

Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) – 1986

This medicine is dispensed without a doctor's prescription

Vita-Merfen Ointment

Active ingredients

chlorhexidine (as gluconate) 0.5% w/w
benzoxonium chloride 0.1% w/w
vitamin A palmitate 0.2% w/w (2000 IU/g)

Inactive ingredients: see section 2 under 'Important information about some of this medicine's ingredients', and section 6 'Additional information'.

Read the entire leaflet carefully before you start using this medicine. This leaflet contains concise information about this medicine. If you have any further questions, consult your doctor or pharmacist.

Use this medicine according to the instructions in the section about dose in this leaflet. Consult your pharmacist if you need further information. Contact your doctor if your symptoms of illness get worse or do not improve within 10–14 days.

1. WHAT IS THIS MEDICINE INTENDED FOR?

Treatment of all kinds of small wounds (such as scratches, abrasions, cuts), cracks, chapped skin, minor burns (first degree).

Therapeutic group: chlorhexidine gluconate and benzoxonium chloride – disinfectants; vitamin A – vitamins.

Vita-Merfen Ointment contains two disinfectant substances, chlorhexidine gluconate and benzoxonium chloride, which affect the microorganisms responsible for inflammation, as well as vitamin A. The combination of disinfectant substances and vitamin A for treating small wounds promotes wound healing while preventing secondary infection.

2. BEFORE USING THIS MEDICINE

Do not use this medicine if:

Do not use Vita-Merfen Ointment if you are sensitive (allergic) to chlorhexidine gluconate, benzoxonium chloride, or other quaternary ammoniums, vitamin A or any of its derivatives, or any of the other substances in this product (see section 6).

Special warnings about using this medicine

Before you start treatment with Vita-Merfen Ointment, tell your doctor if you:

- have some other disease
- are allergic
- are taking other medicines for external use!

Additional warnings

Wounds covering large areas, very dirty or deep wounds such as bite wounds or injuries caused by sharp objects require additional medical care (there is a risk of tetanus and other infections). If the edges of the wound do not shrink together after a while, or the wound does not heal within 10–14 days, consult a doctor too. Consult a doctor also if the edges of the wound are very red, if the wound swells suddenly or becomes very painful or you also have a fever (risk of blood poisoning).

Vita-Merfen Ointment is for external use only. Avoid contact of the ointment with ears (ear canal), and mucous membranes (mouth and nose). If the ointment comes into contact with mucous membranes, rinse immediately with plenty of water.

Vita-Merfen Ointment must not come into contact with the eyes due to the risk of damage to the eyesight. Rinse your eyes immediately and thoroughly with water if it comes into contact with your eyes. Consult a doctor as soon as possible in the event of irritation, reddening or pain in your eyes or in cases of visual disturbance. Severe cases of irreversible damage to the cornea (damage to the surface of the eye) that may require a cornea transplant have been reported in patients whose eyes have accidentally been exposed to similar medicines during surgical interventions under general anaesthetic (deep pain-free sleep).

Do not swallow Vita-Merfen Ointment.

Do not use Vita-Merfen Ointment too often or for long periods without medical advice.

If you notice skin irritation or unusual sensitivity, **stop using the ointment**.

Interactions with other medicines

If you are taking or have recently taken other medicines, including nonprescription medicines and dietary supplements, tell your doctor or pharmacist. No interactions with other medicines are expected due to the low absorption rate of the active ingredients.

Pregnancy and breastfeeding

Pregnancy:

Usually, small amounts (on small wounds) can be used during pregnancy. There is insufficient information on the use of chlorhexidine gluconate and benzoxonium chloride in pregnant women and the risk to the unborn baby; however, the risk is considered very low because very little chlorhexidine gluconate and benzoxonium chloride is absorbed when applied to the skin. The concentrations of vitamin A appearing in blood after local application are probably lower than the concentrations showing after oral administration. High doses of vitamin A taken orally can increase the risk of birth defects in unborn babies. Consult your doctor or pharmacist if you want to use this product during pregnancy, particularly during the first three months.

