non-osmotic secretion of ADH (in pain, anxiety, the post-operative state, nausea, vomiting, pyrexia, sepsis, reduced circulating volume, respiratory disorders, CNS infections, and metabolic and endocrine disorders) may result in hyponatraemia. Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, cerebral oedema and death, therefore acute symptomatic hyponatraemic encephalopathy is considered a medical emergency.

Treatment of overdose:

Depending 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.

Shelf life after dilution:

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.

In patients with chronic hypernatraemia, the serum sodium concentration should not be lowered faster than at a rate of 0.5 $mmol \times l^{-1} \times h^{-1}$.

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