Summary of Product Characteristics

1. **Name of the medicinal product**
   FUTEND-3 CREAM (Clotrimazole, Betamethasone Dipropionate & Neomycin Sulphate)

2. **Qualitative and quantitative composition**
   Clotrimazole USP ....1% w/w
   Betamethasone Dipropionate USP
   Equivalent to Betamethasone.....0.05% w/w
   Neomycin Sulphate USP ..... 0.5% w/w
   Cream base ..... q.s.

   Excipients of known effect: Cetostearyl alcohol
   For full list of excipients, see section 6.1

3. **PHARMACOLOGICAL DOSAGE FORM:**
   Cream for Topical use

4. **Clinical Particulars**

4.1. Therapeutic indications

FUTEND 3 CREAM contains 3 active ingredients. Betamethasone is a highly potent topical corticosteroid, which rapidly and effectively relieves inflammation and itching. Clotrimazole is an anti-fungal treating a very wide variety of fungal infections, and Neomycin is an aminoglycoside antibiotic with a broad spectrum of activity and is very well tolerated when applied topically.

FUTEND 3 CREAM is suitable for superficial skin lesions, infected eczema, and other inflammatory dermatological conditions associated with bacterial or fungal infection.

4.2. Posology and method of administration

FUTEND 3 CREAM should be applied thinly and evenly to the affected area, two or three times a day unless otherwise directed by your doctor. Avoid use on broken skin. Once the cream has been applied, a dressing should not be applied over the wound. If symptoms persist for more than seven days, consult your doctor.

OR AS DIRECTED BY PHYSICIAN.

4.3. Contraindications

FUTEND 3 CREAM is contraindicated in those patients with a history of sensitivity to any of the active or inactive ingredients or to other corticosteroids, aminoglycoside antibiotics, or imidazoles. This medicine should **NOT** be used to treat the following conditions: Rosacea, acne vulgaris, perioral and genital pruritus, primary cutaneous viral infections (e.g., herpes simplex, chickenpox)

4.4. Special warnings and precautions for use

FUTEND 3 CREAM should not be applied large area or for a prolonged period, as significant systemic absorption may occur. Do not apply the cream to the face for more than 5 days. Avoids use in places where the skin folds (e.g. the back in the knee), or on large areas of damaged skin. Keep the cream away from your eyes.

4.5. Interaction with other medicinal products and other forms of interaction

Following significant systemic absorption, neomycin sulphate can intensify and prolong the respiratory depressant effects of neuromuscular blocking agents.

4.6. Fertility, pregnancy and lactation

Pregnancy and Breastfeeding

The doctor will decide whether FUTEND 3 CREAM is safe to use during pregnancy and breastfeeding and therefore this cream should only be used if it has been prescribed by a doctor.

4.7. Effects on ability to drive and use machines

FUTEND 3 CREAM has no influence on the ability to drive and use machines.

4.8. Undesirable effects

Side effects with FUTEND 3CREAMare not common, and any reaction is usually caused by an allergy to any of the ingredients in the cream. If you experience an allergic reaction to the cream, stop using it immediately and consult your doctor at once. In addition, the following side effects have been reported: redness, stinging, blistering, peeling, swelling, itching,

burning, skin rash, dryness of the skin, inflammation of the hair follicles, excessive hair growth, darkening of the skin, reaction, dermatitis around the mouth, other skin infection, thinning of the skin and red marks. If you experience any of these effects or any other effects not listed above, stop using the cream and contact your doctor immediately

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 the National Regulatory Authority pharmacovigilance reporting channels.

4.9. Overdose

N/A

5. Pharmacological properties

5.1. Pharmacodynamic properties

Beclomethasone 17,21-dipropionate is a dieter of beclomethasone, which has potent glucocorticosteroid and weak mineralocorticosteroid activity. The mechanism for the anti-inflammatory action of beclomethasone dipropionate is unknown. It is postulated that topical steroids control the biosynthesis of potent mediators of inflammation such as prostaglandins and leukotrienes by inhibiting the release of their common precursor, arachidonic acid. Corticosteroids are also thought to act by the induction of phospholipase A2 inhibitory proteins. Clotrimazole exerts antifungal effects by inhibition of fungal sterol synthesis. It appears to inhibit the enzymatic conversion of 2,4-methylenedihydrolanosterol to demethylsterol, the precursor to ergosterol, which is an essential building block of the cytoplasmic membrane of the fungi. Clotrimazole is a broad-spectrum antifungal agent that inhibits the growth of most fungi pathogenic to man, including Candida and Dermatophytes (Trichophyton, Microsporum, Epidermophyton). Neomycin acts on bacteria by interfering with bacterial protein synthesis by binding to 30s ribosomes. The antibacterial spectrum of Neomycin includes specific organisms that are susceptible to it and generally includes all medically important aerobic Gram-negative bacilli except Pseudomonas aeruginosa. Anaerobic bacteria are resistant. Staphylococcus aureus and *Staph. epidermidis* are highly sensitive, but all streptococci are relatively resistant.

5.2. Pharmacokinetic properties

Topical corticosteroids can be absorbed from normal intact skin. The extent of percutaneous absorption of topical corticosteroids is determined by many factors, including the vehicle and the integrity of the epidermal barrier. Inflammation and/or other disease processes in the skin may increase percutaneous absorption. Systemic absorption following use of topical Clotrimazole preparations is very low. Estimated bioavailability is less than 0.5%. Clotrimazole concentrations achieved in the epidermal layers exceed the minimal inhibitory concentrations (MICs) for almost all pathogenic fungi.

6. Pharmaceutical particulars

6.1. Excipients

- Polysorbate – 80
- Sodium Acid Phosphate dihydrate
- Propylene Glycol
- Chlorocresol
- Light Liquid Paraffin
- Cetomacrogol 1000
- Cetostearyl Alcohol
- Purified water

6.2. Incompatibilities

None

6.3. Shelf life

36 Months.

6.4 Special precautions for storage

Store below 30°C.

6.5. Nature and contents of container

30 g collapsible Aluminium tube.

6.6. Special precautions for disposal and other handling

No special requirements for disposal.

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

7.0 Marketing Authorisation Holder

Marketing Authorisation Holder:

MIHIKA PHARMACEUTICALS

506, Parmeshwari Centre, 18 Dalmia Estate, Mulund, Mumbai-400080, India

Manufacturer:

Gopaldas Visram & Co. Ltd.

Address: A - 327, T.T.C. Industrial Area, Mahape, Navi Mumbai 400701, Maharashtra, India.

8.0 Marketing authorization number(s)

H2022/CTD7793/14920

9.0 Date of first authorization/renewal of the authorization

Date of first authorization: 09/11/2022

10. Date of revision of the text

Last revised on 09-November-2022