1. **NAME OF THE MEDICINAL PRODUCT**

Curatoderm 4μg/g Ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One gram of ointment contains 4μg/g of tacalcitol (4.17μg/g of tacalcitol monohydrate).

Excipients with known effect
Butylhydroxytoluene (E 321) contained in the excipient Paraffin, white soft

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Ointment

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Curatoderm ointment is indicated for the treatment of psoriasis vulgaris in adults.

4.2 Posology and method of administration

Posology

Adults and the Elderly:
Apply sparingly, once daily to the affected areas, preferably at bedtime. The amount applied should not exceed l0g of ointment/day. 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 up to twelve months.

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

When used on the scalp the ointment can be shampooed out the next morning.

Paediatric population:
The safety and efficacy of Curatoderm Ointment in children and adolescents under 18 years have not been established.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Patients with hypercalcaemia or other known disorders of calcium metabolism.

4.4 Special warnings and precautions for use

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 erthrodermic psoriasis as the risk of hypercalcaemia may be enhanced.

When applying to the face avoid contact with the eyes. Patients should be advised to wash their hands after applying the ointment to avoid inadvertent transfer to other parts of the body.

Butylhydroxytoluene (E 321) contained in the excipient Paraffin, white soft, may cause local skin reactions (e.g. contact dermatitis), or irritation to the eyes and mucous membranes.

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

4.6 Fertility, pregnancy and lactation

Pregnancy
The safety of this medicinal product for use in human pregnancy has not been established. Evaluation of experimental animal studies does not indicate direct or indirect harmful effects with respect to the development of the embryo or foetus, the course of gestation or peri- or postnatal development. Avoid use in pregnancy unless there are no safer alternatives.

Lactation
During lactation the breast area should not be treated. It is not known whether tacalcitol is excreted in human breast milk.

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 (≥ 1/10)
Common (≥ 1/100 to < 1/10)
Uncommon (≥ 1/1,000 to < 1/100)
Rare (≥ 1/10,000 to 1/1,000)

Very rare (< 1/10,000)

Not known (frequency 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 an ointment 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 X02.

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 1α, 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

Tacalcitol is effective in very low concentrations. The no-effect-level following cutaneous application over 12 months in rat studies amounted to only 4 ng/kg daily. Toxicity is focused to the classic vitamin effects of calciferols. Teratogenicity studies in mice and rats showed no teratogenic effects of tacalcitol. The results of mutagenicity studies (Ames test, chromosomal aberration test and micronucleus test), indicate no genotoxic potential.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Paraffin, white soft, liquid paraffin, diisopropyl adipate.

6.2 Incompatibilities

None known.

6.3 Shelf life

36 months at up to 30°C.
6 months after first opening the tube.

6.4 Special precautions for storage

None.

6.5 Nature and contents of container

Aluminium tubes with internal lacquer, membrane-sealed opening and plastic screw cap, containing 5g, 20g, 30g or 100g.

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
D-21465,
Reinbek
Germany

8 MARKETING AUTHORISATION NUMBER(S)

PL 33016/0012

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01/08/2010

10 DATE OF REVISION OF THE TEXT

28/07/2020