

Patient Package Insert according to Pharmacists' Regulations (Preparations)-1986

This medicine can be sold without a physician's prescription

Merfen Spray First Aid Spray

The active ingredients and their quantity:

Benzoxonium chloride 1 mg

Chlorhexidine gluconate 5 mg

For the list excipients, please see section 6 "Additional information".

Read this entire leaflet carefully before you start using the medicine.

This leaflet contains concise information about the medicine. If you have any further questions, ask your doctor or pharmacist.

Use this product according to the instructions in the dosage section of this leaflet. Consult the pharmacist if you need additional information.

Refer to the doctor if the symptoms of the illness worsen or do not improve after 10-14 days.

1. What is the medicine intended for?

The medicine is intended for the disinfection of wounds, cuts, scratches, mild burns and insect bites.

Therapeutic group:

Benzoxonium chloride: Antiseptic (disinfectant)

Chlorhexidine gluconate: Antiseptic (disinfectant)

2. Before using the medicine:

Do not use the medicine:

If you are hypersensitive (allergic) to the active ingredients (benzoxonium chloride and chlorhexidine gluconate), or to quaternary ammonium compounds, or to any of the other ingredients this medicine contains (see section 6).

Special warnings regarding the use of this medicine:

Before treatment with Merfen Spray First Aid, tell the doctor or pharmacist if:

- you suffer from other illnesses
- you have any allergy
- you are taking any other medicines or using medicines for external use (including non-prescription medicines)

Refer to the doctor:

- if you have very infected or deep wounds spread over a large area, bites or stab wounds - medical treatment is required (due to risks including tetanus).
- If the wound size does not reduce or if the wound does not heal after 10-14 days. Also, if the margins of the wound are very red, the wound suddenly swells, is very painful or the injury is accompanied by fever (due to the risk of a blood infection).
- If you need treatment for wounds or burns covering a large area.

Additional warnings:

- Avoid contact with the eyes, ears (auditory canal) and mucus membranes (e.g., the mouth and nose). If Merfen Spray First Aid accidentally gets into the eyes, rinse them immediately with a large amount of water.
- Do not use this medicine frequently or for an extended period without consulting a doctor.
- Stop the use of Merfen Spray First Aid if you notice skin irritation or unusual sensitivity.

Infants and premature infants:

Caution is required when using the medicine in infants and especially in premature infants. Merfen Spray First Aid can cause chemical burns to the skin.

Drug interactions

If you are taking, or have recently taken other medicines, including non-prescription drugs, vitamins, herbal remedies and nutrition supplements, tell the doctor or pharmacist.

Drug interactions are not expected due to the low absorption rate of the active ingredients (benzoxonium chloride and chlorhexidine gluconate).

Pregnancy and breastfeeding:Pregnancy

There is insufficient data on the use of benzoxonium chloride and chlorhexidine gluconate in pregnant women. Small quantities of the product (on small wounds) can be used during pregnancy. The potential risk in humans is unknown. Despite this, it is assumed that the risk is very low because only small amounts of benzoxonium chloride and chlorhexidine gluconate are absorbed after local application. Consult the doctor if you want to use the medicine during pregnancy, especially during the first three months.

Breastfeeding

There is no data on the excretion of benzoxonium chloride and chlorhexidine gluconate through breastmilk. Small quantities of the product (on small wounds) can be used while breastfeeding, but do not use on the chest.

As a general precaution, it is recommended to wash the nipples thoroughly with water before breastfeeding.

3. How to use this medicine?

Check with the doctor or pharmacist if you are not sure about the dosage and manner of treatment with the product.

Merfen Spray First Aid is intended for use on the skin only.

The usual recommended dosage is:

Spray once or twice per day directly onto the areas to be treated.

Before the first use pump a few times until spray is released. The product can be used in any position, even when the container is upside down. In this case, several pumps will be required until the spray is released.

Make sure that Merfen Spray First Aid does not accumulate in skin folds. Allow the skin to dry after disinfecting, before covering with a light dressing. Do not use Merfen Spray First Aid under a tight dressing to prevent skin irritation.

Do not exceed the recommended dose.

Method of administration:

Do not swallow! This medicine is intended for external use only.

If you have accidentally used a higher dosage,

or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them. If you have further questions regarding use of the medicine, consult the doctor or pharmacist.

4. Side effects

As with any medicine, the use of Merfen Spray First Aid may cause side effects in some users. Do not be alarmed while reading the list of side effects. You might not suffer from any of them.

Very rare side effects (effects that appear in less than one user out of 10,000), **but which may be serious:**

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

Stop using the medicine and refer immediately to a doctor if you notice one of the symptoms noted above (which may be signs of an allergic reaction).

Rare side effects (effects that appear in 1-10 users out of 10,000):

Skin irritation.

Very rare side effects (effects that appear in less than one user out of 10,000):

Hives (urticaria).

Side effects with unknown frequency (effects whose frequency has not been determined yet): Chemical burns in babies, contact dermatitis with possible disruption of wound healing if treatment is continued (see section 2 " Before using the medicine ").

If a side effect appears, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Reporting of side effects

Side effects can be reported to the Ministry of Health via the link 'Reporting Side Effects of Drug Treatment' that can be found on the home page of the Ministry of Health website (www.health.gov.il) directing to the online form of adverse events reporting or via the following link:

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

5. How to store the Medicine?

- Avoid poisoning! This medicine, and all other medicines, must be stored in a closed place out of the reach and sight of children and/or infants, to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Store below 25° C.
- Water containing bleach disinfectants (Javelle water) may cause the color of laundry to change to light brown when it comes in contact with chlorhexidine. Washing tests have shown that detergents containing one or more bleaches (such as perborate) will remove these stains.

6. Additional Information

In addition to the active ingredients, the medicine also contains:

Lauryldimethylamineoxide, Purified water

What the medicine looks like and contents of the package:

Merfen Spray First Aid contains a clear colorless solution, in a 30 ml bottle.

Registration Holder and address: Meditrend Marketing (2004) Ltd., Kibutz Glil Yam.

Manufacturer and address: VERFORA SA, Villars-sur-Glâne, Switzerland

Drug registration number at the national medicines registry of the Ministry of Health: 121-68-30135

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