

SUMMARY OF PRODUCT CHARACTERISTICS

1. Name of the medicinal product

Vita-Merfen Ointment

2. Qualitative and quantitative composition

Active Substances

Chlorhexidine (as gluconate) 0.5% w/w

Benzoxonium chloride 0.1% w/w

Vitamin A palmitate 0.2% w/w (2000 IU/g)

Excipients

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

3. Pharmaceutical form and active substance quantity per unit

1 g of ointment contains 5 mg of chlorhexidine (as gluconate), 1 mg of benzoxonium chloride, 2000 IU vitamin A palmitate (0.2% w/w).

Soft, shiny, visually homogeneous ointment.

4. Therapeutic indications

Vita-Merfen Ointment is indicated for the treatment of all kinds of small wounds (such as scratches, abrasions, cuts), cracks, chapped skin, minor burns (1st degree).

5. Dosage/Administration

Adults and children

Apply the ointment on the areas of the skin to be treated in a thin layer directly or using a sterile tampon, 2 or 3 times a day. If it is not too painful, rub in with a light massage.

Special dosage instructions

Elderly patients: dosage adjustment based on age is probably not necessary.

Patients with impaired hepatic or renal function: Vita-Merfen Ointment has not been specifically studied in patients with hepatic or renal impairment. However, given the low systematic bioavailability of the active ingredients, no dosage adjustment is probably necessary.

6. Contraindications

Hypersensitivity to chlorhexidine gluconate, benzoxonium chloride or another quaternary ammonium, vitamin A or one of its derivatives or one of the excipients (see "Qualitative and quantitative composition").

7. Warnings and precautions

Vita-Merfen Ointment is intended for external use only. Do not swallow.

Avoid putting Vita-Merfen Ointment in contact with the eyes, ears (ear canal) and mucous membranes (mouth and nose). In case of contact with eyes, rinse immediately with plenty of water.

If symptoms persist or worsen (for example, a swollen or painful sore, accompanied by fever), please consult your doctor.

Interactions

No interaction studies have been performed. Due to the low absorption rate of the active substances chlorhexidine gluconate and benzoxonium chloride, no interaction with other medicines is expected.

Pregnancy, lactation

Pregnancy

The ointment can be used in small quantities (on small wounds) during pregnancy. There are no adequate data concerning the use of chlorhexidine gluconate and benzoxonium chloride in pregnant women. The potential risk to humans is unknown; however, it is assumed to be very weak since chlorhexidine gluconate and benzoxonium chloride are only weakly absorbed after topical application. The plasma concentrations of vitamin A appearing after local application are probably lower than the concentrations appearing after oral administration. High doses of vitamin A taken orally have a potential teratogenic effect.

Lactation

It is unknown if chlorhexidine gluconate and benzoxonium chloride are excreted in breast milk. Vitamin A passes into breast milk. Vita-Merfen Ointment can be used in small amounts (on small wounds) during breastfeeding, but not on the breasts. As a general precaution, nipples should be carefully washed with water before breastfeeding.

Effects on ability to drive and use machines

No corresponding studies have been performed.

8.Undesirable effects

Adverse reactions are listed by system organ class and frequency. The frequencies are defined below "very common" ($\geq 1/10$), "common" ($\geq 1/100$, $< 1/10$), "uncommon" ($\geq 1/1000$, $< 1/100$), "rare" ($\geq 1/10,000$, $< 1/1000$), "very rare" ($< 1/10,000$):

Effects on immune system

Very rare: urticaria (hives), anaphylactic reaction, angioedema

Skin and subcutaneous tissue disorders

Rare: skin irritations.

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>

9.Overdose

No data is available.

10.Properties/Effects

ATC Code

D08AC52

Mechanism of action

Vita-Merfen Ointment contains two disinfectant substances, chlorhexidine gluconate and benzoxonium chloride, which act quickly on the microorganisms responsible for inflammation, as well as vitamin A. The combination of disinfectant substances and vitamin A for treatment of small wounds promotes wound healing and simultaneously prevents secondary infection.

Pharmacodynamics

See "Mechanism of action".

Clinical efficacy

No data exists specific to the preparation as part of recent clinical studies.

11. Pharmacokinetics

Absorption

There are no data specific to the preparation on absorption. After topical application, chlorhexidine gluconate and benzoxonium chloride are only slightly absorbed.

Distribution

Given the low systemic bioavailability of the active ingredients, their distribution after application of Vita-Merfen Ointment has not been studied.

Metabolism

Chlorhexidine is not metabolized.

Elimination

Chlorhexidine is mainly excreted in the stools.

12. Preclinical data

No known safety data exists specific to the use of the preparation.

13. Other information

Linen that has come into contact with Vita-Merfen Ointment should not be treated with hypochlorite (bleach) or other substances releasing chlorine, but with peroxide or perborate, otherwise brown spots may appear.

Shelf-life

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

Special precautions for storage

Do not store above 25°C and keep out of reach of children.

14. Authorisation number

118-17-27599-00

15. Packs

Vita-Merfen Ointment 20 g

Vita-Merfen Ointment 40 g

Vita-Merfen Ointment 100 g

Not all the pack sizes may be marketed.

16. Marketing authorisation holder

Meditrend Marketing (2004) Ltd., Glil-Yam, 4690500

17. Manufacturer

Verfora SA, 1752 Villars-sur-Glâne, Switzerland

Approved in November 2023 according to MOH guidelines.