



PATIENT INFORMATION LEAFLET

ANHYDROUS GLUCOSE 5% w/v AND SODIUM CHLORIDE 0.9% w/v INTRAVENOUS INFUSION (DNS)

About medicine

Prescription only medicine

Read all of this leaflet carefully before you start using this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, health care provider or pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If you get any side effects or if any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor, health care provider or pharmacist.

What is in this leaflet:

- a) What DNS is and what it is used for
- b) What you need to know before you use DNS
- c) How to use/How you will be given DNS
- d) Possible side effects
- e) How to store DNS
- f) Further information

a) What DNS is and what it is used for

DNS is a solution of the following substances in water: • sugar (glucose) • sodium chloride (salt). Glucose is one of the body's sources of energy. This solution for infusion provides 200 kilocalories per litre. Sodium and chloride are chemical substances found in the blood.

DNS is used: • as a source of carbohydrate (sugar) • to treat a loss of sodium from the blood and the body (sodium depletion) • to treat a loss of body water, for example after being sick or having diarrhoea (extracellular dehydration) • to treat you, if the volume of blood in your blood vessels is low (hypovolaemia).



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(b) Before you use DNS

DO NOT use DNS:

- when you know you are allergic to the product
- when there is too much fluid in the spaces around the cells of the body (extracellular hyperhydration)
- when there is a larger volume of blood in the blood vessels than there should be (hypervolaemia)
- when there is more fluid and sodium than normal in the body (fluid and sodium retention)
- severe kidney problems that mean you produce less urine than usual or none at all (oliguria or anuria)
- uncompensated heart failure. This is heart failure that is not adequately treated and causes symptoms such as: - shortness of breath - swelling of the ankles
- higher levels of sodium in the blood than normal (hypernatraemia)
- higher levels of chloride in the blood than normal (hyperchloraemia)
- buildup of fluid under the skin, affecting all parts of the body (general oedema)
- liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis)
- diabetes that is not adequately treated, allowing your blood sugar levels to rise above normal (uncompensated diabetes)
- other states of glucose intolerance, for example: - metabolic stress (when the body's metabolism does not function correctly, e.g. due to severe illness) - hyperosmolar coma (unconsciousness). This is a type of coma that can occur if you have diabetes and do not receive enough medicine. - a very high amount of sugar in the blood (significant hyperglycaemia) - higher levels of lactate in the blood than normal (hyperlactataemia)

Take special care

Please tell your doctor if you have or have had any of the following medical conditions:

- a disorder in which the blood becomes too alkaline (metabolic alkalosis)
- muscle weakness and periodic paralysis due to low thyroid activity (thyrotoxic periodic paralysis)
- rapid loss of water from the body e.g. due to vomiting or diarrhoea
- being on a low potassium diet for a long time
- taking certain medications, see below: "Other medicines and DNS"
- a disorder in which the blood becomes too acidic (metabolic acidosis)



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- if you have a condition that could cause high levels of vasopressin, a hormone regulating fluid in your body. You may have too much vasopressin in your body because, for example, you have had a sudden and serious illness, you are in pain, - you have had surgery, you have infections, burns, brain disease, diseases linked to your heart, liver, kidneys or central nervous system, because you are taking certain medicines (see also below “other medicines and DNS”)

This may increase the risk of low levels of sodium in your blood and can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain and death. Brain swelling increases the risk of death and brain damage. People who are at higher risk of brain swelling are: children, women (particularly if you are of a fertile age), people who have problems with their brain fluid levels, for example, because of meningitis, bleeding in the skull or a brain injury.

- Conditions associated with sodium retention, fluid overload and oedema, such as:
 - aldosteronism (a disease that causes high levels of a hormone called aldosterone) associated with:
 - poor liver function or liver disease that causes fluid to build up within the abdomen (ascitic cirrhosis), high blood pressure (hypertension), heart failure, poor kidney function
 - high blood pressure during pregnancy (preeclampsia)
 - any other condition associated with sodium retention (when the body retains too much sodium), such as treatment with steroids (see also below, “Other medicines and Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion”)
- allergy, in particular to corn (Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion contains sugar derived from corn)

The infusion may cause: changes in the concentrations of the chemicals in the blood (electrolyte disturbances) buildup of fluid under the skin, affecting all parts of the body (general oedema), around the ankles (peripheral oedema) or in the lungs (pulmonary oedema) & a higher amount of sugar in the blood than normal (hyperglycaemia).

