## 1.3 Product Information

### 1.3.1 Summary of Product Characteristics (SmPC)

**1. NAME OF THE MEDICINAL PRODUCT**

SAMGUARD, Betamethasone Dipropionate, Clotrimazole and Neomycin Sulphate Cream

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Composition:
Betamethasone Dipropionate BP
eq. to Betamethasone 0.05% w/w
Clotrimazole BP 1.0% w/w
Neomycin Sulphate BP 0.5% w/w
Cream Base q.s.

**3. PHARMACEUTICAL FORM**

Cream
A white colour smooth cream filled in laminated tube.

**4. CLINICAL PARTICULARS**

**4.1 Therapeutic indications**

Betamethasone Dipropionate, Clotrimazole and Neomycin Sulphate Cream is a combination of medicine primarily used to treat various fungal and bacterial skin infections. It treats skin inflammation due to allergies or irritants, eczema (inflamed, itchy, cracked and rough skin patches), psoriasis (skin cells multiply rapidly to form bumpy (uneven) red patches covered with white scales), ringworm, athlete's foot (fungal infection between the toes), jock itch (fungal infection in the skin of the genitals, inner thighs and buttocks), insect bites, and stings. Bacterial infection occurs when harmful bacteria grow in the body and causes infection. Fungal infection is caused when a fungus invades and affects the tissue on the skin.

**4.2 Posology and method of administration**

Creams are especially appropriate for moist or weeping surfaces.

Betamethasone Dipropionate, Clotrimazole and Neomycin Sulphate Cream is a combination of three medicines: Betamethasone, Clotrimazole and Neomycin. Betamethasone is a steroid which blocks the production of certain chemical messengers (prostaglandins) that make the skin red, swollen and itchy. Clotrimazole is an antifungal which stops the growth of fungi while Neomycin is an antibiotic which stops bacterial growth in the skin. Together, they treat your skin infection effectively.

Use this medication on the skin only. Clean and thoroughly dry the area to be treated. Apply a thin layer of the medication to the affected area and gently rub in, usually twice daily (in the morning and evening) or as directed by your doctor. Wash your hands after using unless you are using this medication to treat the hands. Do not wrap, cover, or bandage the area unless directed to do so by your doctor. Wear loose-fitting clothes after applying the medication to the groin area.

Do not apply the medication in the eyes, nose, mouth, or inside the vagina. If you do get the medication in those areas, flush with plenty of water.

The dosage and length of treatment depends on the type of infection being treated. Ringworm or jock itch is usually treated for 2 weeks, and athlete's foot is usually treated for 4 weeks. Do not use more than 45 grams of the cream or 45 milliliters of the lotion per week unless directed and closely monitored by your doctor.

Do not apply more often or use longer than prescribed. This may increase the risk of side effects.

Use this medication regularly to get the most benefit from it. To help you remember, use it at the same times each day.
Continue to use this medication until the full prescribed amount is finished, even if symptoms disappear after a few days. Stopping the medication too early may result in a return of the infection.
Inform your doctor if your condition worsens or does not improve after 1 week of treatment for jock itch or ringworm or 2 weeks of treatment for athlete's foot.

## 4.3 Contraindications

Use of Betamethasone Dipropionate, Clotrimazole and Neomycin Sulphate Cream is considered to be harmful for patients with known allergy to any of the components or excipients of this medicine. Avoid its use in case of any fungal infections (ringworm or athlete's foot), viral infections (herpes or chickenpox) or for treatment of acne or rosacea. Consult your doctor before using it for any condition.

## 4.4 Special warnings and precautions for use

Betamethasone Dipropionate, Clotrimazole and Neomycin Sulphate Cream should not be used on the face and contact with eyes should be avoided. Do not apply a bandage or dressing on the area being treated, as this will increase absorption of the medicine and increase the risk of side-effects. This medicine should only be used for the condition it is prescribed for. Do not use it for any other condition without consulting your doctor. Do not give it to other people even if their condition appears to be the same.

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

Antagonism with polyene antibiotics.

## 4.6 Fertility, pregnancy and lactation

Contraindicated; since Neomycin is contraindicated in pregnancy, the combination generic cannot be used in pregnant woman.

Pregnancy
There is inadequate evidence of safety in pregnancy. Clotrimazole has shown no teratogenic effect in animals but is foetotoxic at high oral doses.

Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There may therefore be a very small risk of such effects in human foetus. Hence Clotrimazole should only be used in pregnancy if the benefit justifies the potential risk to the foetus and such use should not be extensive i.e. in large amounts or for long periods.

Breast-feeding
It is not known whether the Clotrimazole components of are excreted in human milk and therefore caution should be exercised when treating nursing mothers.

