

PACKAGE LEAFLET

Refill jar

PACKAGE LEAFLET: INFORMATION FOR THE USER

Canoderm 5 % cream

Urea

Read all of this leaflet carefully because it contains important information for you.

This medicine is available without prescription. However, you still need to use Canoderm carefully to get the best results from it.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- You must contact a doctor if your symptoms worsen or do not improve.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

In this leaflet:

1. What Canoderm is and what it is used for
2. Before you use Canoderm
3. How to use Canoderm
4. Possible side effects
5. How to store Canoderm
6. Further information

1. WHAT CANODERM IS AND WHAT IT IS USED FOR

Canoderm is a white emollient cream containing 5 % urea. The water-binding ability of urea contributes to normalization of dry skin.

Canoderm is used to moisturise dry skin of different origin and to prevent relapses of atopic eczema.

2. BEFORE YOU USE CANODERM

Do not use Canoderm

if you are allergic (hypersensitive) to urea or any of the other ingredients of Canoderm.

Take special care with Canoderm

Avoid application into eyes, nose, ears or to open wounds or mucous membranes.

Pregnancy and breast-feeding

Canoderm can be used during pregnancy and breast-feeding.

Driving and using machines

Canoderm has no effect on the ability to drive or use machines.

Important information about some of the ingredients of Canoderm

Canoderm contains ethyl and methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

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

Canoderm cream contains propylene glycol, which may cause skin irritation.

3. HOW TO USE CANODERM

For moisturising dry skin of different origin:

The cream should be applied when needed, preferably several times daily, and always after contact with water. Apply as much as the skin can absorb without feeling sticky.

For prevention of relapses of atopic eczema:

Apply at least twice daily and preferably after contact with water.

4. POSSIBLE SIDE EFFECTS

Like all medicines, Canoderm may have side effects, although not everybody experiences them.

Common (experienced by more than 1 out of 100 users): The cream can give transient, local sensation of burning and heat. The face is most sensitive.

If any of the side effects worsen, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.

5. HOW TO STORE CANODERM

Keep out of the reach and sight of children.

Do not store above 25 °C.

Do not use Canoderm after the expiry date which is stated on the packaging.

6. FURTHER INFORMATION

What Canoderm contains

- The active substance is urea 50 mg/g.
- The other ingredients are triglycerides medium-chain, polysorbate 60, cetostearyl alcohol, hydrogenated canola oil, propylene glycol, carbomer, dimethicone, hard paraffin, glycerol polymetacrylate, ethyl parahydroxybenzoate (E 214), methyl parahydroxybenzoate (E 218), sodium lactate solution, lactic acid, glyceryl stearate, polyoxyethylene stearate, purified water.

What Canoderm looks like and contents of the pack

Appearance: White cream

Pack:

Plastic tube (polyethylene), 30 g, with screw on cap.

Plastic tube (polyethylene), 100 g, with snap cap.

Plastic tube (polyethylene), 210 g, with snap cap.

Plastic jar (polypropylene) with pump, 380 g.

Plastic jar (polypropylene) with pump, 500 g.

Plastic jar (polypropylene), refill jar to plastic jar with pump, 500 g.

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

Not all pack sizes may be marketed.

This is a refill jar. The pump from an emptied jar of Canoderm is moved to the refill jar.

- Wash your hands before changing pump.
- First, dry the outer parts of the pump and the cover.
- Remove the sealing ring around the cover on both the refill jar and the emptied jar with the pump (if this has not been done previously)
- Remove the outer cover from the refill jar. Let the inner cover stay.
- Remove the outer cover with the pump from the emptied jar. Leave the inner cover.
- AVOID touching the inside of the refill jar, the pump cover and the ascending pipe of the pump, in order not to deteriorate the durability of the product.
- Fix the pump's ascending pipe into the hole on the refill jar's inner cover.
- Press carefully the pump down into the jar until it stops. Then, fix the edges of the outer cover properly around the whole jar.
- Check that the cover has been fixed. The jar is ready to use. Pump a couple of times until cream is coming out.

Marketing Authorisation Holder and Manufacturer

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Manufacturer:

Bioglan AB, Malmö, Sverige

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