When you are given this infusion, your doctor will take blood and urine samples to monitor: the amount of chemicals such as sodium and chloride in your blood (your plasma electrolytes) and the amount of sugar (glucose).



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As DNS contains sugar (glucose), it can cause a high level of sugar in the blood (hyperglycaemia). If this occurs, your doctor may: adjust the speed of infusion and/ or give you insulin to reduce the blood sugar levels. This is particularly important: if you are diabetic, if you have not been eating well, if you have been drinking too much alcohol for a long time, if you have recently had a stroke (acute ischaemic stroke). High levels of sugar in the blood can worsen the effects of stroke and affect recovery if you have had head injury within the past 24 hours.

Your doctor will take into account if you are receiving parenteral nutrition (nutrition given by infusion into a vein). During long-term treatment with Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion, you may need to be given extra nutrition.

Your doctor should also monitor the level of potassium in your blood to avoid this becoming lower than normal (hypokalaemia).

Children

Special care should be taken when giving this solution to children, infants, and newborns (especially premature babies and those with low birth weight). Children, infants and newborns may not have a good ability to handle the chemicals in the solution.

Newborns – especially those born premature and with low birth weight - are at increased risk of developing a too low or too high level of sugar in the blood (hypo- or hyperglycaemia) and therefore need close monitoring during treatment with intravenous solutions containing glucose to ensure adequate control of the sugar levels in order to avoid potential long term adverse effects.

Low sugar levels in newborns can cause prolonged seizures, coma and brain damage.

High sugar levels have been associated with bleeding into the brain, late onset bacterial and fungal infection, damage to the eye (retinopathy of prematurity), infections in the intestinal track (necrotizing enterocolitis), lung problems (bronchopulmonary dysplasia), prolonged hospital stay and death. Children are at higher risk for having or developing a too low sodium concentration in their blood (hyponatraemia).

Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death. Acute hyponatraemic encephalopathy is a serious complication, especially in children. Your doctor knows this and will closely monitor the amount of chemicals such as sodium and chloride in your child's blood (plasma electrolytes).



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Other medicines and DNS

Tell your doctor if you are using, have recently used or might use any other medicines. It is particularly important that you inform your doctor if you are taking:

corticosteroids (anti-inflammatory medicines) These medicines can cause the body to accumulate sodium and water, leading to: tissue swelling due to fluid collection under the skin (oedema) & high blood pressure (hypertension)

Some medicines act on the hormone vasopressin. These may include:

- anti-diabetic medication (chlorpropamide)
- cholesterol medicine (clofibrate)
- some cancer drugs (vincristine, ifosfamide, cyclophosphamide)
- selective serotonin reuptake inhibitors (used to treat depression)
- antipsychotics or opioids for severe pain relief
- medicines for pain and/or inflammation (also known as NSAIDs)
- medicines that imitate or strengthen the effects of vasopressin such as desmopressin (used to treat increased thirst and urination)
- terlipressin (used to treat bleeding of the gullet) and oxytocin (used to induce labour)
- anti-epileptic medication (carbamazepine and oxcarbazepine)
- diuretics (water tablets).

Other medicines that can affect or be affected by Sodium Chloride 0.9% w/v and Glucose 5% w/v Infusion:

- lithium (used to treat psychiatric illnesses)
- insulin (used to treat diabetes)
- beta blockers (heart tablets)

DNS must not be given through the same needle as a blood transfusion. This can damage the red blood cells or cause them to clump together

DNS with food and drink

You should ask your doctor about what you can eat or drink.



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Pregnancy and breast feeding

Pregnancy

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

Breast-feeding

DNS can be used during breastfeeding.

Driving and using machines

Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion does not affect your ability to drive or use machines.

If another medicine is to be added to your solution for infusion during pregnancy or breast-feeding you should:

- consult your doctor
- read the Package Leaflet of the medicine that is to be added.

(c) How to use DNS

You will be given Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion by a doctor or nurse. Your doctor will decide on how much you need and when it is to be given. This will depend on your age, weight, condition and the reason for treatment. The amount you are given may also be affected by other treatments you are receiving.

