

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Merfen spray first aid

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 ml of solution contains:

5 mg chlorhexidine gluconate

1 mg benzoxonium chloride

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Dermal solution

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

To disinfect wounds and injuries, such as cuts, scratches, mild burns and insect stings.

4.2 Posology and method of administration

Prior to first use, pump several times until a spray appears.

Apply 1-2 sprays to the sites requiring treatment. The container will work in any position as it only contains aqueous solution (without propellant), even if the spray head is pointing downwards. Several pumps are required in this case until the first spray appears. Ensure that Merfen, aqueous solution, does not accumulate in skin folds. Allow the skin to dry after disinfecting, before applying a light dressing. Do not use Merfen aqueous solution under a tight dressing.

4.3 Contraindications

Merfen spray first aid is contraindicated in patients who have experienced hypersensitivity to the active ingredients (chlorhexidine gluconate and benzoxonium chloride), quaternary ammonium compounds, or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

- Merfen spray first aid is only intended for external use.
- Contact between Merfen spray first aid and the ears (auditory passage) and mucous membranes (such as mouth and nose) should be avoided.
- Contact must be avoided between Merfen spray first aid and the eyes. Severe cases of irreversible damage to the cornea that may require a cornea transplant have been reported after accidental exposure of the eyes to medicinal products containing chlorhexidine. In these cases, the solution reached areas outside the region requiring preparation for the surgical intervention, in spite of protective measures for the eyes being in place. Extreme caution is required during use to ensure that Merfen spray first aid does not get into the eyes from the intended application area. Particular caution is

advised in patients under anaesthetic who cannot report ocular exposure immediately. The eyes must be rinsed immediately and thoroughly with water if Merfen spray first aid comes into contact with the eyes. An ophthalmologist should be consulted.

- Merfen spray first aid should not be ingested.
- Merfen spray first aid must not be used too frequently or over lengthy periods without medical consultation.
- Medical treatment is required in very dirty and deep wounds, injuries or burns which cover a large area, as well as bite and stab wounds (risks include tetanus).
- Medical advice is required if the size of the wound remains unchanged in size for some time, does not heal within 10-14 days, or if the margins of the wound are very red, the wound suddenly swells up, it is very painful or the injury is accompanied by fever (risk of blood poisoning).
- The use of Merfen spray first aid should be stopped if there's irritation to the skin or unusual sensitivity.

Newborn babies, especially premature babies

Caution is required in newborn babies, especially premature babies. Merfen spray first aid can cause chemical burns to the skin (see also chapter 4.8 – Undesirable effects).

4.5 Interaction with other medicinal products and other forms of interaction

Merfen spray first aid is not expected to have an interaction with other medicinal products, because of the low extent of absorption of the active ingredients.

4.6 Fertility, pregnancy and lactation

Pregnancy:

The preparation can be used in small quantities (on small wounds) during pregnancy. There are no adequate data on the use of chlorhexidine digluconate and benzoxonium chloride in pregnant women. The potential risk to humans is unknown; however, it is assumed to be very low as only small quantities of chlorhexidine digluconate and benzoxonium chloride are absorbed after topical application.

Breast feeding:

There is no information on whether chlorhexidine digluconate and benzoxonium chloride are excreted in human milk. Merfen spray first aid can be used in small quantities (on small wounds) during breast feeding, except on the breast. As a general precaution, you should wash your nipples thoroughly with water before breast feeding.

4.7 Effects on ability to drive and use machines

Merfen spray first aid has no influence on the ability to drive and use machines.

4.8 Undesirable effects

- Side effects which are very rare (occur in fewer than 1 in 10,000 patients), but may be serious:

Breathing difficulties, dizziness (anaphylactic reaction), swelling of the face and neck (angioedema).

Treatment should be stopped if these symptoms occur, as these are signs of an allergic reaction.

- Side effects which are rare (occur in 1-10 in 10,000 patients): Skin irritation.
- Side effects which are very rare (occur in fewer than 1 in 10,000 patients: hives (urticaria).
- Side effects with unknown frequency: chemical burns in newborn babies, contact dermatitis with possible disruption of wound healing if treatment is continued, corneal erosion, epithelial defect/corneal injury, significant permanent visual impairment*.
*There are post-marketing reports of cases of severe corneal erosion and significant permanent visual impairment due to accidental ocular exposure, resulting in some patients requiring a cornea transplant (see section 4.4 "Special warnings and precautions for use").

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. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form:

<https://sideeffects.health.gov.il>

4.9 Overdose

Not stated

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antiseptic
ATC code: D08AC52

5.2 Pharmacokinetic properties

Not stated

5.3 Preclinical safety data

Not stated

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lauryldimethylamineoxide,
Purified water

6.2 Incompatibilities

Not known

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials.

6.4 Special precautions for storage

Store below 25°C.

6.5 Nature and contents of container

Bottle of 30ml, which contains a clear and colorless aqueous solution.

6.6 Special precautions for disposal and other handling

Not stated

7. MANUFACTURER

VERFORA SA, SWITZERLAND
CH-1752 VILLARS-SUR-GLANE, SWITZERLAND

8. MARKETING AUTHORISATION HOLDER

Meditrend marketing (2004) Ltd., Israel
Kibutz Glil-yam 46905, Israel

9. MARKETING AUTHORISATION NUMBER

121-68-30135

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