UGOLAB PRODUCTIONS (NIG.) LTD.

MANUFACTURERS OF PHARMACEUTICAL PRODUCTS AND GENERAL MERCHANTS

Head office: 31A Burma Road, Sabon Gari, Kano. **Factory:**157/159, Club Road, Bompai Ind. Layout, Kano.

Tel: +234 (80) 23094219 **Website**: www.ugolab.com **Email**: ugolabpharm@yahoo.com

SUMMARY OF PRODUCT CHARACTERISTICS HYDROGEN PEROXIDE

SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

Of

UGOLAB HYDROGEN PEROXIDE SOLUTION

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SUMMARY OF PRODUCT CHARACTERISTICS HYDROGEN PEROXIDE

Summary of Product Characteristics

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SUMMARY OF PRODUCT CHARACTERISTICS HYDROGEN PEROXIDE

1. NAME OF THE MEDICINAL PRODUCT

Ugolab Hydrogen Peroxide Solution.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Hydrogen Peroxide with stabilizer. For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

A clear colourless solution.

4. Clinical particulars

4.1 Therapeutic indications

Hydrogen Peroxide Solution is used as Disinfectant and deodorant for cleansing of wounds as 6% w/v solution. It is used as a mouth wash in the treatment of acute stomatitis and as a deodorant gargle in 1.5% solution.

4.2 Posology and method of administration

Topical

Method of administration

For Wound Dressing Removal: Dilute Hydrogen Peroxide Solution with an equal amount of water. Soak the dressing in this solution and let it sit for a few minutes before gently removing it.

For Mouthwash: Mix one tablespoon of Hydrogen Peroxide Solution with half a tumbler of water and use it regularly

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As First Aid: Dilute Hydrogen Peroxide Solution with an equal volume of water. Apply the mixture to cotton wool or lint to help stop bleeding and disinfect the area. Secure the dressing lightly with a bandage or adhesive strip.

4.3 Contraindications

Hypersensitivity to any of the ingredients.

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.

The Product bleaches fabric.

4.5 Interaction with other medicinal products and other forms of interaction

Not Applicable.

4.6 Pregnancy and Lactation

Not Applicable.

4.7 Effects on ability to drive and use machines

Not Applicable.

4.8 Undesirable effects

Hydrogen Peroxide Solution (6%) is well tolerated when applied externally. However, it is dangerous to inject or instill Hydrogen Peroxide into closed body cavities from which the released oxygen has no free exit.

The continued use of Hydrogen Peroxide as a mouth wash may cause reversible hypertrophy of the papillae of the tongue.

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4.9 Overdose

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 Pharmacodynamics properties

Pharmacotherapeutic group: Over-The-Counter (OTC) Product
Hydrogen Peroxide Solution is used as Disinfectant and deodorant for cleansing of wounds as 6% v/v solution. It is used as a mouth wash in the treatment of acute stomatitis and as a deodorant gargle in 1.5% solution.

5.2 Pharmacokinetic properties

Hydrogen Peroxide Solution (6%) is not meant for internal use due to its toxic nature hence its pharmacokinetics is not available.

5.3 Preclinical safety data

Hydrogen Peroxide Solution (6%) has no teratogenic effect as the product is applied topically and is not absorbed from the site of application.

6. PHARMACEUTICALPARTICULARS

6.1 List of excipients

- Acetanilide Powder

SUMMARY OF PRODUCT CHARACTERISTICS HYDROGEN PEROXIDE

6.2 Incompatibilities

Incompatible with reducing agents including organic matter and oxidizable 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

36 months

6.4 Storage condition:

Store below 30^0C Keep

out of reach of children.

6.5 Nature and contents of container

100ml Brown Amber Bottle with Rubber Cap

6.6 Special precautions for disposal

No special requirements apart from NAFDAC guidelines

7. Applicant
UGO LAB PRODUCTIONS (NIG). LTD, 31A, BURMA ROAD, SABON GARI, KANO STATE.

Manufacturer
UGOLAB PRODUCTIONS NIGERIA LIMIED., 206 Barde Road/ Independence Road, off Airport Road, Kano, Kano State.

8. Marketing authorisation number(s)
04-5745

SUMMARY OF PRODUCT CHARACTERISTICS
HYDROGEN PEROXIDE

9. Date of first authorisation/renewal of the authorisation

05 Nov 10

10. Date of revision of the text

Not Applicable

Company Contact Details

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