

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Glycerol Evolan 200 mg/g cream

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g of cream contains: glycerol 200 mg.

Excipient(s) with known effect

Ethyl parahydroxybenzoate, methyl parahydroxybenzoate, cetostearyl alcohol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Cream.

White cream.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Dry skin.

4.2 Posology and method of administration

The cream can be applied when needed, preferably several times daily and always after contact with water.

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

Risk of systemic effects has not been observed in clinical studies of this medicinal product.

Glycerol Evolan cream contains ethyl and methyl parahydroxybenzoate, which may cause allergic reactions (possibly delayed).

Glycerol Evolan cream 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

Glycerol Evolan can be used during pregnancy and lactation.

4.7 Effects on ability to drive and use machines

Glycerol Evolan has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Common (>1/100)	<i>Skin and subcutaneous tissue disorders:</i> Transient smarting, itching, stinging and redness. However, Glycerol Evolan does not cause any more undesirable skin reactions than its vehicle.
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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 national reporting system listed in [Appendix V](#).*

4.9 Overdose

No known risk.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Protectives and emollients. ATC code D02AX.

Glycerol Evolan cream contains 20 % glycerol in an emollient cream base with a fat content of 24 %. The water-binding ability of glycerol contributes to normalization of dry skin.

Glycerol Evolan cream can be used for treatment of dry skin in children and adults.

5.2 Pharmacokinetic properties

Formal pharmacokinetic studies have not been performed.

5.3 Preclinical safety data

There are no preclinical data considered relevant to the safety assessment beyond what has already been taken into consideration in other parts of the SPC.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Hydrogenated canola oil
Cholesterol
Stearoyl macroglycerides
Cetostearyl alcohol
Dimeticone
Light liquid paraffin
Hard paraffin
White soft paraffin
Ethyl parahydroxybenzoate (E214)
Methyl parahydroxybenzoate (E218)
Citric acid
Sodium citrate
Purified water.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

3 years

6.4 Special precautions for storage

No special storage conditions.

6.5 Nature and contents of container

Aluminium laminated plastic tube (polyethylene), 100 g, with snap cap.
Plastic jar (polypropylene) with pump (polypropylene, polyethylene, glass), 500 g.
Twin pack 600 g containing, plastic jar (polypropylene) with pump, 500 g + aluminium laminated plastic tube (polyethylene), 100 g, with snap cap.

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

2025-12-02

<To be completed nationally>