SKINSERV® ANTISPETIC LIQUID

SUBMITTED BY

NALIS PHARMACEUTICALS LTD

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SUMMARY OF PRODUCT CHARACTERISTICS

(SmPC)

1. NAME OF THE DRUG PRODUCT

Skinserv® Antiseptic Liquid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

A clear, pale-yellow liquid.

100 ml contains:

Chlorhexidine Gluconate……**0.3 % w/v**

Cetrimide……**3.0 % 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

A topical antiseptic for prevention and management of infection or superficial skin trauma.

4.2 Posology and method of administration

For cutaneous use.
Two capfuls to ½ litre of warm water.

4.3 Contradindications

Hypersensitivity to chlorhexidine, cetrimide or to any of the excipients listed in Section 6.1.

4.4 Special warnings and precautions for use

If symptoms persist or condition worsens or if a skin reaction occurs, discontinue use and consult a doctor.

For external use only.

Avoid contact with the eyes, ears, mouth or other mucosa.

If accidentally splashed into the eye, the open eye should be irrigated with water for at least 10 minutes.

4.5 Interaction with other drug products and other forms of interaction

No interaction studies have been performed with the topical forms.

4.6 Fertility, pregnancy and lactation

Pregnancy
There are no adequate data from the use of chlorhexidine and cetrimide in pregnant women. The potential risk for humans is unknown but is most likely very low since chlorhexidine and cetrimide are poorly absorbed following topical application (see section 5.2).

Breastfeeding
It is not known whether chlorhexidine and cetrimide are excreted in breast milk. There are no adequate data from the use of chlorhexidine and cetrimide in breast-feeding women. However, it is unlikely that the products are excreted in breast milk, since the products are poorly absorbed. After topical usage of the product, as a general precaution, rinse nipples thoroughly with water before breastfeeding.

Fertility
No data are available on fertility outcomes.

4.7 Effects on ability to drive and use machines

Has no influence on the ability to drive and use machines

4.8 Undesirable effects

Within each system organ class, the adverse drug reactions are presented in order of decreasing seriousness. The frequency categories for each adverse drug reaction include: very common (≥1/10); common (≥1/100, <1/10); uncommon (≥1/1,000, <1/100); rare (≥1/10,000. <1/1,000); very rare (<1/10,000); not known (cannot be estimated from the available data). The listed adverse events have estimated frequencies from post-marketing reporting.
Immune system disorders:
Very rare: Anaphylactic reaction, angioedema, urticaria

Skin and subcutaneous tissue disorders:
Very rare: Skin irritation
Not known: blistering

Paediatric population:
No investigations in children have been performed. However, frequency, type, and severity of adverse reaction in children are expected to be the same as in adults

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

While accidental ingestion is unlikely to cause any systemic effects due to poor absorption of chlorhexidine and cetrimide, ingestion of high concentrations could cause irritation of the gastrointestinal mucosa/gastritis.
Gastric lavage might be needed. Symptomatic treatment should be employed.
If swallowed, wash out mouth, drink plenty of milk or water and seek medical advice.
In case of overdose, seek medical attention or contact a poison control centre.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Chlorhexidine, combination – Pharmacotherapeutic group: Antiseptics and disinfectants.
ATC Code: D08AC52.

Chlorhexidine is an effective antiseptic with a wide range of activity against microorganisms, including gram-positive and gram-negative bacteria, fungi and viruses.
Cetrimide is a quaternary ammonium compound with surfactant and antiseptic properties.

5.2 Pharmacokinetic properties

Chlorhexidine and cetrimide are poorly absorbed from the gastro-intestinal tract and skin.

5.3 Preclinical safety data

There is minimal systemic absorption of chlorhexidine following topical administration. Preclinical data do not show genotoxic risk for chlorhexidine. Reproductive studies with chlorhexidine gluconate in animals have not revealed any teratogenic potential nor risk to the foetus. No additional information is available for cetrimide.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

N-propyl alcohol

Terpineol

Liquid deodoriser

Benzyl benzoate

Sodium Hydroxide

Purified water.

6.2 Incompatibilities

None known

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Transparent PVC bottles with polypropylene screw caps.
Pack size: 100 ml

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:

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9. NAFDAC REGISTRATION NUMBER(S):

Not available