PACKAGE LEAFLET: INFORMATION FOR THE USER

Nutraplus 100 mg/g Cream Urea

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 have 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.

What is in this leaflet

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

1. What Nutraplus is and what it is used for

- Nutraplus is an emollient, a moisturising and protective cream for the treatment of dry or damaged skin.
- The active substance in this product is urea, a natural substance found in healthy skin.
- The presence of urea in the cream moisturises the skin. This helps bring back soft and supple skin.

2. What you need to know before you use Nutraplus Do not use Nutraplus

• If you are allergic to urea or any of the other ingredients of this medicine (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 Nutraplus.

- If you have severe kidney problems, as you may need to limit your use of Nutraplus
- Apply carefully only to damaged or inflamed skin or to the face
- If you experience redness, a burning sensation or itching of the skin after applying Nutraplus, wash the cream off and stop using it.
- If irritation occurs, discontinue use temporarily and consult your doctor.
- Avoid getting Nutraplus in your eyes, mouth, nose or ears (mucous membranes). Upon accidental contact, rinse the affected area with clean water.
- Nutraplus should only be used under medical supervision in children under 2 years of age

Other medicines and Nutraplus

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Nutraplus might interfere with other medicines such as topical corticosteroids, which are a group of medicines used on the surface of the skin to reduce the redness and itchiness caused by certain skin problems.

Pregnancy and breast-feeding

- If you are pregnant or breast-feeding, it may not be advisable to use this medicine, unless your doctor considers it essential.
- If you are able to use Nutraplus while breast-feeding, you should remove this product from the breast-area before 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 taking this medicine.

Nutraplus contains:

- cetearyl alcohol which may cause local skin reactions (e.g. contact dermatitis)
- propylene glycol which may cause skin irritation
- propyl parahydroxybenzoate and methyl parahydroxybenzoate which may cause allergic reactions (possibly delayed).

3. How to use Nutraplus

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

This medicine is for external use only.

Adults and children over 2 years;

- First gently wash and dry the affected areas of your skin.
- Apply evenly to dry skin areas 2 to 3 times a day, or as advised by your doctor or pharmacist.
- Wipe away any excess cream with a tissue.
- How long you will have to use this medicine will depend on how quickly your condition improves.

Use in children under 2 years should under the guidance of a doctor.

If you use more Nutraplus than you should or accidentally swallow any of the cream

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

If you forget to use Nutraplus

Do not worry if you forget to use your cream at the right time. When you remember, start using this 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, this medicine can cause side effects, although not everybody gets them.

If you experience redness, a burning sensation or itching of the skin after applying Nutraplus, wash the cream off and stop using it. Talk to your doctor or pharmacist **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 (see details below). By reporting side effects, you can help provide more information on the safety of this medicine.

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5. How to store Nutraplus

- 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.

• Do not store above 25°C.

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 Nutraplus contains

- The active substance is urea. Each gram of Nutraplus contains 100mg of urea.
- The other ingredients are glyceryl monostearate, octyl palmitate, myristyl lactate, liquid paraffin (mineral oil), Promulgen D (containing cetearyl alcohol and ceteareth-20), propylene glycol, methyl parahydroxybenzoate (E218), propyl parahydroxybenzoate (E216) and purified water.

What Nutraplus looks like and contents of the pack

- Nutraplus is a white cream.
- It is available in 60 and 100 g tubes. Not all sizes of the tube may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Galderma International S.A.S.

Tour Europlaza, 20 Avenue André Prothin, La Défense 4 92927 Paris La Défense CEDEX, France (PA22743/011/001)

Manufacturer:

Laboratoires Galderma

ZI-Montdésir, 74540 Alby-sur-Chéran, France.

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