

1. NAME OF THE MEDICINAL PRODUCT

Galways Hydrogen Peroxide

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

20 volumes contains 6% w/v (approx) of Hydrogen Peroxide with stabilizer.

For full list of excipients, see section 6.1.

3. Pharmaceutical form

Solution.

A clear colourless solution.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

- As a mouth wash.
- To remove dressing from wounds.
- As a first aid to treat cuts, wounds and abrasions.

4.2 Posology and method of administration

Topical.

As a mouthwash: to half a tumbler of water, add one tablespoonful of Hydrogen Peroxide Solution and use frequently.

To remove dressing from wounds: Hydrogen Peroxide Solution should be diluted with an equal volume of water and the dressing is soaked with it. Leave for a few minutes before removal.

As a first aid: Hydrogen Peroxide Solution should be diluted with an equal volume of water and then applied on cotton wool or lint to arrest the bleeding and disinfect the tissue. Lightly, fix the dressing in place with a bandage or strip plaster adhesive.

4.3 Contraindications

- Hypersensitivity to any of the ingredients.
- Not for use in closed body cavities or on surgical wounds due to the risk of oxygen released into the circulation causing gas embolism.
- Not for use as a disinfection agent for surgical instruments (particularly endoscopes) and as an enema.

4.4 Special warnings and precautions for use

Hydrogen Peroxide is an irritant liquid. Contact with eyes should therefore be avoided. In accidental spillage in eyes, wash thoroughly with water and seek medical attention immediately.

Keep the bottle capped and stored in a cool place below 30°C. Keep all medicines out of the reach of children. Not for use in closed body cavities or on surgical wounds due to risk of oxygen released into the circulation causing gas embolism.

Avoid use on normal skin.

Product bleaches fabric.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

All medicines should be avoided if possible during pregnancy and lactation. No evidence is available as to the safety of use of this product in these conditions.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Cases of gas embolism, sometimes resulting in cardiac arrest, have been reported when hydrogen peroxide has been instilled in closed body cavities or deep surgical wounds.

Strong solutions of hydrogen peroxide produce irritating burns on the skin and mucous membranes with a white eschar. The pain disappears after about 1 hour. Continued use of the product as a mouthwash may cause reversible hypertrophy of the papillae of the tongue.

4.9 Overdose

Symptoms and signs

Accidental ingestion may cause sore throat, gastric disturbances and vomiting. Sudden evolution of oxygen may cause injury by acute distension of the stomach and internal bleeding. Water may be given to drink. Ingestion of large volumes can lead to gas embolism following evolution of oxygen in the stomach.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other Antiseptics and Disinfectants

ATC code: D08AX01

Hydrogen peroxide is used as a disinfectant and deodorant. It releases oxygen when applied to tissues, the effect lasts only as long as the oxygen is being released and is of short duration. The antimicrobial effect of the liberated oxygen is reduced in the presence of organic matter. It is used to cleanse wounds and ulcers in concentrations of up to 6%. Adhering and blood-soaked dressings may be released by the application of a solution of hydrogen peroxide. A 1.5% solution has been used as a mouthwash in the treatment of acute stomatitis and as a deodorant gargle.

5.2 Pharmacokinetic properties

No further information available.

5.3 Preclinical safety data

No data of relevance which is additional to that already included in other sections of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Acetanilide
Sulphuric Acid (1M)
Deionized Water

6.2 Incompatibilities

Incompatible with reducing agents including organic matter and oxidisable substances and with alkalis, iodides, permanganates and other stronger oxidising agents. Its decomposition is increased by metallic salts, light, agitation, heat and metals.

6.3 Shelf Life

3 years

6.4 Special precautions for storage

Store in a cool place below 30°C. Store in the original container

6.5 Nature and contents of container

100ml Amber Glass bottle with aluminium screw cap.

6.6 Special precautions for disposal and other handling

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. APPLICANT/MANUFACTURER

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