

PRESCRIBING INFORMATION

(Please consult the Summary of Product Characteristics (SmPC) before prescribing.)

Curatoderm 4 micrograms/gram Ointment & Lotion Tacalcitol monohydrate

Active Ingredient:

Ointment & Lotion: Each gram contains 4.17 micrograms per gram of tacalcitol monohydrate (tacalcitol 4 micrograms/g)

For a full list of excipients, see SmPC section 6.1.

Indication:

Ointment: For the treatment of psoriasis vulgaris.

Lotion: For the treatment psoriasis vulgaris, especially on the scalp.

Dosage and Administration: *Adults and the Elderly:* Apply sparingly once daily to the affected areas, preferably at bedtime. The amount applied should not exceed 10 g of ointment/day or 10 ml of lotion/day. Duration of treatment depends on the severity of the lesions and should be decided by the physician. Curatoderm can be used on all areas of the body (including face, hairline, scalp, axilla and other flexures). *For more information see SmPC section 4.2.*
Children: Not recommended. There is limited clinical experience with tacalcitol in children.

Contraindications, Special warnings etc:

Contraindications: Ointment and Lotion - Hypersensitivity to any of the constituents. Hypercalcaemia. Other known disorders of calcium metabolism. *See SmPC section 6.1*

Special warnings, etc: At the doctor's discretion, in patients at risk of hypercalcaemia, or patients taking high Vitamin D preparations (in excess of 500 IU vitamin D) albumin corrected serum calcium levels should be closely monitored. Treatment should be stopped if hypercalcaemia occurs. Serum calcium levels should also be monitored in patients with renal impairment. Care should be exercised in patients with generalised pustular or erythrodermic psoriasis as the risk of hypercalcaemia may be enhanced. Contact with the eyes should be avoided. Patients should be advised to wash their hands after applying Curatoderm to avoid inadvertent transfer to other parts of the body.

Interactions: Unlikely in patients using multivitamin preparations with up to 500 IU vitamin D. UVB radiation can be combined.

Experience and information on concomitant use with other topical treatments is limited. *For more information see SmPC section 4.5.*
Pregnancy and lactation: Safety of this medicine in human pregnancy is not established. Exercise caution when prescribing to pregnant women. It is not known if tacalcitol is excreted in breast milk.

Ability to drive and use machines: Not applicable.

Undesirable Effects:

These are ranked under heading of frequency using the following convention: very common ($\geq 1/10$); common ($\geq 1/100 < 1/10$); uncommon ($\geq 1/1,000 < 1/100$); rare ($\geq 1/10,000 < 1/1,000$); very rare ($< 1/10,000$).

Rare: Skin irritation (e.g. burning, erythema), itching, contact dermatitis, worsening of psoriasis. Skin irritation and itching are generally mild and transient.

Frequency unknown: Hypercalcaemia.

Legal Category: POM

Product Authorisation Number(s): PL 33016/0012 (ointment) & PL 33016/0011 (lotion).

NHS cost (excluding VAT):

Lotion: £12.73 – 30 ml HDPE bottle with screw cap

Ointment: £13.40 – 30 g tube

£30.86 – 100 g tube

Marketing Authorisation Holder:

Almirall Hermal GmbH, Scholtzstrasse 3, D-21465, Reinbek, Germany.

Further information is available from:

Almirall Limited, Harman House, 1 George Street, Uxbridge, Middlesex, UB8 1QQ, UK.

Tel: 0800 0087 399.

Email: almirall@professionalinformation.co.uk

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Curatoderm is a trademark.

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard. Adverse events should also be reported to Almirall Ltd.