Breastfeeding:

It is unknown whether chlorhexidine gluconate and benzoxonium chloride pass into breast milk. Vitamin A passes into breast milk. You can use small amounts of Vita-Merfen Ointment (on small wounds) during breastfeeding, but not on your breasts. As a precaution, wash your nipples carefully with water before breastfeeding.

Important information about some of this medicine's ingredients

This ointment contains chlorhexidine.

Bleach (hypochlorite) and other substances that release chlorine can cause some brown discoloration on fabrics that come into contact with chlorhexidine. Laundry tests have shown that detergents containing one or more whitening agents (such as perborate) can remove these stains.

3. HOW TO USE THIS MEDICINE?

Check with your doctor or pharmacist if you are not sure about your dose or about how to take this medicine.

The recommended dosage is usually: Apply a thin layer of the ointment to the affected skin areas, directly or using a sterile pad, two or three times a day. If not too painful, rub in gently.

For external use only. Use Vita-Merfen Ointment on skin only.

Do not exceed the recommended dose.

If you use more Vita-Merfen Ointment than you should, or if you accidentally swallow some Vita-Merfen Ointment, consult your doctor. If you believe the effect of this medicine is either too weak or too strong, consult your doctor or pharmacist.

Do not take medicines in the dark! Check the label and dose every time you take medicine. Wear glasses if you need them.

If you have any further questions about using this medicine, consult your doctor or pharmacist.

4. SIDE EFFECTS

As with any medicine, using Vita-Merfen Ointment may cause side effects in some users. Do not be alarmed by this list of side effects; you may not experience any of them.

Although some side effects are very rare they can still be serious, for example, serious allergic reactions with difficulty breathing, dizziness (anaphylactic reaction), or swelling of the face and throat (angioedema). If you notice any of these symptoms, **stop using Vita-Merfen Ointment and seek medical advice immediately.**

Additional side effects

Rare side effects (may affect 1 to 10 in 10,000 users):
skin irritation.

Very rare side effects (may affect less than 1 in 10,000 users):
hives (urticaria), serious allergic reactions.

Side effects with unknown frequency (effects whose frequency has not been determined yet):

Contact dermatitis with possible disruption of wound healing if treatment is continued, corneal damage (damage to the surface of the eye) and permanent damage to the eye,

including permanent visual disturbance after accidental contact with the eyes during surgical interventions (see section 2 " Before using the medicine ").

If you experience any side effect, if any side effect gets worse, or if you experience a side effect not mentioned in this leaflet, consult your doctor.

You can report side effects to the Ministry of Health by following the 'Reporting Side Effects of Drug Treatment' link on the Ministry of Health home page (www.health.gov.il) which opens an online form for reporting side effects, or you can also use this link:
<https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

Prevent poisoning! To prevent poisoning, keep this and all other medicines in a closed place, out of the reach and sight of children and/or infants. Do not induce vomiting unless explicitly instructed to do so by a doctor.

Do not use the medicine after the expiry date (exp. date) which is stated on the package/label. The expiry date refers to the last day of that month.

Storage conditions:

- Do not store above 25°C.

6. ADDITIONAL INFORMATION

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

White soft paraffin, glyceryl isostearate, polyglyceryl-3-oleate, white beeswax, glycerol, castor oil hydrogenated, trometamol, acetic acid glacial, disodium edetate, purified water.

What the medicine looks like and contents of the pack:

Soft, glossy, homogenous looking ointment in a 20 gram, or 40 gram, or 100 gram tube.

Not all pack sizes may be marketed.

Registration holder's name and address:

Meditrend Marketing (2004) Ltd., Kibutz Gilil Yam, 4690500.

Manufacturer's name and address:

Verfora SA, 1752 Villars-sur-Glâne, Switzerland.

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Registration number of the medicine in the Ministry of Health's National Drug Registry:

118-17-27599-00