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 eyes, ears (auditory passage) and mucous membranes (such as mouth and nose) should be avoided. Rinse the eye immediately with copious amounts of water if any Merfen spray first aid gets into the eye by accident.
- Merfen spray first aid should not be ingested.
- Merfen spary 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 diguconate 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 spary 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 spary 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.

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

Revised in April 2023 according to MOHs guidelines.