Approved
Order of Ministry of
Healthcare of Ukraine
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INSTRUCTION
for medical use
PHORCAL®

Composition:
active substance: calcitriol;
1 g of ointment contains 3 μg of calcitriol;
excipients: white soft paraffin, light mineral oil, alpha-tocopherol.

Pharmaceutical form. Ointment.
Basic physical and chemical properties: white or almost white uniform ointment.

Pharmacotherapeutic group.
Antipsoriatic drugs for local use. ATC code D05A X03.

Pharmacological properties.
Pharmacodynamics.
Mechanism of action.
Calcitriol inhibits proliferation and stimulates keratinocyte differentiation.
Also calcitriol reduces adhesion and accelerates the exfoliation of horny cells. Calcitriol inhibits the proliferation of T-lymphocytes and normalizes the production of various factors of the inflammatory process.
Pharmacokinetics.
Absorption.
When applying locally, the absorption of calcitriol is approximately 10%.
After absorption, both calcitriol in unchanged form and its metabolites are detected in the blood plasma. The effect of metabolites on calcium homeostasis is insignificant. In most patients, circulating levels of exogenous calcitriol are below detection levels (2 μg/ml).
Distribution.
In clinical trials, there was no significant increase in plasma levels of calcitriol after treatment of a significant body surface area of up to 6000 cm^2 (35% of the skin surface).

Indications.
Plaque psoriasis of mild and moderate severity (local treatment of skin manifestations) with lesion up to 35% of the skin surface.

Contraindications.
- Hypersensitivity to the active substance or to any of the medicinal product components.
- Hypercalcaemia and other pathological conditions characterized by calcium dysmetabolism.
- Systemic therapy of calcium homeostasis.
- Liver and kidney dysfunction.

Drug interactions and other kinds of interactions.

Phorcal® ointment should be used with caution in patients receiving medicinal products that increase blood calcium levels, such as thiazide diuretics or medicinal products whose pharmacological effects depend on changes in calcium levels, such as digoxin. Caution should also be exercised in patients receiving calcium supplements or high doses of vitamin D.
There is no experience of simultaneous use of calcitriol and other medicinal products for the treatment of psoriasis.
Information on the interaction of systemic medicinal products after the use of an ointment with calcitriol is limited.
Phorcal® ointment has a weak irritant effect, therefore its simultaneous use with peeling agents or preparations that have an irritating or astringent effect may cause increased irritating effects.

Special warnings and precautions for use.
Ointment is recommended for use on the face with caution, since there is a risk of irritation in this area. Avoid getting ointment into the eyes. After applying the ointment on the affected area, wash your hands to avoid accidental use in uninfected areas. Daily application of the ointment should not exceed 35% of the skin surface. Do not apply more than 30 g of ointment per day.
Because of the potential effect on calcium metabolism, do not add the substances that enhance the ointment penetration, or apply bandage on the skin coated with the drug.
If severe irritation or allergic manifestations occur at the site of application of the ointment, treatment with the drug should be discontinued and, if necessary, a doctor should be consulted. If contact dermatitis is detected, treatment should be discontinued permanently.
Although clinically significant hypercalcemia was not observed during clinical studies using calcitriol ointment at a dose of less than 30 g/day, some absorption of calcitriol through the skin still occurs, and excessive use of the ointment may lead to systemic side effects, such as increased urinary and serum calcium levels, which is a known effect of calcitriol.
There is no information on the use of calcitriol with other clinical implications of psoriasis (another than plaque psoriasis), including *Psoriasis guttata acuta*, pustular psoriasis, *Psoriasis erythrodermica*, progressive plaque psoriasis.
Patients using Phorcal® ointment should not smoke or be near an open flame, as there is a risk of clothing catching fire and causing severe burns. Fabric (clothing, bedding, dressings, etc.) that has come into contact with the ointment is highly flammable and poses a serious fire hazard. Washing clothing or bedding may reduce the accumulation of the ointment, but will not remove it completely.
There is limited clinical data on the use of calcitriol ointment in children. Given preclinical data on the greater sensitivity to the toxic effects of calcitriol in newborn rodents compared to adult animals, the use of calcitriol ointment in children should be avoided.

Pregnancy and lactation.
Pregnancy.
It is not recommended to administer the drug during pregnancy due to the lack of sufficient data regarding the drug application in pregnant women.
Lactation.
Calcitriol was found in the milk of nursing females. It is not known whether calcitriol penetrates into breast milk, so if it is necessary to use the Phorcal® ointment during lactation, one should decide on termination of breast-feeding.

Effects on ability to drive and operate machinery.
Phorcal® ointment has no or negligible effect on the ability to drive or use machines.

Administration and dosage.
For external use only. Apply thin layer of the ointment to the skin areas affected by psoriasis 2 times a day (in the morning and in the evening before bedtime after washing). Daily application of the ointment should not exceed 35% of the skin surface. Do not apply more than 30 g of ointment per day. The clinical experience of using ointment for more than 6 weeks is limited.
Paediatric population
The safety and efficacy of calcitriol ointment in children under 18 years of age have not been established. Currently available data are described in the "Children" section, but no dosage recommendations can be made.
Special patient groups
Patients with renal or hepatic impairment should not use Phorcal® ointment (see "Contraindications").

Children.
The safety and effectiveness of calcitriol in children under 18 years of age have not been established.

Overdose.
The most common symptoms that may occur after accidental ingestion of calcitriol ointment are anorexia, nausea, vomiting, constipation, hypotension, and depression. Lethargy and coma may occasionally occur. If hypercalcemia or hypercalciuria occurs, the use of Phorcal® ointment should be discontinued until serum or urine calcium levels return to normal.
Overuse of the ointment will not result in faster or better results and may result in noticeable redness, peeling, or discomfort.

Side effects.
Adverse reactions usually occur in 10-20% of patients at the site of application of the ointment to the skin and are mild to moderate in intensity. The following adverse reactions are listed by system organ class and frequency: very common (≥ 1/10), common (≥ 1/100, < 1/10), uncommon (≥ 1/1000, < 1/100), rare (≥ 1/10000, < 1/1000), very rare (< 1/10000, including isolated cases), unknown (frequency cannot be estimated from the available data).
Skin and subcutaneous tissue disorders:
often – itching, discomfort, skin irritation, erythema (redness);
infrequently – dry skin, psoriasis (exacerbation);
unknown* – skin swelling, contact dermatitis.
*Adverse reactions registered during post-marketing surveillance.
In case of severe irritation or contact allergy, the use of Phorcal® ointment should be discontinued and medical attention should be sought. If contact allergy is detected, the use of the medicinal product should be discontinued permanently.
Reporting of suspected adverse reactions.
Reporting of adverse reactions after registration of a medicinal product is important. This allows monitoring of the benefit/risk ratio when using this medicinal product. Medical and pharmaceutical professionals, as well as patients or their legal representatives, should report all cases of suspected adverse reactions and lack of efficacy of a medicinal product via the Automated Information System for Pharmacovigilance at the link: https://aisf.dec.gov.ua.

Shelf-life. 3 years.

Storage conditions.
Store below 25°C in original package and in a dark place.
Keep it out of reach of children.

Package.
30 g, 100 g in tubes, 1 tube in a carton package.

Conditions of supply.
By prescription.
Manufacturer.
KUSUM HEALTHCARE PVT. LTD.

Manufacturer's location and address of the place of business.
SP 289 (A), RIICO Indl. Area, Chopanki, Bhiwadi (Raj.), India.

Last revision date.
27.03.2025