SUMMARY OF PRODUCT CHARACTERISTICS (SmPC)

[Instructions in this font/colour are from the World Health Organisation Public Assessment Report WHOPAR guidelines.]

1. NAME OF THE MEDICINAL PRODUCT

SkinoRita Cream

Cream of Urea with Natural Moisturing Factors

2. QUALITATIVE AND QUANTITATIVE COMPOSITION Qualitative Composition

Urea	BP	12%w/w
Lactic Acid	BP	6.0%w/w
Glycine	BP	3.0%w/w
Ammonium Chloride	BP	0.5 % w/w
Sodium Chloride	BP	0.5% w/w
Potassium Chloride	BP	0.5% w/w
Calcium Lactate	BP	0.5 % w/w
Magnesium Chloride	BP	0.3% w/w
Sodium Dihydrogen Phosphate Dihydrate	BP	0.5% w/w
Cream Base		q.s.

For External Use Only.

Quantitative composition

Excipients with known effect:

Stearic acid (Emulsifying agent), Cetyl alcohol (Emulsifying agent), Disodium EDTA (prevent the deterioration), Vanzan NFC (viscosity-increasing agent), Natrosol HEC

(viscosity-increasing agent), Steareth-21 (Emulsifying agent), Carnavel 165 (Arlacel 165) (Emulsifying agent), Euxyl K 703 Phenoxyethanol benzoic acid

(Antimicrobial/preservative), Dimethicone (Antifoaming agent), Sepinav

EMT10 (Stabilizing agent), PEG 150 disterate (Ointment base; plasticizer), Triethanolamine (Emulsifying agent), Purified water (Solvent).

3. PHARMACEUTICAL FORM

Cream

White to Off White colour homogenous soft mass filled in HDPE Jar container.

pH - 4.00 to 6.50

4. Clinical particulars

Therapeutic indications

For the treatment of ichthyosis, xeroderma (especially in the elderly), hyperkeratosis and other chronic dry skin conditions such as atopic eczema (dermatitis

4.1 Posology and method of administration

Urea 12% w/w Cream is applied topically. Wash affected areas well, rinse off all traces of soap, dry, and apply sparingly twice daily. Occlusive dressings may be used but are usually unnecessary because of the self-occlusive nature of the cream.

Method of administration

Topical use only

4.2 Contraindications

SkinoRita Cream should not be used in patients with a known hypersensitivity to any of the ingredients. It should not be used to treat excoriated acute inflammation of the skin. It should not be used on large areas in patients with renal insufficiency

4.3 Special warnings and precautions for use

A doctor should be consulted if symptoms persist.

Application of the product to broken skin should be avoided

4.4 Interaction with other medicinal products and other forms of interaction

Urea may potentiate the release of active substances from topical preparations and their penetration into the skin. This is known in particular for corticosteroids, dithranol and fluorouracil.

4.5 Pregnancy and Lactation There are no known risks.

4.6 Effects on ability to drive and use machines No effects would be anticipated.

4.7 Undesirable effects

Local skin irritation may occasionally occur particularly if the product is applied in acute inflammatory skin conditions or to sensitive skin. If the condition is aggravated or if there is no improvement the doctor should be consulted**.**

4.8 Overdose

Excessive topical use or overdose may cause skin irritation. This tends to resolve quickly and automatically when use of the product is discontinued.

Accidental ingestion of the lotion is unlikely to produce toxic effects as oral doses of up to 100g/day urea (present in four 250 ml bottles of lotion) are considered safe

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamics properties Pharmacotherapeutic group: Urea acts as a hydrating and keratolytic agent

ATC Code: V04CX05

Urea is a recognised hydrating agent that has been widely used topically to treat dry or damaged skin.

5.2 Pharmacokinetic properties

Only a small percentage of the amount of the urea applied to the skin penetrates to the epidermis and dermis. Urea is primarily excreted unchanged in the urine. A small amount is also eliminated in the sweat.

5.3 Preclinical safety data

In man, doses of up to 80g/day iv or 100g/day p.o. urea are considered safe. Such high doses of urea are not absorbed following topical use, even when the whole body is treated exclusively externally. Whilst only very limited preclinical data are available, there is no evidence to suggest that urea would have teratogenic, carcinogenic or mutagenic potential in therapeutic use

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Stearic acid, Cetyl alcohol, Disodium EDTA, , Vanzan NFC, Natrosol HEC, Steareth-21, Carnavel 165 (Arlacel 165), Euxyl K 703 Phenoxyethanol benzoic acid, Dimethicone, , Sepinav EMT10, PEG 150 disterate, Triethanolamine, Purified water.

6.2 Incompatibilities

Not applicable

6.3 Shelf life

24 months form the date of manufacturing

6.4 Special precautions for storage

No *special requirements*

6.5 Nature and contents of container <and special equipment for use, administration or implantation>

100g cream filled in white colour HDPE jar. Such one jar packed in a printed carton along with package insert

6.6 Special precautions for disposal <and other handling> Store

at a temperature below 30°C. Protect from light.

Do not freeze.

7. <APPLICANT/MANUFACTURER>

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