Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nutraplus 100mg/g Cream

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram of cream contains 100mg of Urea

Excipients with known effect: Methylparahydroxybenzoate (E218) 1.8mg/g, Propylparahydroxybenzoate (E216) 0.9mg/g, Propylene glycol 45mg/g, Cetearyl alcohol 18.0mg/g-22.5mg/g

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Cream.
A smooth white cream.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

As an emollient, moisturising and protective cream for the treatment of dry or damaged skin.

4.2 Posology and method of administration

For external use only.

Adults and children over 2 years:
Apply two to three times daily to the affected skin areas or as directed by a physician.

Use in children under two should be under the direction of a physician.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.

4.4 Special warnings and precautions for use

Because of the potential transcutaneous penetration of urea, the product should not be used extensively in subjects with severe renal impairment without medical supervision.
Apply with caution only to damaged or inflamed skin or to the face. Avoid contact with the eyes and mucous membranes.
Treatment must be discontinued in case of erythema, skin burning sensation, pruritus, rash or hypersensitivity reactions after application (see section 4.8).
If undue irritation occurs, discontinue use and consult your physician. Do not use in children under 2 years of age except under medical supervision.

Nutraplus cream contains the excipients; Methyl parahydroxybenzoate (E218) and propyl parahydroxybenzoate (E216) which may cause allergic reactions (possible delayed). Propylene glycol may cause skin irritation. Cetearyl alcohol and ceteareth-20 may cause local skin reactions such as contact dermatitis.

4.5 Interaction with other medicinal products and other forms of interactions

Urea may enhance the efficacy of 5-fluorouracil and anthralin, and increase the release and the permeation into the skin of active ingredients from other topical products such as corticosteroids.

4.6 Fertility, pregnancy and lactation

There are no clinical data available on the use in pregnant women. Animal studies are insufficient with respect to effects on pregnancy, embryonal development, foetal development and/or postnatal development. Caution should be exercised when prescribing to pregnant women.
However, indications of risks associated with topical applications of urea during pregnancy and while breastfeeding are not known.
In breast-feeding women, the product should be removed from the breast area before breast-feeding.

4.7 Effects on ability to drive and use machines

Nutraplus has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

Tabulated list of adverse reactions
The adverse reactions are classified by System Organ Class and frequency, using the following convention: very common (≥ 1/10), common (≥ 1/100 to < 1/10), uncommon (≥ 1/1,000 to < 1/100), rare (≥ 1/10,000 to <1/1,000), very rare (< 1/10,000), not known (cannot be estimated from the available data).

The following adverse events have been reported during Nutraplus postmarketing surveillance:

System Organ Class	Frequency	Adverse drug reaction
Skin and subcutaneous tissue disorders	not known	Rash, pruritus, skin irritation, erythema, skin burning sensation
Immune system disorders	not known	Hypersensitivity reaction

Reporting of suspected adverse reactions:
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via: HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2. Tel: +353 1 6764971; Fax: +353 1 6762517; Website: www.hpra.ie; e-mail: medsafety@hpra.ie.

4.9 Overdose

Intoxication from the use of Nutraplus is not known and on account of the product ingredients is not to be expected. Skin irritations due to overuse quickly disappear upon discontinuation of use.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:Protectives and emollients, ATC code: D02 AE01
The active ingredient urea, is used as a hydrating agent.

5.2 Pharmacokinetic properties

Nutraplus is a topical preparation. Although absorption through the skin in adults would not be expected to be significant, urea should be applied only under medical direction to the skin of neonates or young babies, as significant systemic absorption may occur, leading to dehydration.

5.3 Preclinical safety data

Urea is a long established material, whose pre-clinical profile is well known.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Glyceryl monostearate
Propyl parahydroxybenzoate (E216)
Propylene glycol
Methyl parahydroxybenzoate (E218)
Purified water
Octyl palmitate
Myristyl lactate
Liquid paraffin (Mineral Oil)
Promulgen D (contains Cetearyl Alcohol and Ceteareth-20)

6.2 Incompatibilities

Not applicable

6.3 Shelf life

3 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

A collapsible white low density polyethylene tube, with a white polypropylene screw cap.

Pack sizes: 1 tube of 60g or 100g
Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Galderma International S.A.S.
Tour Europlaza
La Défense 4
20 Avenue André Prothin
France

8 MARKETING AUTHORISATION NUMBER

PA22743/011/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 29th January 1991
Date of last renewal: 29th January 2011

10 DATE OF REVISION OF THE TEXT

May 2019