SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE MEDICINAL PRODUCT

UMA 10 (Urea Cream BP 10.0 % w/w)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition:

Urea BP	10% w/w
In a Cream Base	q.s.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Topical Cream.
A smooth white to off white cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

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

4.2 Posology and method of administration

UMA 10 should be applied sparingly twice daily to the affected areas of skin and rubbed in. It should not be allowed to come into contact with the eyes or mucosae. It should not be applied on large areas in patients with renal insufficiency. The duration of use depends on the particular condition of the skin and shouldbe established on an individual basis.

4.3 Contraindications

UMA 10 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.

4.4 Special warnings and precautions for use

A doctor should be consulted if symptoms persist.

4.5 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.

4.6 Pregnancy and lactation

There are no known risks.

4.7 Effects on ability to drive and use machines

No effects would be anticipated.

4.8 Undesirable effects

Local skin irritation may sometimes 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.

4.9 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 cream is unlikely to produce toxic effects as oral doses of up to 100g/day urea (present in more than six 150g tubes of cream)are considered safe.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

ATC Code: DO2A E Carbamide products

Urea acts as a hydrating and keratolytic agent.

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. Very limited preclinical data are available.

6. PHARMACEUTICAL PARTICULARS

1.1 List of excipients

Sr.No.	Raw materials	Pharmacopoeia
1.	Cetostearyl Alcohol	BP
2.	Light Liquid Paraffin	BP
3.	Glycerol	BP
4.	Cetomacrogol 1000	IHS
5.	IsononylIsononanoate	IHS
6.	Phenoxyethanol	BP
7.	Fragance Lemon Cologne	IHS
8.	Citric Acid	BP
9.	Cibafast H Liquid (Sodium Benzotriazoylyl,Butylphenolsulfonate Biteth-3, Tributyl Citate)	IHS
10.	Disodium Edetate	BP
11.	Methyl Hyroxybenzoate	BP
12.	Propyl Hydroxybenzoate	BP
13.	Purified Water	BP

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

24 months.

6.4 Special precautions for storage

Store below 30ºC in dry and dark place.

6.5 Nature and contents of container

50 g filled in Plastic HDPE bottle packed in a carton.

6.6 Special precautions for disposal and other handling

No special requirement

7. Marketing Authorisation Holder

Kilitch Drugs (India) Limited
37, Ujagar Industrial Estate,
W.T Patil Marg, Deonar,
Mumbai 400 088,Maharashtra, India.
Website- www.kilitch.com

8. Marketing Authorisation Number(S) issued by Ethiopian FDA

08003/08861/NMR/2021

9. Date of First Authorisation/Renewal of theAuthorisation

26-10-2022

10. Date of Revision of the Text

05/07/2023