SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

Recreol 50 mg/g ointment

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

1 g ointment contains 50 mg of dexpanthenol *(Dexpanthenolum)*.
Excipient(s) with known effect: 1 g ointment contains 250 mg wool fat, 18 mg cetyl alcohol and 12 mg stearyl alcohol.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Ointment.
Homogenous yellowish ointment with specific odour.

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

Supportive treatment of superficial skin lesions of different genesis by moisturizing epidermal barrier, supporting epithelialisation with subsequent anti-inflammatory and antipruritic effects.

4.2 Posology and method of administration

Posology
Unless prescribed otherwise, in adults and children dexpanthenol should be applied in a thin layer to the affected skin once to several times a day.

The duration of treatment depends on the nature and course of the disease.
Patients should be instructed to consult a doctor if they do not feel better or if they feel worse after 14 days.
Most studies of topical effects of dexpanthenol have been short-term, typically 3-4 weeks or so.

Paediatric population
Dexpanthenol can be used in pediatric population.

Patients with renal and hepatic impairment
No studies performed in patients with renal and hepatic impairment.

Elderly patients
No studies have been performed in elderly patients (65 years old and over).

Method of administration
For cutaneous use.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1;
- Administration on wounds in patients with haemophilia because of risk of severe bleeding.

4.4 Special warnings and precautions for use

Contact of dexpanthenol with the eyes should be avoided.
Dexpanthenol should be discontinued if signs of hypersensitivity occur during use.

Recreol contains cetyl alcohol, stearyl alcohol and wool fat – may cause local skin reactions (e.g. contact dermatitis).
Due to paraffin tear strength of condoms could be affected in case of treatment in the anogenital region.

Flammability risk
This product contains paraffin. Instruct patients not to smoke or go near naked flames due to the 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

Interaction studies have not been performed with dexpanthenol. There are no known interactions. There is no evidence that topical dexpanthenol interacts with any medicines.

4.6 Fertility, pregnancy and lactation

Pregnancy
The possible effect of dexpanthenol on reproduction was not studied. There are no data related to use of dexpanthenol in pregnant women. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity. However, dexpanthenol can be used during pregnancy only with approval of the doctor.

Breast-feeding
No effects on the breastfed newborn/infant are anticipated since the systemic exposure of the breastfeeding woman to dexpanthenol is negligible. Recreol can be used during breast-feeding, however, the local use on the breast should be avoided in order to prevent oral contact of the baby.

Fertility
No studies on the effect on human fertility have been conducted with dexpanthenol. The effects, if any, on the developing foetus are unknown.

4.7 Effects on ability to drive and use machines

Dexpanthenol has no effects on ability to drive and use machines.

4.8 Undesirable effects

Adverse reactions are ranked according to system organ class, using the following convention: 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).

Immune System Disorders
Very rare: allergic reactions.

Skin and Subcutaneous Tissue Disorders
Very rare: hypersensitivity reactions (e. g. skin inflammation/allergic and irritative skin 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 the national reporting system.

4.9 Overdose

No data concerning overdose in humans are available. Even in case of unconventional use of excessive dexpanthenol amounts it has low systemic toxicity and causes no undesirable effects that would be dangerous to patient's health.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: preparations for treatment of wounds and ulcers, other cicatrizants.
ATC code: D03AX03.

Dexpanthenol is converted in tissues to pantothenic acid, a component of coenzyme A (CoA) that is essential to normal epithelial function, increased fibroblast proliferation and accelerated re-epithelialization in wound healing.
This process of cell division and formation of new skin tissue restores skin elasticity and promotes wound healing.

5.2 Pharmacokinetic properties

Absorption
Studies with tritium-marked panthenol showed that the substance is absorbed by the skin.

Biotransformation
After absorption dexpanthenol is readily converted to pantothenic acid, which is widely distributed into body tissues, mainly as coenzyme A.

Distribution
Pantothenic acid is bound to plasma proteins (essentially β-globulins and albumin). In healthy adults, concentrations of about 500-1000 µg/l and 100 µg/l are detected in whole blood and serum, respectively.

Elimination
Pantothenic acid is not degraded in the body; therefore, it is excreted unchanged. About 60 to 70 % of an oral dose is excreted in the urine and the remaining in the faeces. Adults excrete 2 – 7 mg and children 2 – 3 mg daily in the urine.

5.3 Preclinical safety data

Acute toxicity
Panthenol, pantothenic acid and its salts are described as non-toxic.
The LD50 of dexpanthenol administered orally to the mouse is 15 g/kg. In two other acute toxicity studies of oral dexpanthenol, the dose of 10 g/kg did not cause any death and the dose of 20 g/kg caused the death of all animals.

Subacute toxicity
Daily oral doses of 20 mg of dexpanthenol administered to the rat and 500 mg/day to the dog for 3 months did not cause toxic effects or histopathological changes.
Oral doses of dexpanthenol were administered to 24 rats for 6 months; 2 mg of dexpanthenol were given daily. No histopathological changes were reported.
The daily administration of 50 mg/kg of calcium pantothenate over a period of 6 months to the dog and 1 g of calcium pantothenate for 6 months to the monkey, showed no toxic symptoms or histopathological changes.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearyl alcohol
Cetyl alcohol
White beeswax
Protegin XN (Paraffinum liquidum, petrolatum, ozokerite, glyceryl oleate, lanolin alcohol)
Refined almond oil
White soft paraffin
Liquid paraffin

Wool fat
Purified water.

6.2 Incompatibilities

There is no information regarding possible incompatibilities.

6.3 Shelf life

2 years.

6.4 Special precautions for storage

Do not store above 25 °C.

6.5 Nature and contents of container

30 g or 50 g of ointment in aluminium tube, interior lacquered with epoxy phenolic coating, and with sealing compound in the fold. Tube is closed with an aluminium membrane and fitted with a white HDPE screw cap. Aluminium tube in carton box.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal and other handling

No special requirements for disposal.
Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER(S)

Nr.: 140431

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23.12.2020
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10. DATE OF REVISION OF THE TEXT

10/2021