SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Phorcal 3 mcg/g Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of ointment contains:
Calcitriol BP……3 mcg
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

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

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.

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 rapid progressive plaque psoriasis.

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.

4.5 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 nor or negligible influence on the ability to drive and use machines.

4.8 Undesirable 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.

Very common adverse reactions: Adverse reactions occurring in ≥1/10 of patients. Common adverse reactions: Adverse reactions occurring in ≥1/100, <1/10 of patients. Uncommon adverse reactions: Adverse reactions occurring in ≥1/1000, <1/100 of patients.

Rare adverse reactions: Adverse reactions occurring in ≥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.		
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.

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. Healthcare professionals are asked to report any suspected adverse reactions via EFDA yellow Card Scheme, online at https://primaryreporting.who-umc.org/ET or toll-free call 8482 to Ethiopian food and drug authority (EFDA).

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 Pharmacokinetic

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 cm^2(35% body surface area) was noted.

5.3 Preclinical safety data

Animal studies show that repeated excessive exposure to calcitriol leads to renal failure and tissue calcification due to hypervitaminosis D associated with hypercalciuria, hypercalcaemia, and hyperphosphataemia.

No indication of teratogenicity was observed in embryofoetal toxicity studies designed to assess the teratogenic potential of calcitriol. Some evidence of developmental toxicity was obtained in a cutaneous rabbit study at doses which caused maternal toxicity. No such effect was found in rats.

Local toxicity studies in animals with Calcitriol showed slight skin and eye irritation.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

White soft paraffin, light liquid paraffin, alpha tocopherol

6.2 Incompatibilities

Not applicable

6.3 Shelf life

2 years

6.4 Special precautions for storage

Store below 30°C. Do not freeze.

Keep all the medicines 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.

6.6 Special precautions for disposal and other handling

Not applicable

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

07834/08414/NMR/2020

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30 September 2022

10. DATE OF REVISION OF THE TEXT

08/2023

11. REFERENCES

SmPC published on electronic medicines compendium
https://www.medicines.org.uk/emc#gref

The MHRA published product information
https://products.mhra.gov.uk/

Human medicine European public assessment report
https://www.ema.europa.eu/en/medicines