1.1 Name of the medicinal product:
FAMAZORAL (Ketoconazole Cream BP 2% W/W)

1.2 Qualitative and quantitative composition:
Composition:
-Ketoconazole BP.....2% W/W
- Cream Base (- QS)

Sr. No.	Ingredients	Specifi - cation	Label Claim w/w	Over- ages added (In %)	Quantity in % w/w	Reason for Function
1.	Ketoconazole	BP	2.00%	NA	2.00%	Medicament
2.	Cetostearyl Alcohol	BP	NA	NA	8.00%	Thickening Agent, Stabilizing Agent
3.	Cetomacrogol 1000	IH	NA	NA	2.00%	Emollient
4.	Light liquid paraffin	BP	NA	NA	10.00%	Emollient
5.	Hard paraffin Wax	BP	NA	NA	4.20%	Emollient
6.	Micro Crystalline Wax	IH	NA	NA	1.00%	Thickening agent
7.	Propylene Glycol	BP	NA	NA	3.00%	Solvent
8.	Butylated Hydroxytoluene	BP	NA	NA	0.05%	Preservative
9.	Chlorocresol	BP	NA	NA	0.10%	Preservative
10.	Purified Water	BP	NA	NA	69.65%	Vehicle

1.3 Pharmaceutical form: Cream
Description: White coloured cream

1.4 Clinical Particulars
4.1 Therapeutic indications
FAMAZORAL is indicated for topical application in the treatment of dermatophyte infections of the skin such as tinea corporis, tinea cruris, tinea manus and tinea pedis infections due to Trichophyton spp, Microsporon spp and Epidermophyton spp.
Ketoconazole cream is also indicated for the treatment of cutaneous candidosis (including vulvitis), tinea (pityriasis) versicolor and seborrhoeic dermatitis caused by Malassezia (previously called Pityrosporum) spp.

4.2 Posology and method of administration
Route: Topical
Posology
Ketoconazole cream is for use in adults.
Tinea pedis:
Ketoconazole Cream should be applied to the affected areas twice daily. The usual duration of treatment for mild infections is 1 week. For more severe or extensive infections (eg involving the sole or sides of the feet) treatment should be continued until a few days after all signs and symptoms have disappeared in order to prevent relapse.

For other infections:
Ketoconazole Cream should be applied to the affected areas once or twice daily, depending on the severity of the infection.
The treatment should be continued until a few days after the disappearance of all signs and symptoms. The usual duration of treatment is: tinea versicolor 2–3 weeks, tinea corporis 3–4 weeks.
The diagnosis should be reconsidered if no clinical improvement is noted after 4 weeks. General measures in regard to hygiene should be observed to control sources of infection or reinfection.
Seborrhoeic dermatitis is a chronic condition and relapse is highly likely.
Paediatrics
There are limited data on the use of ketoconazole 2% cream in paediatric patients.

4.3 Contraindications
-If you previously had an allergic reaction to Ketoconazole Cream BP 2% W/W (the active ingredient in this medicine) or any of the other ingredients of this medicine.
- For eye infections
Do not use this medicine if the above applies to you. If you are not sure, talk to your doctor or pharmacist before using FAMAZORAL cream.

4.4 Special warnings and precautions for use
Ketoconazole cream is not for ophthalmic use.
If co-administered with a topical corticosteroid, to prevent a rebound effect after stopping a prolonged treatment with topical corticosteroids it is recommended to continue applying a mild topical corticosteroid in the morning and to apply Ketoconazole Cream in the evening, and to subsequently and gradually withdraw the topical corticosteroid therapy over a period of 2-3 weeks

4.5 Interaction with other medicinal products and other forms of interaction
None Known

4.6 Pregnancy and Lactation
Pregnancy
There are no adequate and well-controlled studies in pregnant or lactating women. To date, no other relevant epidemiological data are available. Data on a limited number of exposed pregnancies indicate no adverse effects of topical ketoconazole on pregnancy or on the health of the foetus/newborn child. Animal studies have shown reproductive toxicity at doses that are not
relevant to the topical administration of ketoconazole. Plasma concentrations of ketoconazole are not detectable after topical application of ketoconazole cream to the skin of non-pregnant humans. There are no known risks associated with the use of ketoconazole cream in pregnancy or lactation.
Lactation
It is not known whether Ketoconazole cream, 2% administered topically could result in sufficient systemic absorption to produce detectable quantities in breast milk. Nevertheless, a decision should be made whether to discontinue nursing or discontinue the drug, taking into account the importance of the drug to the mother.

