SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Oviderm 250 mg/g cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 gram cream contains 250 mg propylene glycol.

Excipient with known effect:

50 mg cetostearyl alcohol per gram cream.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.
White, odourless cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Oviderm is used for treatment of dry skin.

4.2 Posology and method of administration

Posology

Adults (including older people), adolescents and children:
The cream can be applied as needed, preferably several times daily and always after contact with water.

Method of administration
Cutaneous use.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Oviderm should not be used on burned skin. Toxic effects (hyperosmolality, metabolic acidosis) has been reported after cutaneous administration of large quantities of preparations containing propylene glycol. It has mainly been seen during treatment of extensive burns. Children seem to be more sensitive than adults.

Avoid application in the ear canals since propylene glycol may be ototoxic.

Oviderm contains cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

No interaction studies have been performed.

4.6 Fertility, pregnancy and lactation

Pregnancy
No known risks during pregnancy.

Breast-feeding
In order not to unnecessarily expose the child to oral ingestion of propylene glycol Oviderm should not be used on or around the nipples during breast-feeding.

Fertility
No know risks.

4.7 Effects on ability to drive and use machines

Not relevant.

4.8 Undesirable effects

The adverse events are presented according to MedDRA system organ classification within each frequency area and after decreasing degree of severity:
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 (cannot be estimated from the available data)

System organ class	**Undesirable effects**
Skin and subcutaneous tissue disorders	
Common	Transient smarting, itching, stinging and redness. Allergic reactions.

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 [To be completed nationally].

4.9 Overdose

Not relevant.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Dermatologicals, Emollients and Protectives, Other emollients and protectives.
ATC code: D02AX.

Mechanism of action and pharmacodynamic effects
Oviderm contains 25% propylene glycol in an emollient cream base with a fat content of 20%.
Propylene glycol has keratolytic and water-binding properties. The water-binding properties result in a moisturizing effect that prevents xerosis. Some antimicrobial effect has been shown against certain bacteria and yeast fungae, in particular *Malassezia furfur*.
The cream base has emollient and protective properties.

5.2 Pharmacokinetic properties

Not relevant.

5.3 Preclinical safety data

There are no preclinical data.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Coconut oil, refined
Cetostearyl alcohol
Stearic acid
Macrogol stearate
Glycerol monostearate
Sodium citrate (for pH adjustment)
Citric acid, anhydrous (for pH adjustment)
Water, purified

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

This medicinal product does not require any special storage conditions.

6.5 Nature and contents of container

Plastic tube (polyethylene), 100 g with a withe flip-top cap made of polypropylene.

Plastic container (polypropylene), 500 g with pump mechanism.

Twin pack 600g containing, plastic container (polypropylene) with pump, 500 g + plastic tube (polyethylene), 100 g, with a white flip-top cap made of polypropylene.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7. MARKETING AUTHORISATION HOLDER

[To be completed nationally].

8. MARKETING AUTHORISATION NUMBER(S)

[To be completed nationally].

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

[To be completed nationally].

10. DATE OF REVISION OF THE TEXT

2024-10-04