Consumer Medicine Information (CMI) summary

The <u>full CMI</u> on the next page has more details. If you are worried about using this medicine, speak to your doctor or pharmacist.

1. Why am I using Sodium Chloride Injection BP 0.9%?

Sodium chloride Injection BP 0.9% contains the active ingredient sodium chloride. Sodium Chloride 0.9% is used to replace lost body fluids and salts, dilute other medicines, and/or act as a sterile liquid for washing wounds, nasal passages or during surgery.

For more information, see Section 1. Why am I using Sodium Chloride Injection BP 0.9%? in the full CMI.

2. What should I know before I use Sodium Chloride Injection BP 0.9%?

Do not use if you have ever had an allergic reaction to Sodium Chloride Injection BP 0.9% or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding.

For more information, see Section 2. What should I know before I use Sodium Chloride Injection BP 0.9%? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with Sodium Chloride 0.9% and affect how it works.

A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I use Sodium Chloride Injection BP 0.9%?

- Sodium Chloride Injection BP 0.9% will be given to you by your doctor or specially trained nurse.
 They will decide what dose and how long you will receive it for. This depends on your medical condition and other factors.
- More instructions can be found in Section 4. How do I use Sodium Chloride Injection BP 0.9% ? in the full CMI.

5. What should I know while using Sodium Chloride Injection BP 0.9%?

Things you should do	 If you become pregnant while being given Sodium Chloride Injection BP 0.9% tell your doctor immediately. Remind any doctor, dentist or pharmacist or nurse you visit that you have been given using Sodium Chloride 0.9% Injection. Before surgery, tell the surgeon or anaesthetist that you have been given this medicine.
Driving or using machines	 Be careful driving or operating machinery until you know how Sodium Chloride 0.9% affects you. If you feel light-headed, dizzy or faint when getting out of bed or a chair, get up slowly.
Looking after your medicine	 Sodium Chloride Injection BP 0.9% will be stored in the surgery, by your doctor or pharmacist under the recommended conditions of 'Store below 25°C'.

For more information, see Section 5. What should I know while using Sodium Chloride Injection BP 0.9%? in the full CMI.

6. Are there any side effects?

Sodium Chloride 0.9% may cause nausea, vomiting, diarrhoea, cramps, decrease in saliva, tears or urination, increase in thirst and sweating, increase in heart rate, difficulty breathing or breathlessness which may worsen when lying down, swelling of hands, ankles and feet, dizziness, light headedness, drowsiness, restlessness or irritability, headaches, confusion, muscle weakness, twitching, rigidity or convulsions.

For more information, including what to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

Sodium Chloride Injection BP 0.9%

Active ingredient(s): sodium chloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sodium Chloride Injection. You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using Sodium Chloride Injection.

Where to find information in this leaflet:

- 1. Why am I using Sodium Chloride Injection?
- 2. What should I know before I use Sodium Chloride Injection ?
- 3. What if I am taking other medicines?
- 4. How do I use Sodium Chloride Injection ?

5. What should I know while using Sodium Chloride Injection?

- 6. Are there any side effects?
- 7. Product details

1. Why am I using Sodium Chloride Injection ?

Sodium Chloride Injection contains the active ingredient Sodium Chloride.

Sodium Chloride Injection is used to:

- replace lost body fluids and salts.
- dilute other medicines, which may be given by injection or drip
- act as a sterile liquid for washing wounds, nasal passages or during surgery

Your doctor may have prescribed it for another reason.

Ask your doctor if you have any questions about why this medicine has been prescribed for you.

2. What should I know before I use Sodium Chloride Injection?

Warnings

Your doctor will have considered the need to give you Sodium Chloride 0.9% carefully. Make sure to tell the doctor if you have any allergies.

Do not use Sodium Chloride Injection if you are allergic to

- Sodium chloride
- Any other medicines
- Any other substance such as food dyes, preservatives or plastics
- Any of the ingredients listed at the end of this leaflet.

Some of the symptoms of an allergic reaction may include:

- shortness of breath
- wheezing or difficulty breathing
- swelling of the face, lips, tongue, or other parts of the body
- rash, itching or hives on the skin.
- Always check the ingredients to make sure you can use this medicine.

Check with your doctor if you:

- have any other medical conditions such as :
 - Heart problems
 - Severe kidney disease
 - Breathlessness which may be severe or worsen when lying down
 - Excess fluid in the lungs
 - Swelling due to excess fluid
 - Kidney disease
 - High blood pressure including high blood pressure due to pregnancy
 - Problems with urinary tract

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section <u>6. Are there any side effects?</u>

Pregnancy and breastfeeding

Check with your doctor if you are pregnant or intend to become pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed.

Unless specifically prescribed by your doctor, you should not be given Sodium Chloride 0.9% if you are pregnant or breast feeding. Ask your doctor about the risks and benefits involved.

Use in Children

• Sodium Chloride 0.9% should be administered with care to very young patients.

