PROFESSIONAL INFORMATION FOR SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS

SCHEDULING STATUS

S1

PROPRIETARY NAME AND DOSAGE FORM

SODIUM CHLORIDE 0,9 % FOR IRRIGATION FRESENIUS

(Irrigation solution)

COMPOSITION

Each 500 ml contains 4,5 g sodium chloride

Each 1 000 ml contains 9,0 g sodium chloride

Each 3 000 ml contains 27,0 g sodium chloride

The inactive ingredient is water for injection.

PHARMACOLOGICAL CLASSIFICATION

A 34 Other

PHARMACOLOGICAL ACTION

Sodium chloride solution exerts a mechanical cleansing action for sterile irrigation of body cavities, tissues or wounds, indwelling urethral catheters, and surgical drainage tubes and for washing, rinsing, or soaking surgical dressings, instruments, and laboratory specimens. It acts as a diluent or vehicle for medicines used for irrigation or other pharmaceutical preparations.

INDICATIONS

Sodium Chloride 0,9 % for irrigation Fresenius being isotonic,

is a useful fluid for sterile irrigation, for example, of the eye or bladder,

and general skin or wound cleansing.

CONTRA-INDICATIONS

None

WARNINGS AND SPECIAL PRECAUTIONS

Not to be administered by parenteral injection.

Not for use in electrosurgery.

Solutions for urological irrigation should be used with caution in patients with severe cardiopulmonary or renal dysfunction, since systemic absorption of large amounts of the solutions may substantially alter cardiopulmonary or renal function.

DOSAGE AND DIRECTIONS FOR USE

As required for irrigation. For single use only. Discard unused portion.

SIDE EFFECTS

Systemic absorption of the irrigation solution may cause fluid and/or solute overload resulting in dilution of serum electrolytes, overhydration, congestive conditions, or pulmonary oedema.

KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT

See “SIDE EFFECTS”.

If adverse effects, overhydration, or solute overload occur with the irrigation solution, it should be discontinued, the patient closely evaluated, and appropriate corrective therapy instituted if necessary.

Treatment is symptomatic and supportive.

IDENTIFICATION

Clear, colourless solution.

PRESENTATIONS

1 000 ml Polypropylene bottles

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

1 000 ml Freeflex bags (1’s; 12’s)

3 000 ml PVC bags (1’s; 4’s)

STORAGE INSTRUCTIONS

Store at or below 25 ºC.

KEEP OUT OF REACH OF CHILDREN.

REGISTRATION NUMBER

L/34/337

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION

Fresenius Kabi Manufacturing SA (Pty) Ltd

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DATE OF PUBLICATION OF THE PACKAGE INSERT

Last approval date: 29 June 2000

Date of implementation of Regulation 9: 17 Nov 2015