

FOLAT® HYDROGEN PEROXIDE B.P.

SUBMITTED BY

NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE DRUG PRODUCT

Folat® Hydrogen Peroxide B.P.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

20 Volumes contains:

Hydrogen Peroxide.....6% w/v

Excipients.....q.s

Excipients with known effect
For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Folat Hydrogen Peroxide is used as a mild disinfectant for minor cuts, wounds and skin ulcers. It is also used as a mouthwash or gargle.

4.2 Posology and method of administration

As a Mouthwash
Dilute half a tumbler of water with one table spoonful of hydrogen peroxide, gargle frequently.

To Remove Dressing from Wound
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
To treat cuts, wounds and abrasions, hydrogen peroxide solution should be diluted with an equal volume of water and then applied on cotton wool or lint to arrest bleeding and disinfect the tissue lightly. Fix 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

For external use only.
Keep all medicines away from 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 normal skin.
Product bleaches fabric.

4.5 Interaction with other drug 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.

Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions to the regulatory bodies such as NAFDAC.

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 Pharmacodynamic properties

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

Not available

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phosphoric acid BP
Purified water BP.

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

24 months unopened
Use within 28 days of first opening

6.4 Special precautions for storage

Store below 25° C.
Protect from light

6.5 Nature and contents of container

Colourless, transparent liquid in 100 ml amber-coloured pet bottle with red cap.

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

No special requirements

7. APPLICANT/HOLDER OF CERTIFICATE OF PRODUCT REGISTRATION

NAME:
FOLAT PHARMA LTD

ADDRESS:

4 Olaleke Taiwo Street,
Ojodu Grammar School, Lagos State.

8. DRUG PRODUCT MANUFACTURER

NAME:
NALIS PHARMACEUTICALS LTD

ADDRESS:

R67-68 Nekede-Naze
Industrial Clusters,
Nekede, Owerri,
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9. NAFDAC REGISTRATION NUMBER(S):

Not available

