Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Sodium Chloride (Normal Saline) 0.9% w/v Eye Drops Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Contains: Sodium Chloride 9mg/ml (0.9% w/v).

Excipients: Also contains benzalkonium chloride 0.01%w/v

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Eye Drops Solution
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Preserved multidose isotonic Sodium Chloride Eye Drops which are sterile until opened and may be used for up to 28 days after opening.

Sodium Chloride Eye Drops are used for irrigation (washing) of the eye as required, including first aid and the removal of harmful substances.

4.2 Posology and method of administration

Eye drops for topical administration.

Adults (including the elderly) and children

One or two drops to be instilled into the eye as required, or as directed by the Doctor or Pharmacist.

4.3 Contraindications

The product should not be used by patients with known hypersensitivity to any component of the preparation.

4.4 Special warnings and precautions for use

The drops should be discarded 28 days after first opening. During use care should be taken not to contaminate the dropper nozzle by contact with the eyelid or other surface. The product is for topical external use only and should be stored out of the reach of children.

This product contains benzalkonium chloride which may cause eye irritation. Avoid contact with soft contact lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion. Benzalkonium chloride is known to discolour soft contact lenses.

4.5 Interaction with other medicinal products and other forms of interaction

The product contains Benzalkonium Chloride, which may interact with soft contact lenses, resulting in damage to the lenses. Remove contact lenses prior to application and wait at least 15 minutes before reinsertion.

4.6 Fertility, pregnancy and lactation

No information is available on the use of Sodium Chloride Eye Drops during pregnancy or lactation. The product should only be used after consultation with a Doctor or Pharmacist.

4.7 Effects on ability to drive and use machines

Transient stinging and blurring of vision may occur on instillation of eye drops. Users should not drive or operate any hazardous machinery unless vision is clear.

4.8 Undesirable effects

None known.

4.9 Overdose

Not relevant to topical ocular use.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium and chloride ions are essential electrolytes of body fluids responsible for the maintenance of osmotic pressure within cellular structures and also contribute to various transport mechanisms. Sodium chloride 0.9% solutions are isotonic with body fluids and are thus used orally or via intravenous injection to correct conditions associated with the loss of body fluids, dehydration and sodium depletion.

5.2 Pharmacokinetic properties

Not applicable as product is for topical irrigation.

5.3 Preclinical safety data

No additional data of relevance to the prescriber.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzalkonium Chloride
Purified Water
May contain Sodium Hydroxide or Hydrochloric Acid (for pH adjustment)

6.2 Incompatibilities

None known.

6.3 Shelf life

3 years unopened.
Discard 28 days after first opening.

6.4 Special precautions for storage

Do not store above 25^{o}C.
Keep the bottle in the outer carton.
Protect from light.

6.5 Nature and contents of container

10 ml capacity white polyethylene eye dropper bottle with integral eye drop insert. Fitted with tamper evident white polyethylene cap. Pack size 10 ml.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

Sterile until opened.
Discard 28 days after first opening.

7 MARKETING AUTHORISATION HOLDER

Martindale Pharmaceuticals Ltd.
Bampton Road
Harold Hill
Romford
Essex RM3 8UG
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 361/12/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 07 July 2000

Date of last renewal: 07 July 2010

10 DATE OF REVISION OF THE TEXT

June 2012