Use in Elderly

• Sodium Chloride 0.9% should be administered with care to elderly patients

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins or supplements that you buy without a prescription from your pharmacy, supermarket or health food shop.

Some medicines may interfere with Sodium Chloride 0.9% and affect how it works.

These include:

- Corticosteroids
- Corticotrophin
- Other drugs that cause sodium to be retained in the body.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect Sodium Chloride Injection.

4. How do I use Sodium Chloride Injection?

How much to use

 Your doctor will decide what dose, how often and how long you will receive it. This depends on your condition and other factors, such as your weight, age, blood tests, how well your kidneys are working, and whether or not other medicines are being given at the same time.

How to use Sodium Chloride 0.9%

Sodium Chloride 0.9% Injection will be given to you by your doctor or specially trained nurse.

If you are given too much Sodium Chloride Injection

This rarely happens as Sodium Chloride Injection is administered under the care of a trained professional in a hospital or clinic setting.

However, the first signs of an overdose can be nausea, vomiting, diarrhoea, cramps, reduced saliva, increased thirst and sweating.

You should immediately:

- phone the Poisons Information Centre (by calling 13 11 26), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while using Sodium Chloride Injection?

Things you should do

If you are about to be started on any new medicine, remind your doctor and pharmacist that you have been given Sodium Chloride 0.9%.

Tell any other doctors, dentists, and pharmacists who treat you that you have been given Sodium Chloride 0.9%.

If you are going to have surgery, tell the surgeon or anaesthetist that you have been given Sodium Chloride 0.9%. It may affect other medicines used during the surgery.

If you feel lightheaded or faint when getting out of bed or standing up, get up slowly.

Standing up slowly, especially when you get up from a bed or a chair, will help your body get used to the change in position and blood pressure. If this problem continues to get worse talk to your doctor

Call your doctor straight away if you:

• become pregnant during the course of Sodium Chloride 0.9% treatment.

Remind any doctor, dentist, pharmacist or nurse you visit that you have been given Sodium Chloride 0.9%.

Driving or using machines:

Be careful before you drive or use any machines or tools until you know how Sodium Chloride 0.9% affects you.

Sodium Chloride 0.9% may cause dizziness, lightheadedness, drowsiness, or weakness in some people. If you have any of these symptoms, do not drive, operate machinery, or do anything else dangerous.

Looking after your medicine

- Sodium Chloride Injection 0.9% will be stored in the surgery, pharmacy or ward of a hospital. The medicine is kept in a cool dry place where the temperature stays below 25°C.
- Sodium Chloride Injection 0.9% will only be opened when it is time for you to have the injection.
- It should not be stored after it is opened nor used for more than one person

Keep it where young children cannot reach it.

Getting rid of any unwanted medicine

Any Sodium Chloride 0.9% Injection which is not used and which is left in the container, will be disposed of in a safe manner by your doctor or pharmacist.

6. Are there any side effects?

All medicines can have side effects. The use of Sodium Chloride 0.9% to replace lost body fluids and salts or addition to intravenous fluids is unlikely to result in any side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
A decrease in saliva, tears or urination and/or an increase in thirst and sweating may be experienced.	Speak to your doctor if you have any of these less serious side effects and they worry you.
Other side effects may include: Nervous system: • headaches, confusion	
Musculoskeletal: • cramps	

Serious side effects

Serious side effects	What to do	
Swelling of hands, ankles and feet may be experienced.	Call your doctor straight away	
Other side effects may include: Cardiovascular: • increase in heart rate	or go straight to the Emergency	
Gastrointestinal: • nausea, vomiting, diarrhoea	Department at your nearest hospital if you	
Respiratory: • difficulty breathing or breathlessness which may worsen when lying down	notice any of these serious side effects.	
Musculoskeletal: • muscle weakness, twitching, rigidity, or convulsions		
Nervous system:		
 dizziness, light headedness, drowsiness, restlessness, or irritability 		

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

Other side effects not listed here may occur in some people.

If you are over 65 years of age or very young, you may have an increased chance of getting side effects

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at <u>www.tga.gov.au/reporting-problems</u>. By reporting side effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

This medicine is only available with a doctor's prescription.

What Sodium Chloride Injection contains

Active ingredient	Sodium Chloride
(main ingredient)	
Other ingredients	Water for Injections
(inactive ingredients)	

Potential allergens	None
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Do not take this medicine if you are allergic to any of these ingredients.

What Sodium Chloride Injection looks like

Sodium Chloride Injection is a clear, colourless solution supplied in ampoules in the following strengths:

5 mL AUST R 197200 10 mL AUST R 197198 20 mL AUST R 197199

Who distributes Sodium Chloride Injection

Fresenius Kabi Australia Pty Limited Level 2, 2 Woodland Way Mount Kuring-gai NSW 2080 Australia Telephone: (61-2) 9391 5555

Fresenius Kabi New Zealand Limited c/o GNZCC, HSBC Tower, Level 14, 188 Quay Street, Auckland New Zealand Freecall: 0800 144 892

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