You should NOT be given DNS if there are particles floating in the solution or if the pack is damaged in any way. DNS will usually be given to you through a plastic tube attached to a needle in a vein. However, your doctor may use another method to give you the medicine. Any unused solution should be thrown away. You should NOT be given an infusion of from a bottle that has been partly used.

Before and during the infusion, your doctor will monitor: the amount of fluid in your body, the acidity of your blood and urine, the amount of electrolytes in your body (particularly sodium, in patients with high levels of the hormone vasopressin, or if are taking other medicines which increase the effects of vasopressin)



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If you receive more Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion than you should

If you are given too much DNS (over-infusion) or if it is given too fast, this may lead to the following symptoms:

- high levels of sugar in the blood (hyperglycaemia) Symptoms include: - dry mouth due to lack of water in body tissues (dehydration) - thirst - fatigue - frequent urination due to increased urine production (osmotic diuresis) - blurred vision
- low levels of sodium in the blood (hyponatraemia). Hyponatraemia can lead to headache, nausea, seizures, lethargy, coma, swelling of the brain (cerebral oedema) and death
- high blood levels of sodium (hypernatraemia). If this occurs, the most serious effect is a reduction in the water content of the brain (dehydration of the brain). This causes drowsiness and confusion and may lead to fits (convulsions), unconsciousness (coma), stopping breathing (respiratory failure) and even death. Other symptoms include: - thirst - dry mouth and eyes - fever - rapid heart rate (tachycardia) - high blood pressure (hypertension) - headache - dizziness - restlessness - irritability - weakness.
- build-up of fluid in the body causing swelling (oedema).

If you develop any of these symptoms you must inform your doctor immediately. Your infusion will be stopped and you will be given treatment depending on the symptoms.

If a medicine has been added to your Infusion before over infusion occurs, that medicine may also cause symptoms. You should read the Package Leaflet of the added medicine for a list of possible symptoms.

To Stop receiving your Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion

Your doctor will decide when to stop giving you this infusion. If you have any further questions on the use of this product, ask your doctor or nurse.

(d) Possible side effects

Like all medicines, DNS, solution for infusion can cause side effects, although not everybody gets them. In rare cases (more than 1 out of 10,000 persons and less than 1 out of 1,000 persons), the following may occur: a malaise, a drop in blood pressure or changes in laboratory test results: abnormally high levels of hepatic enzymes found during blood checks. Should this occur, inform your doctor as regular blood checks may be required later.



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In very rare cases (less than 1 out of 10,000 persons, including isolated reports), a serious skin rash or allergic reaction may occur. Stop the treatment immediately and inform your doctor.

In isolated cases, other changes in laboratory test results have been observed which have necessitated regular blood checks: abnormally low levels of some types of blood cells (platelets, white cells), possibly leading to bleeding from the nose or gums. Should this occur, inform your doctor.

Cases of redness of the skin, flushing, itching and abnormally rapid beating of the heart have been reported.

Reporting of side effects

If you get any side effects, talk to your doctor or nurse. This includes any possible side effects not listed in this leaflet. If any side effects occur, the infusion must be stopped. You can also report side effects via email on drugsafety@abacuspharma.com or through telephone on +256 786 557 530. By reporting side effects you help provide more information on the safety of this medicine

(e) How to store DNS

Keep this medicine out of the sight and reach of children. Sodium Chloride 0.9%w/v & Glucose 5%w/v Infusion does not require special storage conditions. DNS should NOT be given to you after the expiry date which is stated after "EXP". The expiry date refers to the last day of that month. You should not be given DNS, if there are particles floating in the solution or if the unit is damaged in any way

(f) Further information

What DNS contains

The active substances are: • sugar (glucose): 50 g per litre • sodium chloride: 9 g per litre The only other ingredient is water for injections

What DNS looks like and the contents of the pack

DNS is a clear colourless to faintly straw coloured solution, free from visible particles. It is supplied in LDPE bottles of 250mL and/or 500mL. Each bag is flow wrapped in a sealed, protective, outer plastic over pouch.



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(DNS)**

Marketing authorisation holder and manufacturer

Abacus Parenteral Drugs Limited
Block 191, Plot no.114, Kinga Mukono
P. O. Box 31376, Kampala, Uganda.
Phone: +256-312 380 800
Fax: +256-312 380 820
Email: apdl@abacuspharma.com

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