4.7 Effects on ability to drive and use machines
No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects
- Acne
- bleeding from sore in the mouth
- blistering, crusting, irritation, itching, or reddening of the skin
- burning, crawling, itching, numbness, prickling, "pins and needles", or tingling feelings
- cracked, dry, or scaly skin
- discoloration of the fingernails or toenails
- dizziness
- eye dryness, irritation, or swelling
- red rash with watery, yellow-colored, or pus filled blisters with or without thick yellow to honey-colored crusts
- skin dryness, pain, rash, redness, or swelling

- sore in the mouth or on the gums
- swelling of the face

4.9 Overdose
Topical Application
Excessive topical application may lead to erythema, oedema and a burning sensation, which will disappear upon discontinuation of the treatment.
Ingestion
In the event of accidental ingestion, supportive and symptomatic measures should be carried out.

5 Pharmacological properties
5.1 Pharmacodynamic properties
Pharmacotherapeutic group: Antifungals for Topical Use, Imidazole and triazole derivatives
ATC Code: D01AC08
Usually ketoconazole cream acts rapidly on pruritus, which is commonly seen in dermatophyte and yeast infections, as well as skin conditions associated with the presence of Malassezia spp. This symptomatic improvement is observed before the first signs of healing are observed.
Ketoconazole, a synthetic imidazole dioxolane derivative, has a potent antimycotic activity against dermatophytes such as Trichophyton spp., Epidermophyton floccosum and Microsporum spp. and against yeasts, including Malassezia spp. and Candida spp. The effect on Malassezia spp. is particularly pronounced.

5.2 Pharmacokinetic properties
Plasma concentrations of ketoconazole were not detectable after topical administration of **FAMAZORAL** in adults on the skin. In one study in infants with seborrhoeic dermatitis (n = 19), where approximately 40 g of **FAMAZORAL** was applied daily on 40% of the body surface area, plasma levels of ketoconazole were detected in 5 infants, ranging from 32 to 133 ng/mL.

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
Cetostearyl Alcohol, Cetomacrogol 1000, Light liquid paraffin, Hard paraffin Wax, Micro Crystalline Wax, Propylene Glycol, Butylated Hydroxytoluene, Chlorocresol, Purified Water.

6.2 Incompatibilities
Not applicable

6.3 Shelf life
36 months

6.4 Special precautions for storage
- Store at a temperature below 30° C.
- Do not freeze, Protect from direct sunlight.
- Keep all medicines out of the reach of children.
- Avoid contact with eyes.
- Keep the tube tightly close after use.

6.5 Nature and contents of container
Primary packing : 30 gm of cream filled in lami tube.
Secondary packing: Such one lami tube is packed in a carton along with leaflet.
Tertiary packing: 10 Cartons are packed in a shrink. Such 50 shrinks are packed in 5 ply shipper. Shippers to be sealed with BOPP tape.

6.6 Special precautions for disposal and other handling
None

7 Applicant / Manufacturer
Applicant

Applicant name and address	**M/s. BRANDS PHARMA AND GENERAL ENTERPRISES** A1, Umma Dantata Complex, Murtala Muhammad Way, Kano, Nigeria
Contact person's phone number	
Contact person's email	

Manufacturer

Manufacturer name and address	**M/s. ASTAMED HEALTHCARE (I) PVT. LTD.** Plot No. 2 & 3, Phase II, Genesis Ind. Complex, Kolgaon, Dist. Thane, Tal. Palghar, 401404 Maharashtra State, India
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