PACKAGE LEAFLET: INFORMATION FOR THE USER

Balneum Plus Cream
Active Substances: Urea 5,0 %, Lauromacrogols 3,0 %
Cream

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.
- This medicine has been prescribed for you. Do not pass it 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. .
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What is in this leaflet:

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

1. WHAT BALNEUM PLUS CREAM IS AND WHAT IT IS USED FOR

Balneum Plus Cream is an easily absorbed cream containing an ingredient called lauromacrogols which relieves itching. It has a soothing and softening effect on your skin and also works by replacing the much needed oils in your dry skin. This helps to prevent loss of skin moisture.

The cream also contains urea. This substance is found naturally in the skin and helps the skin retain water. Many people with eczema and psoriasis have reduced amounts of urea in their skin and Balneum Plus Cream can help by replacing it.

This cream has been shown to increase skin moisture for up to 24 hours.

Balneum Plus Cream is for the treatment of itching and dry skin seen with eczema, dermatitis and scaling skin conditions. All of these worsen when the skin is allowed to become dry.

2. WHAT YOU NEED TO KNOW BEFORE YOU USE BALNEUM PLUS CREAM

Do not use Balneum Plus Cream

- If you are allergic (hypersensitive) to urea, lauromacrogols or any of the other ingredients listed in section 6.
- If you are suffering from severe and widespread reddening of the skin.
- If the affected area has suddenly become inflamed or is oozing and/or infected.

If this applies to you, do not use this medicine and speak to your doctor.

Warnings and precautions

- Your medicine may cause irritation if applied to broken or inflamed skin.
- Avoid contact to mucous membranes and eyes.

Other medicines and Balneum Plus Cream
Please tell your doctor or pharmacist if you are taking other medicines.
Urea may increase the penetration through the skin barrier of other topically applied medicines (e.g. corticosteroids, dithranol and fluorouracil) when used at the same time

Pregnancy and breast-feeding
Ask your doctor or pharmacist for advice before taking any medicine.

- Balneum Plus Cream can be used during pregnancy.
- **Do not** use this medicine on the breasts immediately prior to breast feeding.

3. HOW TO USE BALNEUM PLUS CREAM

Always use Balneum Plus Cream exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.

- The medicine is for external use by adults, the elderly and children.

- Using clean hands, apply the cream to the affected areas twice a day until the symptoms have eased.

Duration of treatment
Your doctor will tell you for how long you need to use Balneum Plus Cream

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

4. POSSIBLE SIDE EFFECTS

Like all medicines, Balneum Plus Cream can cause side effects, although not everybody gets them. Treated skin can get worse after using it.

- You may experience a burning sensation, redness, itching or the formation of pustules or your eczema may get worse if Balneum Plus Cream is used on inflamed skin.

If this happens stop using the cream and talk to your doctor or pharmacist.

5. HOW TO STORE BALNEUM PLUS CREAM

Keep out of the reach and sight of children.

Do not use Balneum Plus Cream after the expiry date which is stated on the label, the carton and the tube after EXP.
The expiry date refers to the last day of that month.

Do not store above 25°C.

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

6. CONTENT OF THE PACK AND OTHER INFORMATION

What Balneum Plus Cream contains
The active substances are urea 5% and lauromacrogols 3%.

The other ingredients are dimethicone, phenyl dimethicone, liquid paraffin, cetylpalmitate, stearic palmitic acid, octyldodecanol, glycerol 85 %, polysorbate, carbomer, trometamol, benzyl alcohol and purified water.

What your medicine looks like and content of the pack
Balneum Plus Cream is a white smooth cream .

It comes in either 10g, 35g, 50g, 75g or 100g aluminium tubes with a screw cap or in plastic pump dispensers containing : 175g, 180g, 185g, 190g, 200g and 500g.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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