#### Attention!

Your country's information for the user could be different. Please, see registered information for the user for your country.

# Package leaflet: Information for the user

# RECREOL 50 mg/g ointment

Dexpanthenolum

# Read all of this leaflet carefully before you start using this medicine because it contains important information for you.

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

#### What is in this leaflet

- 1. What RECREOL is and what it is used for
- 2. What you need to know before you use RECREOL
- 3. How to use RECREOL
- 4. Possible side effects
- 5. How to store RECREOL
- 6. Contents of the pack and other information

#### 1. What RECREOL is and what it is used for

RECREOL ointment contains the active substance dexpanthenol, which belongs to the group of preparations for treatment of wounds and ulcers. Dexpanthenol is converted in tissues to pantothenic acid. Pantothenic acid restores skin elasticity and promotes wound healing.

#### RECREOL ointment is used for:

- Supportive treatment of superficial skin lesion (such as small burns and lacerations, skin abrasions and cracking), skin inflammation (resulting from exposure of radiation therapy, phototherapy or ultraviolet radiation).

## 2. What you need to know before you use RECREOL

Do not use RECREOL ointment:

- if you are allergic to dexpanthenol or any of the other ingredients of this medicine (listed in section 6);
- on wounds if you have haemophilia because of risk of severe bleeding.

# Warnings and precautions for use

In case of allergic reaction, RECREOL ointment use should be stopped.

Accidental contact of RECREOL ointment with the eyes should be avoided. You must talk to a doctor if you do not feel better or if you feel worse after 14 days.

#### Other medicines and RECREOL

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines.

There is no evidence that RECREOL ointment interacts with any medicines.

# Pregnancy, breast-feeding and fertility

RECREOL ointment can be used during pregnancy and breast-feeding period. No studies on the effect on human fertility have been conducted with dexpanthenol.

# **Driving and using machines**

RECREOL ointment has no effects on ability to drive and use machines.

## RECREOL ointment contains cetyl alcohol, stearyl alcohol and wool fat

Cetyl alcohol, stearyl alcohol and wool fat may cause local skin reactions (e.g. contact dermatitis).

#### 3. How to use RECREOL

Always use this medicine exactly as described in this leaflet or as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

For external use.

Unless prescribed otherwise the usual dose of preparation is to be applied once or several times a day in a thin layer to the affected skin. The duration of treatment depends on the nature and course of the disease.

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).

#### Use in children

RECREOL ointment can be used in children.

If you feel that the effect of RECREOL ointment is too strong or too weak, talk to your doctor or pharmacist.

#### 4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them

Very rare (may affect up to 1 in 10,000 people): allergic reactions and allergic skin reactions, contact dermatitis, allergic dermatitis, itching, redness, eczema, rash, urticaria, skin irritation, ulcers.

# Reporting of side effects

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via national reporting system.

By reporting side effects you can help provide more information on the safety of this medicine

#### 5. How to store RECREOL

Do not store above 25 °C.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton after the "EXP". The expiry date refers to the last day of that month.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

## 6. Contents of the pack and other information

#### What RECREOL ointment contains

- The active substance is dexpanthenol. 1 g ointment contains 50 mg of dexpanthenol.
- The other ingredients are 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.

# What RECREOL looks like and contents of the pack

Homogenous yellowish ointment with specific odour.

30 g or 50 g of ointment in aluminium tube. Tube is closed with an aluminium membrane and fitted with white screw cap. Aluminium tube in carton box.

Not all pack sizes may be marketed.

# **Marketing Authorisation Holder and Manufacturer**

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