PROPOSED ANNOTATED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

Proposed PI, page 1 line 4

S1

SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS

Proposed PI, page 1 line 8

Sodium Chloride

Proposed PI, page 1 line 20

Sugar free

Read all of this leaflet carefully because it contains important information for you

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

- 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.
- SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

1. What SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS is and what it is used for
2. What you need to know before you use SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS
3. How to use SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS
4. Possible side effects

5. How to store SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS
6. Contents of the pack and other information

1. What SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS is and what it is used for

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Proposed PI, page 2 line 41 - 43

Your doctor or nurse will use SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS during surgical procedures for cleansing of tissues, body cavities, wounds or irrigation of a special tube called a catheter which is used to drain your bladder and has been designed to be left in place for a prolonged period of time.

2. What you need to know before you use SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Proposed PI, page 3 line 51 - 52

There are no known conditions or diseases that prevent the use of SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS.

Warnings and precautions

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Take special care with SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS:

Proposed PI, page 3 line 56 - 57

Not to be administered by parenteral injection. For external use only.
Not for use in electrosurgery.

Proposed PI, page 3 line 58 - 62

Solutions for bladder irrigation should be used with caution in patients with severe hart, lung and kidney problems.

Proposed PI, page 3 line 64 - 67

Use with caution in patients with high blood pressure, heart failure, kidney failure or other conditions associated with sodium retention.

Do not be use to induce vomiting; this practice is dangerous and deaths associated with having too much sodium in the blood have been reported.

Proposed PI, page 3 line 69 - 71

Other medicines and SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

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

No interactions with other medicines are known.

Proposed PI, page 3 line 74

Pregnancy, breastfeeding and fertility

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

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 using this medicine.

Pregnancy

Generally, water for irrigation can be used during pregnancy.

Proposed PI, page 4 line 77

Fertility

No data available.

Driving and using machines

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS has no influence on the ability to drive and use machines.

Proposed PI, page 4 line 80

SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS contains sodium

Electrolyte concentrations:

Proposed PI, page 1 line 17 - 19

Sodium: 154 mmol/L

Chloride: 154 mmol/L

3. How to use SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

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

Use SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS exactly as your doctor had told you.

Check with your doctor or pharmacist if you not sure.

SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS will be given to you by a doctor or nurse. It is used for external use only as required for irrigation to wash and clean body cavities, tissues or wounds.

Proposed PI, page 2 line 46

It should not be injected or swallowed.

Your doctor will tell you how long your treatment with SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS will last. Do not stop treatment early because you feel better. If you have the impression that the effect of SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS is too strong or too weak , tell your doctor or pharmacist.

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Your doctor or nurse will decide how much of the irrigation to use which will be sufficient for your needs. As the irrigation solution is

sterile, your doctor or nurse will use a new solution each time. If you are given this product to use at home it must be used as directed by your doctor or nurse. Use a new solution each time. Discard the unused portion.

Proposed PI, page 2 line 47

If you use more SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS than you should

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Since a health care provider will administer the SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS he/she will control the dosage. However in the event of over dosage your doctor will manage the over dosage.

4. Possible side effects

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS can have side effects.
Not all side effects reported for SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS are included in this leaflet. Should your general health worsen or if you experience any untoward effects while using SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS, please consult your health care provider for advice.

However, when SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS is used according to the instructions and side effects are expected to occur – overhydration and excess fluid in lungs.

Proposed PI, page 4 line 87 - 89

If you notice any side effects not mentioned in this leaflet, please

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

inform your doctor or pharmacist.

Reporting of side effects

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to SAHPRA via the Med Safety APP (Medsafety X SAHPRA) and eReporting platform (whoumc.org) found on SAHPRA website. By reporting side effects, you can help provide more information on the safety of SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS.

Patients are asked to report any suspected adverse drug reactions to their healthcare provider or Holder of the Certificate of Registration at the following email address: safety.fksa@fresenius-kabi.com and to the relevant medicine's regulatory authority in the country where the product is marketed.

5. How to store SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Your doctor or pharmacist is responsible for storing this medicine. They are also responsible for disposing of any unused medicine correctly.

Store all medicines out of reach of children.

Proposed PI, page 6 line 154 - 155

Store at or below 25 ºC.

Store in original packaging until required for use.

Do not use after the expiry date stated on the label.

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Do not use SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS if the solution is not clear and the container and seal are

not intact.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

What SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS contains

The active substance is sodium chloride.

Proposed PI, page 1 line 13 - 15

The other ingredient is water for injection.

Proposed PI, page 6 line 130

What SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS looks like and contents of the pack

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Clear, colourless solution.

Proposed PI, page 2 line 36

1 000 ml Polypropylene bottles

500 ml Freeflex bags (1’s; 18’s; 20’s)

Proposed PI, page 7 line 159 - 163

1 000 ml Freeflex bags (1’s; 12’s)

3 000 ml PVC bags (1’s; 4’s)

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

Fresenius Kabi Manufacturing SA (Pty) Ltd

6 Gibaud Road

Korsten

Proposed PI, page 7 line 176 - 183

Gqeberha

South Africa

183 6020

184 Telephone: +27 (0)11 545 0000

185

186 **This leaflet was last revised in**

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

187 TBC

188

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

189 **Registration Numbers**

190 L/34/337

Proposed PI, page 8 line 186

191

192 **Access to the corresponding Professional Information**

SAHPGL-CEM-03_V8 Guideline for PIL for Human Medicines

193 The professional information will be printed and packaged with the

194 product.

195