

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Curatoderm 4 micrograms/g Lotion

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of lotion contains 4 micrograms of tacalcitol (as monohydrate).

Excipients with known effect

1 g of lotion contains 100 mg of propylene glycol and 0.2 mg of dodecyl gallate.

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cutaneous emulsion.

White, thin emulsion.

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Curatoderm Lotion is indicated for the treatment of psoriasis vulgaris in adults, especially on the scalp.

4.2 Posology and method of administration

Posology

Adults and the Elderly:

Apply once daily to the affected areas, preferably at bedtime. The amount applied should not exceed 10 ml of lotion/day. When used together with Curatoderm Ointment, the total dose of tacalcitol should not exceed 280 µg/week (e.g. 30 ml of Curatoderm Lotion plus 40 g of Curatoderm Ointment). Normally duration of treatment depends on the severity of the lesions and should be decided by the physician.

There is clinical trial experience with continuous and intermittent treatment in adults with tacalcitol ointment up to 18 months, and with tacalcitol lotion for up to 8 weeks.

Curatoderm Lotion can be used on all areas of the body (including face, hairline, scalp, axilla and other flexures).

Paediatric population:

Not recommended. There is limited clinical experience with tacalcitol in children.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1
- Psoriasis punctata or psoriasis pustulosa
- Patients with severe hepatic, renal or heart diseases because there is no experience
- Patients with hypercalcaemia or other known disorders of calcium metabolism.

4.4 Special warnings and precautions for use

Children and adolescents (< 18 years): The use of Curatoderm Lotion in children and adolescents under 18 years is not recommended as there is no experience.

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.

Contact with the eyes should be avoided. If Curatoderm Lotion accidentally comes into contact with the eyes, thorough rinsing with water is recommended. Patients should be advised to wash their hands after applying the lotion to avoid inadvertent transfer to other parts of the body.

This medicine contains 100 mg propylene glycol and 0.2 mg dodecyl gallate in each gram. Propylene glycol may cause irritation of the skin. Dodecyl gallate may be mildly irritant to the skin, the eyes and mucous membrane.

Instruct patients not to smoke or go near naked flames - risk of severe burns. Fabric (clothing, bedding, dressings etc) that has been in contact with this product burns more easily and is a serious fire hazard. Washing clothing and bedding may reduce product build-up but not totally remove it.

4.5 Interaction with other medicinal products and other forms of interaction

No interactions are likely in patients using multivitamin preparations with up to 500 IU vitamin D.

There is no experience with the concomitant use of other antipsoriatics.

UVB radiation can be combined with Curatoderm Lotion. This approach increases the efficacy of tacalcitol treatment and shortens the radiation period. UV radiation should be given in the morning and Curatoderm Lotion at bedtime. There has been limited experience of the concomitant use of tacalcitol with topical corticosteroids, urea, emollients, dithranol cream and PUVA.

4.6 Fertility, pregnancy and lactation

Pregnancy

For Curatoderm Lotion no clinical data on exposed pregnancies are available. Animal studies do not indicate direct or indirect harmful effects with respect to pregnancy, embryonal/foetal development, parturition or postnatal development. The potential risk to humans is unknown. Therefore, treatment with Curatoderm Lotion should be avoided during pregnancy.

Breastfeeding

Tacalcitol and its main metabolite pass into the milk of rats. It is not known whether tacalcitol is excreted in human milk, therefore treatment during lactation is not indicated.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The data given for frequency of adverse reactions is based on the following categories:

very common ($\geq 1/10$),

common ($\geq 1/100$ to $< 1/10$),

uncommon ($\geq 1/1,000$ to $< 1/100$),

rare ($\geq 1/10,000$ to $< 1/1,000$),

very rare ($< 1/10,000$),

not known (cannot be estimated from the available data).

Metabolism and nutrition disorders

Frequency unknown: Hypercalcaemia

Immune system disorders

Frequency unknown: Hypersensitivity reactions (including swelling, oedema and face oedema)

Skin and subcutaneous tissue disorders:

Rare: Skin irritation (e.g. burning, erythema), itching, contact dermatitis, worsening of psoriasis.

Skin irritation and itching are generally mild and transient

Frequency unknown: rash (erythematous, macular, papular, vesicular).

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 the Yellow Card Scheme, Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow card in the Google Play or Apple App Store.

4.9 Overdose

Overdosing by ingestion of a lotion is very unlikely. It cannot be excluded that topical application of excessive amounts may lead to hypercalcaemia. In this case Curatoderm treatment and other possible vitamin D or calcium supplement intakes must be stopped until serum calcium returns to normal.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Other antipsoriatics for topical use

ATC Code: D05A X04

Pharmacotherapeutic group: Other antipsoriatics for topical use, ATC Code: D05A X04.

Tacalcitol is a vitamin D₃ derivative, which inhibits keratinocyte hyper-proliferation and induces differentiation of these cells. The normalisation of these mechanisms is the basis for the efficacy in the treatment of psoriasis. In biopsies from patients treated with tacalcitol specific indicators for inflammation were improved. Tacalcitol binds to the keratinocyte vitamin D receptor to the same extent as natural active vitamin D₃.

5.2 Pharmacokinetic properties

Single or repeated application of tacalcitol ointment in humans results in less than 0.5% of the drug being systemically absorbed through psoriatic skin. Tacalcitol is completely bound to plasma proteins (vitamin D binding protein) The main metabolite is 1 α , 24, 25 (OH)₃ vitamin D₃, a metabolite shared with the natural active vitamin, with 5-10 times less vitamin D activity. Tacalcitol and metabolites are excreted mainly in the faeces in rat and dog studies with excretion in urine in man. It cannot therefore

be excluded that if there is sufficient systemic absorption accumulation may occur in patients with renal failure.

5.3 Preclinical safety data

The toxic effects of tacalcitol are typical of those expected from excessive pharmacological activity of calciferols and resultant hypercalcaemia. The NOEL in rats treated subcutaneously for 12 months was 4 ng/kg/day.

Reproductive toxicity studies in rats and rabbits revealed no teratogenic effects. Tacalcitol was negative in a battery of in vitro mutagenicity studies.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Purified water, light liquid paraffin, medium-chain triglycerides, propylene glycol, octyldodecanol, macrogol (21) stearylether, diisopropyl adipate, phenoxyethanol, disodium phosphate dodecahydrate, xanthan gum, potassium dihydrogen phosphate, disodium edetate, dodecyl gallate

6.2 Incompatibilities

Tacalcitol must not be mixed with salicylic acid

6.3 Shelf life

2 years
6 months after first opening the container.

6.4 Special precautions for storage

Store below 25° C.
Keep bottle in the outer carton.

6.5 Nature and contents of container

20 ml, 30 ml or 50 ml HDPE plastic bottle (with translucent sight stripes at one or both of the smaller sides) and with HDPE screw cap.

6.6 Special precautions for disposal

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Almirall Hermal GmbH
Scholtzstrasse 3
21465 Reinbek
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8 MARKETING AUTHORISATION NUMBER(S)

PL 33016/0011

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

23/12/2024

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