

SUMMARY OF PRODUCT CHARACTERISTICS

EYEWASH DATA SHEET

- 1 **Trade Name of the Medicinal product**
Sterile Eye Wash Solution 0.9% w/v
- 2 **Qualitative and Quantitative Composition**
Sodium Chloride BP 0.9% w/v
- 3 **Pharmaceutical Form**
Topical Solution

Clinical Particulars

4.1 Therapeutic Indications

Sterile Eye Wash Solution 0.9% w/v

Irrigation and cleansing of body cavities, body surfaces, eyes and wounds.

4.2 Posology and Method of Administration

Sterile Eye Wash Solution 0.9% w/v :

Irrigate and cleanse the eye(s) with as much solution as required

4.3 Contra-Indications

None known

4.4 Special Warnings and Precautions for Use

Sterile Eye Wash Solution 0.9% w/v ;

- # Do not use unless solution is clear and unit is intact
- # Discard unused solution
- # Not for injection
- # For irrigation only

4.5 Interactions With Other Medicaments and Other Forms of Interaction

None Known

4.6 Pregnancy and Lactation

Safe for use in pregnancy and lactation

4.7 Effects on Ability to Drive and Use Machinery

None Known

4.8 Undesirable Effects

None Known

4.9 Overdose

Not Applicable

Pharmacological Properties

5.1 Pharmacodynamic Properties

Sodium Chloride is a normal component of serum electrolytes. A 0.9% w/v is iso-osmotic and in most cases isotonic with serum.

5.2 Pharmacokinetic Properties

Not applicable

5.3 Preclinical Safety Data
Not applicable

Pharmaceutical Particulars

6.1 List of Excipients
Purified water BP

6.2 Incompatibilities
None Known

6.3 Shelf Life
Three Years

6.4 Special Precautions for Storage
Store between 5 degrees C and 25 degrees C

6.5 Nature and Contents of Container
Sterile Eye Wash solution 0.9% w/v is supplied in a 500ml polypropylene bottle

6.6 Instructions For Use/Handling

Sterile Eye Wash Wash Solution 0.9% w/v:

- # Do Not Use unless solution is clear and unit is intact
- # Discard unused solution
- # Not for injection
- # For irrigation only

7. HAZARDS

Health No hazard expected

Fire and Explosion No hazard expected
Environment

Environment No hazard expected

8. FIRST-AID

Eyes Not applicable

Skin An excessive amount may cause irritation and should be washed off with soap and water

If Swallowed If conscious give water to drink. Seek medical aid.

If Inhaled Remove to fresh air. Treat symptoms. Seek medical advice.

9. FIRE FIGHTING

Non Flammable therefore not expected to contribute to fire hazard

10. ACCIDENTAL RELEASE

Personal Precautions Not considered necessary in normal consumer use.

Environmental Precautions Standard waste disposal

Methods for Cleaning Up Absorb on inert material and dispose of in accordance with local authority requirements.

11. HANDLING AND STORAGE

Storage Keep out of reach of children. Store in a cool place away from sources of ignition

12. EXPOSURE CONTROLS/PERSONAL PROTECTION

Occupational Exposure Limits Not applicable

Respiratory Protection Not required, work to GMP standards.
Hand Protection Not required, work to GMP standards
Eye Protection Not required, work to GMP standards
Skin Protection Not required, work to GMP standards

13. PHYSICAL AND CHEMICAL PROPERTIES (QC SPEC)

Appearance A colourless liquid
Odour Characteristic odour
Relative Density Not determined
PH 6.0 to 7.5
Flashpoint Not applicable

14. STABILITY AND REACTIVITY

Stability/Reactivity Not applicable
Conditions to Avoid Sunlight and temperatures exceeding 50°C
Materials to Avoid Not applicable
Hazardous None
Decomposition Products

15. TOXICOLOGY INFORMATION

None available, no hazard expected

16. ECOLOGICAL INFORMATION

None available, no hazard expected

17. DISPOSAL CONSIDERATIONS

Full containers should be disposed of in accordance with local authority requirements

18. TRANSPORT INFORMATION

UN Number Not applicable
UN Hazard Class Not applicable
UN Packing Group Not applicable

19. REGULATORY INFORMATION

Classification of risk Non Hazardous
Safety phrase(s) None

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