

Summary of Product Characteristics (SmPC)

1. NAME OF THE MEDICINAL PRODUCTS

DIAFOOT CREAM (Allantoin with Dimeticone and Urea Cream)

2. QUALITY AND QUANTITATIVE COMPOSITION

S.No	Name of the Ingredients	Referenced Monograph	Qty in % w/w
1	Allantoin	BP	0.20
2	Dimeticone	BP	1.00
3	Urea	BP	10.00
4	Liquid Paraffin	BP	8.00
5	Glycerol	BP	5.00
6	Propylene Glycol	BP	5.00
7	Cetostearyl Alcohol	BP	6.33
8	Cetomacrogol 1000	In-House	2.50
9	Glyceryl Monostearate	In-House	1.00
10	Stearyl Alcohol	BP	3.00
11	Sodium Lauryl Sulphate	BP	1.00
12	Methyl Hydroxybenzoate	BP	0.10
13	Propyl Hydroxybenzoate	BP	0.05
14	Lavender	In-House	0.10
15	Purified water	BP	56.72

3. PHARMACEUTICAL FORM

White smooth cream with lavender perfume.

4 . CLINICAL PARTICULARS

4.1 Therapeutics Indications

For burning foot syndrome, numbness, redness or erythema, pain in the leg or calf muscle area, drying of the skin below knee including foot, scaling or blister formation which are associated with Diabetic foot disease. DIAFOOT CREAM offers a prophylactic treatment.

4.2 Posology and method of administration

Diafoot cream can be applied externally from knee to toe; two to three times a day or as directed by the physician.

Before application wash your foot with warm water and dry properly.

4.3 Contraindication

Diafoot cream is contraindicated in patients who have hypersensitivity to any of the ingredients in the formulation.

The safety and efficacy of the use of Diafoot cream during pregnancy and in Nursing mothers has not been established.

4.4 Special warning and precaution for use

FOR EXTERNAL USE ONLY.

Avoid the use of commercial corn pastes, paints, or plasters. They may contain acids and can be dangerous to the diabetic foot.

Avoid using HOT water.

People suffering from diabetes also suffer from severe infections. Bacterial infection also makes the immune system weaker. The patient should be aware of controlling the blood sugar level, proper nutrition, and timely exercise.

Avoid using adhesive pads on your feet.

If your skin is scraped or damaged.

4.5 Interaction with other medicinal products and other forms of interaction

None.

4.6 Pregnancy and lactation

The safety and efficacy of the use of Diafoot cream during pregnancy and in Nursing mothers has not been established.

4.7 Effects on ability to drive and use machine

None Reported

4.8 Undesirable effects

The following side effects reported with the use of Dimeticone are mild itching, burning, or stinging. Severe allergic reactions (rash; hives; difficulty breathing; tightness in the chest; swelling of the mouth, face, lips, or tongue); severe or persistent itching, burning, or stinging; skin irritation; worsening dryness. Seek medical attention if any of these severe side effects occur.

4.9 Overdose

An overdose of this medication is unlikely to occur. This medication is for the use only on the skin. Avoid getting the medication into the mouth or eyes. If it occurs rinse with sufficient of water and seek medical attention.

5. PHARMACOLOGICAL PROPERTIES

5.1 Clinical Pharmacology

The blood glucose level will be high in Diabetes affected patients. This occurs because the body is turning the water into urine to remove excess glucose from the blood. When the blood glucose is high, the body loses fluid. With less fluid in the body, the skin is more likely to become dry. Dry skin may become itchy and cracked. Cracks allow germs to enter and cause infection. With high blood glucose, bacteria have more to feed on and infection can quickly develop. Poor blood circulation also means the body is slower to heal wounds and fight off infections.

Nerve damage, can decrease the amount of sweat. Sweating helps keep the skin soft and moist. Decreased sweating in feet and legs can cause dry skin. Burning feet is a common complaint among many groups of people, most commonly in the older group over 50 years of age. There are many different causes for burning feet. It is most prevalent in diabetics who often have a

mixture of burning feet and loss of sensation on the bottom of the foot. People suffering from diabetes also suffer from severe infections. If a bacterial infection attacks the feet becomes red and experience swelling. They become warm and painful.

Diafoot cream contains Allantoin which is said to clean away dead (necrotic) tissue and hasten the growth of new healthy tissue. Since allantoin stimulates new and healthy tissue growth, skin formation may take place over wounds and sores.

Allantoin has also been termed a counter irritant that helps alleviate the skin-irritation effects of certain cosmetic ingredients including soaps, detergents, surfactants, oils, and acidic or alkaline materials. Allantoin produces its desirable effects by promoting and speeding up the healthy, natural processes of the body. It is said to help the skin to help itself. Allantoin assists in the healing of damaged epithelium, by fibrinolysis of damaged tissue, stimulation of cell granulation and keratolytic activity.

Allantoin is safe and effective in the dosage range recommended (0.5 to 2.0%) as a skin protectant.

Dimeticone in this formulation is a water repellent and protects the skin against water-soluble irritants. This is an emollient. It works by moisturizing the skin. It may also have other uses, such as treating or preventing dry, itchy skin or minor skin irritations.

Urea acts as a humectant. It works by attracting water to the top layer of skin from the lower layers. It is a synthetic material that draws moisture into the skin helping to hydrate and moisturize.

It is also a keratolytic, or exfoliating agent, which helps to loosen dead skin cells and renew the skin's appearance. Also Urea helps for the penetration of Allantoin and Dimeticone into the skin layers.

5.2 Pharmacokinetic properties

Allantoin is safe and effective in the dosage range recommended (0.5 to 2.0%) as a skin protectant.

The permeability constant after treatment with Urea of whole skin and the dermis of rabbits was $2.37 \pm 0.13 \times 10^{-6}$ and $1.20 \pm 0.09 \times 10^{-3}$ cm/min, respectively. The absorption of

Urea across normal and abraded human skin was 9.5% +/- 2.3% and 67.9% +/- 5.6%, respectively. Urea increased the skin penetration of other compounds.

Results shows, that a single application of a barrier cream based on dimethicone offers a high level of protection against penetration that is sustained for at least 48 hr.

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

S.No	Ingredients	Reference
1.	Liquid paraffin	BP
2.	Glycerol	BP
3.	Propylene glycol	BP
4.	Cetostearyl alcohol	BP
5.	Cetomacrogol 1000	In-House
6.	Glyceryl monostearate	In-House
7.	Stearyl alcohol	BP
8.	Sodium lauryl sulphate	BP
9.	Methyl hydroxyl benzoate	BP
10.	Propyl hydroxyl benzoate	BP
11.	Lavender	In-House
12.	Purified water	BP

6.2 Incompatibilities

Not Applicable

6.3 Shelf Life

36 months

6.4 Special Precautions for storage

Store below 30°C. Protect from light. Do not freeze

6.5 Nature and contents of container

50 grams filled in laminated aluminium tube and packed in a carton along with pack insert.

7. MARKETING AUTHORIZATION HOLDER

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8. MARKETING AUTHORIZATION NUMBERS

NAFDAC Reg.No: B4-5375

9. DATE OF REVISION OF THE TEXT

29th June 2020