

Summary of Products Characteristics

1. Name of the Medicinal product

Phorcal Ointment

2. Qualitative and Quantitative composition

Composition:

Active substance: Calcitriol; One gram of ointment contains:

Calcitriol BP3 mcg

For full list of excipients, see section 6.1

3. Pharmaceutical Form

Ointment

Prescription Only Medicine

Description: White or almost white uniform ointment.

4. Clinical Particulars

4.1 Therapeutic Indications

Topical treatment of mild to moderately severe plaque psoriasis (psoriasis vulgaris) with up to 35% of body surface area involvement.

4.2 Posology and method of administration

Administration and dosage

Phorcal Ointment should be applied to the psoriasis affected areas twice per day, once in the morning and once in the evening before retiring and after washing. It is recommended that not more than 35% of the body surface be exposed to daily treatment. Not more than 30 g of ointment should be used per day. There is limited clinical experience available for the use of this dosage regimen of more than 6 weeks.

Paediatric population

In view of the particular sensitivity of neonates versus adult rodents to the toxic effects of calcitriol, exposure of children to calcitriol ointment should be avoided.

4.3 Contraindications

Patients on systemic treatment of calcium homeostasis.

Patients with kidney or liver dysfunction.

Patients with hypercalcaemia and patients known to suffer from abnormal calcium metabolism.

Patients with known hypersensitivity to the active substance or to any of the excipients.

4.4 Special warnings and precautions for use

The ointment can be applied to the face with caution, as there is an increased risk of irritation in this area. Contact with the eyes should be avoided. The hands should be washed after applying the ointment in order to avoid unintentional application to non lesional areas. Not more than 35% of the body surface should be exposed to daily treatment. Not more than 30g of ointment should be used per day.

Due to potential effects on calcium metabolism, substances which stimulate absorption must not be added to the ointment, and the ointment must not be covered with an occlusive dressing.

In case of severe irritation or contact allergy, the treatment with Phorcal should be discontinued and the patient should obtain medical advice. If contact allergy is demonstrated this discontinuation is definitive.

Although no clinically significant hypercalcaemia was observed in clinical studies with a dosage under 30 g/day of Phorcal ointment, some absorption of calcitriol through the skin does occur and excessive use of the ointment can lead to systemic side-effects, such as an increase in urine and serum calcium levels, which is a known class effect for calcitriol.

There is no information about the use of Phorcal in other clinical forms of psoriasis (other than plaque psoriasis) *i.e.* Psoriasis guttata acuta, pustular psoriasis, psoriasis erythrodermica and rapidprogressive plaque psoriasis.

4.5 Interaction with other medicinal products and other forms of interaction

Phorcal must be used with caution in patients receiving medications known to increase the serum calcium level, such as thiazide diuretics. Caution must also be exercised in patients receiving calcium supplements or high doses of vitamin D. There is no experience of the concurrent use of calcitriol and other medications for the treatment of psoriasis.

Information on interaction of systemic medications after the use of calcitriol ointment is limited. Phorcal Ointment has a slight irritant potential, and therefore, it is possible that concomitant use of peeling agents, astringents or irritants products may produce additive irritant effects.

4.6 Fertility, Pregnancy and lactation:

Pregnancy:

There are no adequate data from the use of calcitriol ointment in pregnant women. Studies in animals have shown developmental toxicity at doses which caused maternal toxicity. The potential risk for humans is unknown.

Calcitriol ointment should only be used during pregnancy in restricted amounts when clearly necessary. Calcium levels should be monitored.

Lactation:

Calcitriol has been found in milk of lactating dams. Due to the lack of human data, it should not be used during breastfeeding.

4.7 Effects on ability to drive and use machines

Phorcal has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects Side effects

Between 10% and 20% of patients can be expected to experience adverse reactions. Adverse reactions are usually localised to the application site and mild to moderate in nature.

<p>Very common adverse reactions: Adverse reactions occurring in $\geq 1/10$ of patients. Common adverse reactions: Adverse reactions occurring in $\geq 1/100$, $< 1/10$ of patients. Uncommon adverse reactions: Adverse reactions occurring in $\geq 1/1000$, $< 1/100$ of patients. Rare adverse reactions: Adverse reactions occurring in $\geq 1/10000$; $< 1/1000$ of patients. Very rare adverse reactions: Adverse reactions occurring in $< 1/10000$ of patients Not known: cannot be estimated from the available data. Adverse reactions reported by more than two patients in the clinical studies are included.</p>		
MedDRA System Organ Class	Frequency	Preferred term
Skin and Subcutaneous disorders	Common	Pruritus, Skin discomfort, Skin irritation, Erythema
	Uncommon	Dry skin, Psoriasis (aggravated)
	Not known*	Skin oedema, Contact dermatitis

*Adverse reactions reported from post marketing surveillance.

In case of severe irritation or contact allergy, the treatment with Phorcal should be discontinued and the patient should obtain medical advice. If contact allergy is demonstrated this discontinuation is definitive.

4.9 Overdose:

The most common symptoms which may occur after accidental administration are anorexia, nausea, vomiting, constipation, hypotonia and depression. Lethargy and coma are occasionally observed. If hypercalcaemia or hypercalciuria occurs, the use of Phorcal should be discontinued until the serum or urinary calcium levels have returned to normal.

If the medication is applied excessively no more rapid or better results will be obtained and marked redness, peeling or discomfort may occur.

5. Pharmacological properties

Pharmacotherapeutic group:

Antipsoriatic drugs for local use.

ATC code: D05AX03.

5.1 Pharmacodynamics:

Calcitriol inhibits the proliferation and stimulates differentiation of keratinocytes. Calcitriol inhibits proliferation of T-cells and normalises the production of various inflammation factors.

Topical administration of Calcitriol Ointment to patients with plaque psoriasis results in an improvement of the skin lesions. This effect is noted from 4 weeks after the start of treatment.

5.2 Pharmacokinetics:

Absorption

The mean absorption of calcitriol is estimated at around 10%. Following absorption, both unchanged calcitriol and metabolites have been demonstrated in plasma. The effect of the metabolites on calcium homeostasis is negligible. In most patients, circulating levels of exogenous calcitriol are below the level of detection (2pg/ml).

Distribution

In clinical trials, no relevant increase in plasma calcitriol levels after treatment of large body surface areas of up to 6000 cm²(35% body surface area) was noted.

3. Preclinical safety data

No data

6. Pharmaceutical Particulars

6.1 List of excipients:

White soft paraffin, light liquid paraffin and tocopherol

6.2 Incompatibilities

No data

6.3 Shelf-life:

24 months

6.4 Special precautions for storage

Store below 30°C. Do not Freeze. Keep out of reach of children.

6.5 Nature and contents of container

30 g ointment in aluminium collapsible tube or Laminated tube with screw cap. Such 1 tube is packed along with the insert for medical use in a carton.

7. Manufacturer

Kusum Healthcare Pvt Limited,
SP-289(A), RIICO Industrial Area, Chopanki, Bhiwadi, Dist. Alwar, Rajasthan,
India.

8. Marketing Authorization Number

TAN 22 HM 0094

9. Date of First <Registration> / Renewal of The <Registration>

11/04/2022

10. Date of Revision of the Text