

## Package leaflet: Information for the user

### Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP

**Read all of this leaflet carefully before you start having 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 nurse.
- If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. See section 4.

#### What is in this leaflet

1. What Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP is and what it is used for
2. What you need to know before you use Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP
3. How to use Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP
4. Possible side effects
5. How to store Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP
6. Contents of the pack and other information

#### **1. What Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP is and what it is used for**

This medicine contains normal salt and glucose (also called grape sugar or dextrose). It is given to you as a venous drip (infusion).

It will be given to you

- To maintain your fluid and salt levels especially if your blood has become too alkaline in combination with low chloride blood levels(hypochloraemic alkalosis)
- If you are lacking water and salt
- If you have lost chloride
- As a partial calorie source to meet your energy requirements.

It may also be used to dilute or dissolve medicines that are to be given to you by a venous drip.

## **2. What you need to know before you use Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP**

You should not receive this medicine

If you suffer from any of the following:

- Excess water in your body tissues (hyperhydration), associated with
- Swelling of the limbs
- Abnormally high levels of electrolytes in your body fluids and tissues
- Due to loss of water (hypertonic dehydration)
- Uncorrected low blood potassium levels
- Your blood has become too acidic (metabolic acidosis)
- Abnormally high blood sugar level that only responds to high insulin
- Doses or intolerance to glucose
- Water on the lungs or in your brain
- Heart failure (decompensated cardiac insufficiency)

### **Special care will be taken with this medicine**

If you suffer from any of the following:

- Abnormally high levels of sodium or chloride in your blood
- Disorders where restriction of sodium intake is indicated, such as
  - Heart failure
  - Severe kidney problems
  - Swelling of the limbs, too much water in your body tissues (generalized Oedema)
  - Lung disease or congestion of, or water on the lungs (pulmonary Oedema)
  - High blood pressure (hypertension)
  - Eclampsia (see section ‘pregnancy and breast-feeding’)

If you suffer from acute stroke or if your blood sugar levels are too high, your doctor will take special care with you: He/she will correct your blood sugar level before you receive this solution.

While you are given this medicine your water balance, salt levels (especially potassium)

and blood sugar levels will be monitored by your doctor.

After major operations or severe injuries (post-traumatic and postoperative conditions) you may not be able to metabolise glucose properly (impaired glucose tolerance). Then your blood sugar level will be regularly monitored. If you suffer from diabetes mellitus, your doctor will carefully monitor your blood sugar level and modify your insulin requirements.

If your blood sodium levels are chronically low, your doctor will take into account that your blood sodium levels must not increase too fast.

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

### **Taking or using other medicines**

Please tell your doctor if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

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

### **Pregnancy and breast-feeding**

#### *Pregnancy*

If you think you are likely to be pregnant, tell your doctor immediately.

Your doctor will give you this medicine only with caution. 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.

If you receive this medicine during labour, the blood glucose level of your child may be altered.

Blood glucose levels will be carefully monitored.

#### *Breast-feeding*

If you are breast-feeding, tell your doctor immediately. This medicine can be given while you are breast feeding.

#### *Fertility*

Not relevant

### **Driving and using machines**

This medicine has no influence on the ability to drive or use machines.

### **3. How to use Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP**

The medicine will be administered to you by infusion (a drip) through a vein.

#### **Dosage**

##### *Adults*

The amount of the medicine that you will be given will be determined by your doctor and will depend on your age, weight, clinical condition and other therapies needed. Thus your individual requirements of fluid, electrolytes and energy will be taken into account.

The normal maximum dosage for an adult is 40 ml/kg body weight/day. The maximum infusion rate is 5 ml per kg body weight per hour.

##### *Children*

Children will receive a reduced dosage dependent upon their age, weight and clinical condition. Thus the individual daily requirements of fluid, electrolytes and energy of your child will be taken into account.

##### *Elderly patients*

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

For example heart failure or kidney failure

##### *Other special patient groups*

Special care will be taken if you have an impaired glucose tolerance (e.g. after surgery, severe injury, diabetes, organ failure etc.). In those cases your blood glucose level will be monitored while you receive this solution.

**If you received more Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous**



### **Infusion BP than you should**

It is unlikely that this happens as your infusion will be controlled by a doctor or nurse.

#### *Symptoms*

An overdose may lead to hyperhydration (excess fluid in the body), which will be followed by

- Increased skin tension
- Congestion of your blood
- Swelling
- Water on the lungs and in your brain
- Disorders of your salt and acid-base balance.

It may also lead to

- High blood sugar values.

#### *Treatment*

The therapy to normalise your condition will be determined by your doctor.

It may include stopping of the infusion, supervision of blood salt level and administration of suitable medicines to treat the symptoms observed (e.g. diuretics, insulin). In extreme situations you may also need dialysis.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

## **4. Possible side effects**

Like all medicines, Sodium Chloride 0.9% w/v and Glucose 5% w/v IV Infusion BP can cause side effects although not everybody gets them.

Side effects may be associated to the technique of administration including febrile response, infection at the site of injection, local pain or reaction, vein irritation, venous thrombosis or phlebitis.

If you notice any side effects, please tell your doctor or pharmacist.

#### Reporting of side effects

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

You can also report side effects directly to [info@aculife.co.in](mailto:info@aculife.co.in).

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

## **5. How to store Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP**

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

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

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

Do not reconnect partially used containers.

This medicine does not require any special storage conditions.

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

Store below 30°C

## **6. What Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP contains**

Each 100 ml of the solution contain

Sodium chloride BP

Glucose (As Anhydrous) BP            0.9 gm

Water for Injections                    5.0 gm

q.s

**What Sodium Chloride 0.9% w/v and Glucose 5% w/v Intravenous Infusion BP looks like and contents of the pack**

Glucose and Sodium chloride infusion is a sterile solution of Anhydrous Glucose and Sodium Chloride for Intravenous Infusion. The drug product is clear colorless solution, presented in a Plastic bottle with a protective cap.

The product is packed in 500ml and 1000 ml Plastic Bottle.

**Holder of Certificate of Registration**

Aculife Healthcare Pvt. Ltd.

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