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1.3.2 Proposed Patient Information Leaflet For Human Medicines

SCHEDULING STATUS: S1

0,9 % w/v SODIUM CHLORIDE B BRAUN, solution

Sodium chloride

Sugar free

Read all of this leaflet carefully before you are given 0,9 % w/v SODIUM CHLORIDE B BRAUN

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse, or other health care provider.

What is in this leaflet

1. What 0,9 % w/v SODIUM CHLORIDE B BRAUN is and what it is used for
2. What you need to know before you are given 0,9 % w/v SODIUM CHLORIDE B BRAUN
3. How to use 0,9 % w/v SODIUM CHLORIDE B BRAUN
4. Possible side effects
5. How to store 0,9 % w/v SODIUM CHLORIDE B BRAUN
6. Contents of the pack and other information

1. What 0,9 % w/v SODIUM CHLORIDE B BRAUN is and what it is used for

0,9 % w/v SODIUM CHLORIDE B BRAUN is a saline solution for dissolving or diluting medicines you receive as an injection.

2. What you need to know before you are given 0,9 % w/v SODIUM CHLORIDE B BRAUN

0,9 % w/v SODIUM CHLORIDE B BRAUN should not be administered to you:

- if you are hypersensitive (allergic) to Sodium chloride or any of the other ingredients of 0,9 5 w/v SODIUM CHLORIDE B BRAUN (listed in section 6).

There are no known conditions or diseases that are contraindicated with the use of 0,9 % w/v SODIUM CHLORIDE B BRAUN.

Warnings and Precautions

Take special care with 0,9 % w/v SODIUM CHLORIDE B BRAUN if you have been told that you have elevated blood sodium and/ or chloride levels.

The solution is used as a solvent and side effects will probably be those of the injectable drug being administered with the aid of the solution. If the product is to be administered subcutaneously, then one needs to be aware that any additions to this solution could render it hypertonic and thus cause pain at the site of injection.

Other medicines and 0,9 % w/v SODIUM CHLORIDE B BRAUN

Always tell your healthcare provider if you are taking any other Medicines. (This includes all complementary or traditional medicines).

Interactions of other medicines with 0,9 % w/v SODIUM CHLORIDE B BRAUN should be considered.

Pregnancy, breastfeeding and fertility

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before being given this medicine.

However, no specific risks from the use of 0,9 % w/v SODIUM CHLORIDE B BRAUN during pregnancy and lactation are known.

Fertility:

No data available.

Driving and using machines

0,9 % W/V SODIUM CHLORIDE B BRAUN has no influence on the ability to drive and use machines.

It is not always possible to predict to what extent 0,9 % w/v SODIUM CHLORIDE B BRAUN may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which 0,9 % w/v SODIUM CHLORIDE B BRAUN affects you.

3. How to use 0,9 % W/V SODIUM CHLORIDE B BRAUN

Do not share medicines prescribed for you with any other person.

Use 0,9 % W/V SODIUM CHLORIDE B BRAUN exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

You will not be expected to administer 0,9 % w/v SODIUM CHLORIDE B BRAUN to yourself. It will be given to you by a person who is qualified to do so.

The quantity you receive will depend on how much of the solution is required to prepare the reconstituted solution. You will receive the reconstituted solution as an injection either into the vein or under the skin.

Your doctor will tell you how long your treatment with 0,9 % w/v SODIUM CHLORIDE B BRAUN will last.

If you have the impression that the effect of 0,9 % w/v SODIUM CHLORIDE B BRAUN is too strong or too weak, tell your doctor or nurse administering the medicine to you.

If you are given more 0,9 % W/V SODIUM CHLORIDE B BRAUN than you should.

Since a health care provider will administer 0,9 % w/v SODIUM CHLORIDE B BRAUN, he/ she will control overdosage.

However, in the event of over dosage your doctor will manage the overdosage.

If you forget to use 0,9 % w/v SODIUM CHLORIDE B BRAUN

Since a health care provider will administer 0,9 % w/v SODIUM CHLORIDE B BRAUN**,** it is unlikely that the dose will be missed.

4. POSSIBLE SIDE EFFECTS

0,9 % w/v SODIUM CHLORIDE B BRAUN can have side effects.

Administration of large amounts of 0,9 % w/v SODIUM CHLORIDE B BRAUN may lead to hypernatraemia (high levels of sodium in the blood) or hyperchloraemia (high levels of chloride in the blood).

Not all side effects reported for 0,9 % w/v SODIUM CHLORIDE B BRAUN are included in this leaflet. Should your general health worsen or if you experience any untoward effects while being given 0,9 % w/v SODIUM CHLORIDE B BRAUN, please consult your health care provider for advice.

Reporting of side effects

If you get side effects. Talk to your doctor, pharmacist, or nurse. You can also report side effects to SAHPRA via the **"6.04 Adverse Drug Reaction Reporting Form",** found online under SAHPRAs publications: https://www.sahpra.org.za/Publications/index/8/. By reporting side effects, you can help provide more information on the safety of 0,9 % w/v SODIUM CHLORIDE B BRAUN.

5. How to store 0,9 % w/v SODIUM CHLORIDE B BRAUN

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 carton and label after "EXP". The expiry date refers to the last day of that month.

Store at or below 25 °C.

This medicinal product is for single use only. Discard any unused medicine immediately after use.

The solution should be inspected visually prior to use. Do not use 0,9 % w/v SODIUM CHLORIDE B BRAUN if the solution is not clear and the container and seal are damaged.

6. Contents of the pack and other information

What 0,9 % w/v SODIUM CHLORIDE B BRAUN contains

The active substance is sodium chloride (saline solution).

100 ml of solution contains: Sodium Chloride 0,9 g.

The other ingredient is Water for injections.

Electrolyte concentrations:

Sodium 154 mmol/l

Chloride 154 mmol/l

What 0,9 % w/v SODIUM CHLORIDE B BRAUN looks like and contents of the pack

0,9 % w/v SODIUM CHLORIDE B BRAUN is a clear colourless solution for injection or infusion.

0,9 % w/v SODIUM CHLORIDE B BRAUN is packed into:

Cartons containing 20, 50 or 100 x 5 ml colourless polyethylene ampoules;

Cartons containing 20, 50 or 100 x 10 ml colourless polyethylene or polypropylene ampoules;

Cartons containing 20, 50 or 100 x 20 ml colourless polyethylene or polypropylene ampoules.

Not all packs or pack sizes are necessarily marketed.

Holder of Certificate of Registration

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