

B. PACKAGE LEAFLET

Package leaflet: Information for the user

Curemid 50 mg/g cream

carbamide (urea)

refill jar

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, pharmacist or nurse 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, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you don't feel better or if you feel worse.

What is in this leaflet

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

1. What Curemid is and what it is used for

Curemid is a white emollient cream that contains 5% carbamide. Carbamide has water binding properties, which contribute to normalization of dry skin.

For adults and children: moisturizing treatment of dry skin of various origins.

2. What you need to know before you use Curemid

Do not use Curemid

- if you are allergic to carbamide or any of the other ingredients of this medicine (listed in section 6).

Warnings and precautions

Avoid applying cream into eyes, nose, ears, open wounds or mucous membranes.

Talk to your doctor, pharmacist or nurse before using Curemid.

Pregnancy and breast-feeding

Curemid can be used during pregnancy and breast-feeding

Driving and using machines

Curemid does not affect the ability to drive or use machines.

Curemid contains ethyl and methyl parahydroxybenzoate, cetostearyl alcohol and propylene glycol

Ethyl and methyl parahydroxybenzoate may cause allergic reactions (possibly delayed).

Cetostearyl alcohol may cause local skin reactions (eg contact dermatitis).

This medicine contains 50 mg propylene glycol in each gram.

3. How to use Curemid

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

Adults and children: the cream is applied on dry skin when needed. You can apply it several times a day, and always after contact with water. Apply as much as the skin can absorb without feeling sticky.

4. Possible side effects

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

Common (may affect up to 1 in 10 people): The cream can cause transient, local sensation of burning and feeling of heat. The face is particularly sensitive.

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via [the national reporting system listed in Appendix V](#).^{*} By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Curemid

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

Do not store above 25°C.

Do not use this medicine after the expiry date which is stated on the packaging after 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 Curemid contains

The active substance is carbamide (urea). 1 g cream contains 50 mg carbamide (urea).

The other ingredients are medium chain triglycerides, polysorbate 60, cetostearyl alcohol, hydrogenated canola oil, propylene glycol, carbomer, dimethicone, hard paraffin, glycerol polymethacrylate, ethyl parahydroxybenzoate (E 214), methyl parahydroxybenzoate (E 218), sodium lactate solution, lactic acid, glyceryl stearate, polyoxyethylene stearate, purified water.

What Curemid looks like and contents of the pack

Appearance: white cream

Pack sizes:

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

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

Plastic jar (polypropylene) with pump, 500 g.

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

Double pack 600 g 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 Curemid is transferred to the refill jar.

- Wash your hands before changing the pump.
- First wipe the outer parts of the pump and cover.
- Tear off the sealing ring around the lid on both the refill jar and the emptied jar with the pump (if this has not been done before).
- Remove the outer cover from the refill jar. Leave the inner lid.
- Lift the outer cover with the pump from the emptied jar. Leave the inner lid.
- AVOID touching the inside of the refill jar, the pump cover and the ascending pipe of the pump, in order not to impair the durability of the product.
- Insert the pump's ascending pipe into the hole on the inner lid of the refill jar.
- Gently press the pump into the jar until it stops. Then press firmly the edges of the outer cover properly around the entire jar.
- Check that the cover is fixed. The jar is ready to use. Pump a few times until cream comes out.

Marketing Authorisation Holder:

[To be completed nationally]

Manufacturer:

[To be completed nationally]

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