### 4.7 Effects on ability to drive and use machines

There have been no studies to investigate the effect of Betamethasone Dipropionate, Clotrimazole and Neomycin Sulphate Cream on driving performance or the ability to operate machinery. A detrimental effect on such activities would not be anticipated from the adverse reaction profile of topical Betamethasone, Clotrimazole, Neomycin.

### 4.8 Undesirable effects

Adverse reactions reported for Clotrimazole cream include: burning and stinging, maculopapular rash, oedema, paraesthesia and secondary infection.

Reported reactions to clotrimazole include erythema, stinging, blistering, peeling, oedema, pruritus, urticaria and general irritation of the skin.

Reactions to betamethasone dipropionate include: burning, itching, irritation, dryness, folliculitis, hypertrichosis, acneiform eruptions, hyperpigmentation, hypopigmentation, perioral dermatitis, allergic contact dermatitis, maceration of the skin, secondary infection, skin atrophy, striae miliaria, capillary fragility (ecchymoses), blurred vision and sensitisation.

In children receiving topical corticosteroids, Hypothalamic-pituitary adrenal (HPA) axis suppression (HPA) axis suppression, Cushing's syndrome and intracranial hypertension have been reported.

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.

### 4.9 Overdose

This medicine may be harmful if swallowed.

## 5. PHARMACOLOGICAL PROPERTIES

### 5.1 Pharmacodynamic properties

Cream contains the dipropionate ester of betamethasone, a glucocorticoid exhibiting the general properties of corticosteroids, and clotrimazole which is an imidazole antifungal agent. Topical corticosteroids are effective in the treatment of a range of dermatoses because of their anti-inflammatory anti-pruritic and vasoconstrictive actions. Clotrimazole is a broad-spectrum antifungal agent with activity against Trichomones, Staphylococci and Bacteroides. Neomycin is an aminoglycoside antibiotic that primarily exerts its effect on bacterial cells by inhibiting polypeptide assembly and synthesis on the ribosome.

### 5.2 Pharmacokinetic properties

Cream intended for treatment of skin conditions and is applied topically. Thus there are minimal pharmacokinetic aspects related to bioavailability at the site of action.
Clotrimazole penetrates the epidermis after topical administration but there is little, if any, systemic absorption.
The extent of percutaneous absorption of topical corticosteroids is determined by many factors including vehicle, integrity of skin and use of occlusion.

Systemically absorbed topical corticosteroids are bound to plasma proteins metabolised in the liver and excreted by the kidneys. Some corticosteroids and their metabolites are also excreted in the bile.
Neomycin is poorly absorbed from the gastrointestinal tract and after topical administration an insufficient amount is absorbed to produce systemic effects. Absorption has been reported to occur from wounds and inflamed skin. After absorption neomycin is rapidly excreted by the kidneys in active form.

**5.3 Preclinical safety data**

There are no pre-clinical data of relevance to the prescriber which are additional to that already included in other sections of this SmPC.

## 6. PHARMACEUTICAL PARTICULARS

**6.1 List of excipients**

Para chloro meta cresol (PCMC) IHS
Sodium Methyl Paraben BP
Sodium Propyl paraben BP
Cetosteryl Alcohol BP
Ceto macrogol 1000 BP
White Petroleum jelly BP
Light Liquid Paraffin BP
Propylene Glycol USP
Disodium Edetate BP
Sodium Dihydrogen Phosphate BP
Phosphoric acid BP
Purified water BP

**6.2 Incompatibilities**

None.

**6.3 Shelf life**

36 months

**6.4 Special precautions for storage**

Store below 30C. Protect from light and moisture.

The medicines should be kept out of reach and sight of children.

**6.5 Nature and contents of container**

Betamethasone Dipropionate, Clotrimazole and Neomycin Sulphate Cream is packed in 30 gm laminated tube and packed. One tube is packed in carton along with package insert.

This is available in packs of 10g, 15g, 30g, 50 g and 100g. Not all pack sizes may be marketed.
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**6.6 Special precautions for disposal and other handling**

None.

## 7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

**Applicant**
SAM PHARMACEUTICAL LTD.
8/9, Oyadiran Estate, Sabo, Yaba-Lagos, Nigeria.

**Manufacturer**:
UNIZA LIFECARE PRIVATE LIMITED
SR. No. 919/7, (Old SR. No.404), Kadi-Detroj Road, Balasar,
Tal: Kadi, Dist: Mehsana, Gujarat. PIN: 382715, INDIA.

**8. MARKETING AUTHORIZATION NUMBER**
A4-100781

**9. DATE OF FIRST REGISTRATION / RENEWAL OF THE REGISTRATION**
**27TH MARCH 2024**

**10. DATE OF REVISION OF THE TEXT**
**30TH JULY 2027**