SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Sodium Chloride BP 0.9 %w/v

Anhydrous Glucose BP 5.0% w/v

3. PHARMACEUTICAL FORM

Intravenous Infusion

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

5% Glucose with normal saline is indicated for the use with blood in the patientswho need additional fluid with minimal sodium intake.As an initial hydrating solution for establishing renal function.When calories are needed and when chloride loss has been greater than or equalto sodium loss.When alkalosis is present, in the presence of fluid loss, in case of gastric suctionwith loss of hydrochloric acid. Therefore loss of chloride is compensated.To provide nutrient in a fluid that doesn't hydrate the tissues

4.2 Posology and method of administration

Posology

Dose: 100 to 1000 ml/day for infants200 to 2000 ml/day for children

1 to 3 litres/ day for adults – depends on age, weight and clinical conditions of thepatient.

Rate: 400 ml/hr in Adults.

4.3 Contraindications

5% Glucose with normal saline is contraindicated in renal insufficiency, in oedema, inpatients with cardiac, hepatic or renal disease etc.

4.4 Special warnings and precautions for use

Precautions: sodium salt should be use with caution in patients withHypertension,Heart failure,Peripheral or pulmonary oedema,renal impairment, pre-eclampsia, or other condition associated with sodium retention.Sodium chloride solution should not be used to induce emesis.The use of hyper osmotic dextrose solution is contraindicated in-patient with

AnuriaIntracranial or intraspinalhaemorrhageDelirium tremens where there is dehydration. It has been suggested that glucose solution should not be used after acute ischaemic strokes as hyperglycaemia has been implicated in increasing cerebral ischaemic braindamage and in impairing recovery.Dextrose solution should not be given through the same infusion equipment as wholeblood as haemolysis and clumping can occur.Sodium chloride & Glucose Intravenous Infusion should not be used routinely afterischaemic stroke, unless specifically indicated.Hypoglycemia must also be avoided and for patients who do require Dextrose, it shouldbe administered by continuous Injection, avoiding large infusions or boluses that cancause hyperglycaemia.

4.5 Interaction with other medicinal products and other forms of interaction

No drug interaction has been noticed with Sodium Chloride & glucose Intravenous Infusion

4.6 Fertility, pregnancy and lactation

It is not known whether it can cause fetal harm administered to a pregnant woman orcan affect reproductive capacity. It should only be given to pregnant woman if thebenefits overweight the risk.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Consult the physician or nurse if you do not feel wellReactions, which may occur because of the solution or the technique of administration,include febrile response, infection at the site of injection, venous thrombosis or phlebitisextending from the site of injection, extravasations and hypervolemia.If an adverse reaction does occur, discontinue the infusion, evaluate the patient, instituteappropriate therapeutic countermeasures and save the remainder of the fluid forexamination if deemed necessary

4.9 Overdose

Symptoms of overdose may include: swelling, trouble breathing.

If overdose is suspected, contact your local poison control center or emergency roomimmediately.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Electrolytes with Carbohydrates, ATC code: B05BB02

Glucose is metabolized to CO2 and water and stored as glycogen while sodiumchloride is distributed in the ECF, all over the body.

5% glucose with normal saline supplies energy, along with correction ofelectrolyte imbalance. Glucose also supplies water along with essential salts.

5.2 Pharmacokinetic properties

Sodium chloride is distributed in ECF easily and built up the salt level rapidly.Thus the second and third step of the dehydration therapy is achieved. Thecombination of glucose with electrolyte eliminates the problem of incompatibilitywhich occurs when plain glucose is given along with preserved blood. This resultsin aggregation of erythrocytes which may lead to many transfusion reactions.It is metabolized via pyruvic or lactic acid to carbon dioxide and water withrelease of energy.All body cells are capable of oxidizing glucose and it forms the principal sourceof energy in cellular metabolismthe kidney mainly excretes excess of the Sodium chloride, and small amount arelost in the faeces and sweat.

5.3 Preclinical safety data

Not applicable since Sodium Chloride and Glucose has been used in clinicalpractice for many years and its effects in man are well known.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Water for Injections BP

6.2 Incompatibilities

Not Applicable.

6.3 Shelf life

36 Months from the date of manufacture

6.4 Special precautions for storage

Store below 30˚C

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

The product is packed in 500 mL, 1000 mL Plastic Bottle.

6.6 Special precautions for disposal <and other handling>

7. MARKETING AUTHORISATION HOLDER

Aculife Healthcare Pvt. Ltd.
Commerce House-V,
Beside Vodafone House
Prahladnagar Corporate Road,
Ahmedabad 380051,
Gujarat, India
Tel.: +91-79-26839100
E-mail: info@aculife.co.in

8. MARKETING AUTHORISATION NUMBER(S)

05840/07311/REN/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 06.05.2016
Date of latest renewal: 07.04.2021

10. DATE OF REVISION OF THE TEXT

Date: 12.07.2023