MODULE-1 ADMINISTRATIVE INFORMATION FOR NS

PATIENT INFORMATION LEAFLET (PIL)

Read all of this leaflet carefully before you are given 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 NS is and what it is used for
- 2. What you need to know before you use NS
- 3. How NS is given
- 4. Possible side effects
- 5. How to store NS
- 6. Contents of the pack and other information

1. What NS is and what it is used for

NS contains Sodium Chloride Intravenous Infusion which belongs to a group of medicines called Other IV Solution Additives.

It works by maintaining the fluid and electrolyte balance Ions, such as sodium, circulate through the cell membrane, using various mechanisms of transport, among which is the sodium pump (Na-K-ATPase).

Sodium chloride intravenous infusions are given to add water to tissues which are dehydrated and to help to restore the normal salt balance.

Sodium chloride intravenous infusions may be given alone but may be given with other medicines added You will be given sodium chloride intravenous infusions in hospital by a doctor or nurse.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE NS

Do not use this medicine

• If you have an allergy to sodium chloride or any of the other ingredients.

Warnings and precautions

• Talk to your doctor or nurse if You have cardio – pulmonary disease, high blood

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pressure, kidney disease or oedema (swelling)

- have high serum levels of sodium ("hypernatraemia")
- have pre-eclampsia of pregnancy
- are receiving drugs which may increase sodium retention
- are very young or elderly.

Other medicines and this medicine

Tell your doctor or nurse if you are taking, have recently taken or might take any other medicines.

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 or nurse for advice before taking this medicine.

Driving and using machines

Sodium Chloride Intravenous Infusion has no effect on your ability to drive or use machines.

3. HOW NS IS GIVEN

Sodium chloride intravenous infusion will be given to you in hospital.

You will receive the solution by infusion into a vein (usually in the arm), administered by a doctor or nurse.

The amount and rate at which the infusion is given depends on your requirements. Your doctor will decide on the correct volume for you to receive.

Your doctor will check your response to the treatment by the relief of your symptoms, and will probably take samples of blood and urine for laboratory testing

If you are given more sodium chloride intravenous infusion than you should

It is unlikely you will be given too much solution as your doctor or nurse will be checking your response to the treatment. Infusion of too much sodium chloride solution can lead to the build-up of sodium in the blood, which can lead to dehydration of some organs of the body and to loss of potassium. If you are concerned about the volume of solution given, or are worried about any affects you notice, talk to your doctor or nurse.

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4. POSSIBLE SIDE EFFECTS

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

Stop using this medicine if you experience an adverse reaction.

If you are given the solution for a long time, you may notice the following:

• irritation, swelling, redness and tenderness at the site of injection.

The balance of some chemicals in your blood may become upset. You may notice the following:

- swelling, especially of the legs.
- feel tired, weak, dizzy, have a headache or problems with vision
- or a fast or irregular heart beat
- feel sick (nausea) and have an upset stomach, loss of appetite
- drowziness, lack of energy
- cramp or discomfort of the muscles, confusion or disorientation
- thirst, dry mouth, dark urine

Reporting of side effects

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

5. How to store NS

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 label after EXP.

The expiry date refers to the last day of that month.

Store below 30°C. Protect from light. Do not refrigerate or freeze.

The solution should only be used if it is clear and the container is not damaged. It should be used immediately on removal from the overwrap. For single use only. Any unused solution in the bag must be discarded.

Do not throw away any medicines via wastewater or household waste. The doctor or nurse will dispose of this medicine. These measures will help to protect the environment.

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6. CONTENT OF THE PACK AND OTHER INFORMATION

What **NS** contains

- The active substance is Sodium Chloride BP.
- The other ingredients are Water for Injections BP

What NS looks like and contents of the pack

Clear, colourless solution

Pack: 1 x 500 mL LDPE Bottle with helmet cap/eurohead cap, with pre-printed label, wrapped in a transparent BOPP film.