



Neoxidina Mani

Antiseptic Liquid Soap for **EXTERNAL USE**

Technical Information

1. Composition

100g of solution contains chlorhexidine gluconate 4.0g, excipients.

2. Product characteristics

The hands are one of the most important sources of infections in hospitals and cleansing them is one of the most important procedures in the prevention of infection. The procedure should eliminate transitory organisms and reduce the usual level of flora to the lowest possible degree. Moreover, the product should also remain on the skin to keep the number of surviving organisms low during the course of surgical operations.

NEOXIDINA MANI is an antiseptic solution, perfectly clear, of red color and neutral pH.

3. Microbiological activity

Chlorhexidine gluconate is active against gram-positive and gram-negative bacteria, yeasts and viruses.

As an antiseptic for the hands, Chlorhexidine, compared with other active ingredients, has the following characteristics:

1. Fast acting
2. Immediate effect
3. Long-lasting effect: one of the best features of chlorhexidine is its strong affinity with the skin. It is not absorbed but adsorbed and remains active on the skin for several hours

4. Effectiveness of chlorhexidine + detergent: from scientific bibliography (Disinfection and Sterilisation; Seymour S. Block, 3rd edition page 384) it can be seen that an application of chlorhexidine + alcohol, while effective, is not as effective as a single wash with chlorhexidine + detergent (non-ionic or cationic surfactants);
5. Effective in the presence of blood: a study carried out to determine the effect of blood on the germicidal effectiveness of chlorhexidine showed a decrease in bacterial flora of 90.4% on hands even when contaminated with blood.

As demonstrated by specific studies on the Biocidal activity, NEOXIDINA MANI effectively reduces resident and transient bacterial flora of the skin.

Biocidal effectiveness data:

Basic Bactericidal Activity	EN 1040	1 min.
Suspension Bactericidal Activity	pr EN 12054	1 min.
Surface bactericidal Activity (Hygienic handwash)	EN 1499	1 min.
Surface bactericidal Activity (Hygienic Handrub)	EN 1500	30 sec.
Surface bactericidal Activity (Surgical handrubbing)	EN 12791	1 min.+1 min.
Virucidal Activity (Poliovirus, Adenovirus)	EN 14476	1 min.

4. Range of application and instructions for use

4.1 Field of use and contact time

- a. Antiseptic hand/washing: 4ml for 1 minute.
- b. In the operative field for surgeon antiseptic hand/forearms washing: 3 minutes (4ml for 1 min. + 4ml for 2 min.)
- c. Complete washing of the patient before surgery.

4.2 Contraindications

Hypersensitivity to components.

4.3 Undesirable effects

The hands must remain intact and clean because disinfection is satisfactory. Prolonged washing of the hands could cause irritation in some cases; if this occurs, stop the treatment.

4.4 Special precautions for use

THIS PRODUCT IS FOR EXTERNAL USE ONLY.

Use of topical products, especially if prolonged, may cause hypersensitivity. In this occurs, stop the treatment for a short period.

Accidental swallowing can lead to serious consequences. Avoid contact with eyes and middle ear. NEOXIDINA MANI can cause chemical burns in infants, especially those born prematurely. Use with caution.

4.5 Interactions with other products

Avoid concomitant use of other antiseptics and/or detergents.

4.6 Instructions for use

Antiseptic handwash:

1. Wet the hands under tap water;
2. Apply about 4ml of NEOXIDINA MANI (4ml is one pump of the dispenser) to the cupped hands;
3. Scrub the solution on the hands and wrists for about 1 minute;
4. Rinse under tap water.

Surgical handwash:

1. Wet the hands under tap water;
2. Apply about 4ml of NEOXIDINA MANI (4ml is one pump of the dispenser) to the parts to be treated;
3. Scrub the solution on the hands, wrists and forearms for about 1 minute, using a brush to clean under the nails;
4. Rinse under tap water;
5. Repeat stages 2 and 3 for 2 minutes;
6. Rinse again and dry with a sterile towel.

Complete washing of the patient before surgery:

1. Wet the part of the body to be treated;
2. Wash with NEOXIDINA MANI (30ml);
3. Rinse under tap water;
4. Repeat stages 1, 2 and 3.

If soap is used for initially washing the skin, given the incompatibility of chlorhexidine with soaps, it is best to rinse with tap water before applying NEOXIDINA MANI.

DO NOT EXCEED THE RECOMMENDED DOSE.

4.7 Incompatibilities

The product is incompatible with anionic detergents, hydrogen peroxide, iodides, soaps and emulsifying agents. Chlorhexidine salts are incompatible with borates, bicarbonates, carbonates, chlorides, citrates, phosphates, nitrates and sulphates as the corresponding salts are almost insoluble.

5. Packaging

Bottle

250 x 30ml monodoses ref. PF06740
12 x 1L ref. PF06786
20 x 500ml ref. PF06787

6. Quality control

The components (raw materials, containers, labels etc.) and production steps of each individual batch are carefully controlled in compliance with the SOP (Standard Operative Procedures) required by standard UNI EN ISO 9001 and Good Manufacturing Practices.

7. Storage and stability

Keep the container tightly closed, store at room temperature (below 30°C) and protect the product from light.

The product in its original sealed packaging is valid for 36 months.

If the package is correctly opened and closed at the end of each disinfection operation, without contamination of the residual part, the product maintains its chemical-physical and microbiological characteristics for 90 days.

8. Regulatory references

Holder of the registration:

Nuova Farmec S.r.l. – Via Flemming, 7
37026 Settimo di Pescantina (VR) – Italy.

Presidio Medico Chirurgico authorized by Italian Ministry of Health registration N. 16594.

INFORMATION RESERVED FOR HEALTH CARE PROFESSIONALS AND PROFESSIONAL USERS

