1. Name of the medicinal product
D & M Robin's Hospital Disinfectant& Device

2. Qualitative and quantitative composition
Hydroxide Peroxide	4%
Sodium Lauryl Sulphate	0.05%
Phosphoric Acid	0.08%
Sodium EDTA	H20

3. Pharmaceutical form
Solution.

4. Clinical particulars
4.1 Therapeutic indications

1. As a mild disinfectant for minor cuts, wounds and skin ulcers.
2. As a mouthwash or gargle.

4.2 Posology and method of administration

Topical.
1. As a disinfectant:
Use as required. Dress the wound with cotton wool soaked in a solution of equal parts of peroxide and water.
As a disinfectant this product is suitable for use by adults, children and the elderly.
2. As a mouthwash or gargle:
Dilute one part of peroxide to five parts of water. Rinse the mouth for two to three minutes. This may be repeated up to three times daily.
As a mouthwash or gargle the product is suitable for use by adults, children over 12 years and the elderly. Due to the risk of swallowing it should only be used by younger children under the instruction of a doctor.

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 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.

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 via the Yellow Card Scheme at: www.mhra.gov.uk/yellowcard.

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

None.

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

200ml : Round amber glass bottle with white 28mm cap with Tamper Evident band and EPE/Saranex Liner.

6.6 Special precautions for disposal and other handling

None.

7. Marketing authorisation holder

NALIS PHARMACEUTICALS LTD
Plot R67/68, Nekede-Naze
Industrial Cluster, Nekede,
Owerri-Nigeria.

Manufactured for:
DRUGS AND MEDICAMENT NIG LTD
No. 6/7 Penock Pocket Estate, Old Emene
Airport Road, Enugu, Nigeria