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 nurse.

1. Why am I given Sodium Chloride 0.9% Injection?

Sodium Chloride 0.9% Injection contains the active ingredient sodium chloride. Sodium Chloride 0.9% Injection is given to replace lost body fluids and salts. It may also be used for the dilution of other medicines before injecting into the body. For more information, see Section <u>1</u>. Why am I given Sodium Chloride 0.9% Injection? in the full CMI.

2. What should I know before I am given Sodium Chloride 0.9% Injection?

Do not use if you have ever had an allergic reaction to Sodium Chloride 0.9% Injection 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 am given Sodium Chloride 0.9% Injection? in the full CMI.

3. What if I am taking other medicines?

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

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

4. How is Sodium Chloride 0.9% Injection given?

Sodium Chloride 0.9% Injection will be given to you by a doctor or 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 <u>4. How is</u> <u>Sodium Chloride 0.9% Injection given?</u> in the full CMI.

5. What should I know while being given Sodium Chloride 0.9% Injection?

| Things you should do | • Tell your doctor or nurse if you do not feel well after you have been given Sodium Chloride 0.9% Injection. | |
|-------------------------|---|--|
| Driving or using | ing or using • Be careful driving or operating machinery until you know how Sodium Chloride 0.9% Injection affect | |
| machines | you. Sodium Chloride 0.9% Injection may cause dizziness and weakness in some people. | |

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

6. Are there any side effects?

Sodium Chloride 0.9%Injection may cause nausea, vomiting, stomach cramps, diarrhoea, thirst, dry mouth and eyes, swelling of the hands, ankles or feet, fever, increased heart rate, difficulty breathing or breathlessness which may worsen when lying down, weakness, muscle twitching or rigidity, restlessness or irritability, headache or dizziness, sleepiness and confusion, convulsions.

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

Sodium Chloride 0.9% Injection BP

Active ingredient(s): sodium chloride

Consumer Medicine Information (CMI)

This leaflet provides important information about using Sodium Chloride 0.9%Injection. You should also speak to your doctor or nurse if you would like further information or if you have any concerns or questions about receiving Sodium Chloride 0.9% Injection.

Where to find information in this leaflet:

- 1. Why am I given Sodium Chloride 0.9% Injection?
- 2. <u>What should I know before I am given Sodium</u> <u>Chloride 0.9% Injection?</u>
- 3. <u>What if I am taking other medicines?</u>
- 4. How is Sodium Chloride 0.9% Injection given?
- 5. <u>What should I know after receiving Sodium Chloride</u> 0.9% Injection?
- 6. Are there any side effects?
- 7. Product details

1. Why am I given Sodium Chloride 0.9% Injection?

Sodium Chloride 0.9% Injection contains the active ingredient sodium chloride. Sodium Chloride 0.9% Injection contains chemicals that are naturally present in body fluids and are needed for normal body function.

Sodium Chloride 0.9% Injection is given to replace lost body fluids and salts. It may also be used for the dilution of other medicines before injecting into the body.

2. What should I know before I am given Sodium Chloride 0.9% Injection?

Warnings

Your doctor will have considered the need to give you Sodium Chloride 0.9% Injection carefully.

Tell your doctor if you have or have had:

- any allergies to sodium chloride, any other medicines or any other substance such as foods, preservatives or dyes
- heart problems
- severe kidney disease
- liver disease
- swelling of the hands, ankles or feet due to excess fluid
- high blood pressure, including during pregnancy
- any condition associated with sodium retention.

If you are not sure whether any of these apply to you, check with your doctor.

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

Tell your doctor if you are pregnant or plan to become pregnant or are breast-feeding. Your doctor can discuss with you the risks and benefits involved.

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% Injection. These include:

- corticosteroids or corticotrophin
- other medicines 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 0.9% Injection.

4. How is Sodium Chloride 0.9% Injection given?

How much is given

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 is it given

Sodium Chloride 0.9% Injection will be given to you by a doctor or nurse. The way Sodium Chloride 0.9% Injection will be given will depend on why you need it.

If you are given too much

This rarely happens as Sodium Chloride 0.9% Injection will be given to you in hospital under the care of a highly trained doctor or nurse.

In the unlikely event that you are given too much (an overdose), you may experience some of the effects listed under Section <u>6. Are there any side effects?</u>

The signs of overdose are nausea, vomiting, diarrhoea and cramps, increased thirst, swelling of hands, ankles or feet, fast heart rate, difficulty breathing or breathlessness which may worsen when lying down, headache, dizziness, weakness, muscle twitching or rigidity, convulsions may also occur.

Your doctor has information on how to recognise and treat an overdose. Ask your doctor if you have any concerns.

5. What should I know after receiving Sodium Chloride 0.9% Injection?

Things you should do

Tell your doctor or nurse if you do not feel well after you have been given Sodium Chloride 0.9% Injection.

Driving or using machines

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

Sodium Chloride 0.9% Injection may cause dizziness lightheadedness, drowsiness, or and weakness in some people.

Looking after your medicine

Sodium Chloride 0.9% Injection is usually stored in the hospital, clinic or at the pharmacy.

Your doctor, pharmacist or nurse is responsible for storing Sodium Chloride 0.9% Injection in a cool dry place, where the temperature stays below 25°C and disposing of any unused product correctly.

6. Are there any side effects?

All medicines can have 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 |
|---------------------------|---|---|
| • • • | thirst reduced saliva, dry mouth reduced lachrymation, dry eyes fever | Tell your doctor or nurse as soon as possible if you notice any of these less serious side effects and they worry you. |

Serious side effects

| Serious side effects | What to do |
|--|---|
| swelling of the hands, ankles or feet fast heart rate nausea, vomiting, stomach cramps, diarrhoea difficulty breathing or breathlessness which may worsen when lying down muscle weakness, twitching, rigidity or convulsions dizziness, light headedness , drowsiness, restlessness, or irritability | nurse immediately if you experience any of these serious side effects. |

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

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

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

What Sodium Chloride 0.9% Injection contains

| Active ingredient (main ingredient) | sodium chloride |
|--|----------------------|
| Other ingredients (inactive ingredients) | water for injections |
| Potential allergens | n/a |

Sodium Chloride 0.9% Injection does not contain preservatives.

Tell your doctor if you are allergic to any of these ingredients. Symptoms of an allergic reaction 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.

What Sodium Chloride 0.9% Injection looks like

Sodium Chloride 0.9% Injection is a clear, colourless solution contained in plastic ampoules.

Sodium Chloride 0.9% (45 mg/ 5 mL) injection BP is available in packs of 50 ampoules (AUST R 49272).

Sodium Chloride 0.9% (90 mg/10 mL) injection BP is available in packs of 5, 50 or 600 ampoules (AUST R 49278).

Sodium Chloride 0.9% (180 mg/20 mL) injection BP is available in packs of 30 ampoules (AUST R 49279).

* Not all presentations and pack sizes may be marketed.

Who distributes Sodium Chloride 0.9% Injection

Bridgewest Perth Pharma Pty Ltd 15 Brodie Hall Drive Bentley WA 6102

Telephone: 1800 161 156 safety@lumacina.com

Supplied in New Zealand by: LumaCina New Zealand C/o Quigg Partners Level 7, The Bayleys Building 36 Brandon Street, Wellington 6011, New Zealand Telephone: 0800 822 634 safety@lumacina.com

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