

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

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- Do not pass the product on to others. It may harm them, even if their symptoms are the same as yours.

- 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.

What is in this leaflet:

1. What **UREA-L Cream** is and what it is used for
2. What you need to know before you use **UREA-L Cream**
3. How to use **UREA-L Cream**
4. Possible side effects
5. How to store **UREA-L Cream**
6. Further information

1. What **UREA-L Cream** is and what it is used for

The active substances in **UREA-L Cream** are Urea and Lactic acid which act as moisturizers. This helps make your skin soft and supple. Your doctor or pharmacist has recommended this cream as skin moisturizer.

2. What you need to know before you use **UREA-L Cream**

Do not use **UREA-L Cream**:

If you are allergic to Urea or Lactic acid or any of the other ingredients of **UREA-L Cream** (listed in section 6).

Please seek immediate medical attention if you experience symptoms of an allergic reaction. Signs or symptoms of a severe allergic reaction may include a rash, with or without itching, swelling of the face, eyelids or lips and difficulty in breathing.

Warnings and precautions

- Talk to your doctor or pharmacist before using **UREA-L Cream**.
- Avoid contact with the eyes, eyelids, lips and other mucous surfaces. Upon accidental contact, rinse the affected area with clean water.
- **UREA-L Cream** may cause stinging if applied to damaged skin (raw cracked areas or cracked skin) or sensitive areas of the body such as the mouth or nostrils.

Other medicines and **UREA-L Cream**

• This cream might affect other medicines that you apply to your skin. Please tell your doctor or pharmacist if you are using other medicines in this way.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before using this medicine.

3. How to use **UREA-L Cream**

Always use **UREA-L Cream** 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.

- **UREA-L Cream** for EXTERNAL USE ONLY.
- First gently wash and dry the affected areas of your skin.
- Apply a thick layer over the affected areas. Do not rub it in yet.
- Leave it on your skin for 3 to 5 minutes, then rub it in gently.
- Wipe off any excess cream with a tissue (do not wash it off).
- The cream should be used in this way twice a day, or as advised by your doctor.
- If you need to use **UREA-L Cream** on your feet, soak them in water for 15 minutes and then dry them with a rough towel before use.
- How long you will have to use this medicine will depend on how quickly your condition improves. Always seek the advice of your doctor or pharmacist.

If you use more **UREA-L Cream than you should or accidentally swallow any of the cream**

If you use too much **UREA-L Cream** and stinging occurs, wash the cream off with water.

In the rare event that you accidentally swallow any of this medicine, seek medical advice.

If you forget to use **UREA-L Cream**

Do not worry if you forget to use your cream at the right time. When you remember, start using the medicine again as you did before.

If you have any further questions on the use of this medicine, ask your pharmacist.

4. Possible side effects

Like all medicines, **UREA-L Cream** can cause side effects, although not everybody gets them.

Effects on the skin

- **UREA-L Cream** may cause stinging if applied to raw areas or cracks in the skin or the lips.

- Keep **UREA-L Cream** away from other sensitive areas of your body.
- If stinging occurs, wash the cream off with water.
- Should stinging be a problem, you can mix it with an equal amount of Aqueous Cream BP (ask your pharmacist for this) for a week, after which it would be alright to use the cream on its own again, but you must consult your doctor or pharmacist first.

5. How to store **UREA-L Cream**

- 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 tube and carton. The expiry date refers to the last day of that month.
- Store below 30°C.
- Shelf life after first opening is 30 days
- 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. Further information

What **UREA-L Cream** contains

- The active substances are urea 10% and Lactic acid 5%
- The other ingredients are Vaseline, Paraffin Oil, Cetostearyl Alcohol, Triethanolamine, Eumulgol B2, Propylene Glycol, Methyl Paraben, Propyl Paraben, Sodium Chloride, Perfume and Purified Water.

What **UREA-L Cream** looks like and contents of the pack

UREA-L Cream is a white colored smooth cream. It is available in 100ml tubes either on prescription from your doctor or indirectly from your pharmacist.

Manufacturer & Marketing Authorisation Holder:

Middle East Pharmaceutical Industries Co Ltd (Avalon Pharma)
P.O.Box 4180 Riyadh 11491,
2nd Industrial City, Riyadh, Kingdom of Saudi Arabia
Tel: +966 (11) 2653948 -2653427
Fax: +966 (11) 2654723

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To report any side effect(s):

- **Saudi Arabia:**

The National Pharmacovigilance and Drug Safety Centre (NPC)

- Fax: +966-11-205-7662
- Call NPC at +966-11-2038222, Exts: 2317-2356-2353-2354-2334-2340.
- Toll free phone: 8002490000
- E-mail: npc.drug@sdfa.gov.sa
- Website: www.sdfa.gov.sa/npc

- Other GCC States:

Please contact the relevant competent authority.

THIS IS A MEDICATION

- Medication is a product which affects your health and its consumption contrary to instructions is dangerous for you.
- Follow strictly the doctor's prescription, the method of use and the instructions of the pharmacist who sold the medication.
- The doctor and the pharmacist are the experts in medicines, their benefits and risks.
- Do not by yourself interrupt the period of treatment prescribed for you.
- Do not repeat the same prescription without consulting your doctor.
- Keep all medications out of reach of children.

Council of Arab Health Ministers, Union of Arab Pharmacists