SUMMARY OF PRODUCT CHARACTERISTICS
(REBACTIN CREAM)

1. Name of the Medicinal Product: Rebactin Cream (Betamethasone Dipropionate, Clotrimazole & Neomycin sulphate Cream)

2. Qualitative and Quantitative Composition

Label Claim: w/w
Betamethasone Dipropionate USP
Eq. to Betamethasone …….0.05%
Neomycin sulphate USP
Eq. to Neomycin Base ……0.5%
Chlorocresol USP ……..0.1 %
Preservative:
Chlorocresol USP……...0.1%
Excipients……q.s.

3. Pharmaceutical Form

Cream

4. Clinical Particulars

4.1 Therapeutic indications

For the treatment of:

i. All dermatomycosis due to moulds and other fungi (e.g. *Trichophyton* species)

ii. All dermatomycosis due to yeasts (*Candida* species). These include ringworm (tinea) infections (e.g. athlete's foot), paronychia, pityriasis versicolor, erythrismal and intertrigo.

iii. Skin diseases showing secondary infection with these fungi.

iv. Candidal nappy rash, vulvitis and balanitis.

4.2 Posology and method of administration

Posology

There is no separate dosage schedule for the young or elderly.

Method of administration

The cream should be applied thinly and evenly to the affected area 2 – 3 times daily and rubbed in gently. A strip of cream (½ cm long) is enough to treat an area of about the size of the hand.

If the feet are infected, they should be thoroughly washed and dried, especially between the toes, before applying the cream.
Treatment should be continued for at least one month for dermatophyte infections, or for at least two weeks for Candidal infections.

4.3 Contraindications

Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
Do not use the cream to treat nail or scalp infections.

4.4 Special warnings and precautions for use

This product contains Cetostearyl alcohol, which may cause local skin reactions (e.g. contact dermatitis).

4.5 Interaction with other medicinal products and other forms of interaction

Laboratory tests have suggested that, when used together, this product may cause damage to latex contraceptives. Consequently the effectiveness of such contraceptives may be reduced. Patients should be advised to use alternative precautions for at least five days after using this product.

4.6 Fertility, pregnancy and lactation

Pregnancy:

There is a limited amount of data from the use of clotrimazole in pregnant women. Animal studies with clotrimazole have shown reproductive toxicity at high oral doses (see section 5.3). At the low systemic exposures of clotrimazole following topical treatment, harmful effects with respect to reproductive toxicity are not predicted. Clotrimazole can be used during pregnancy but only under the supervision of a physician or midwife.

Lactation:

Available Pharmacodynamic/toxicological data in animals have shown excretion of Clotrimazole/metabolites in milk after intravenous administration (see section 5.3). A risk to the suckling child cannot be excluded. A decision must be made whether to discontinue breast-feeding or to discontinue/abstain from clotrimazole therapy taking into account the benefit of breast-feeding for the child and the benefit of therapy for the woman.

Fertility:

No human studies of the effects of clotrimazole on fertility have been performed; however, animal studies have not demonstrated any effects of the drug on fertility.

4.7 Effects on ability to drive and use machines

Clotrimazole cream has no or negligible influence on the ability to drive or use machines.

4.8 Undesirable effects

As the listed undesirable effects are based on spontaneous reports, assigning an accurate frequency of occurrence for each is not possible.

Immune system disorders: allergic reaction (syncope, hypotension, dyspnoea, urticaria)

Skin and subcutaneous tissue disorders: blisters, discomfort/pain, oedema, erythema, irritation, peeling/exfoliation, pruritus, rash, stinging/burning.

4.9 Overdose

No risk of acute intoxication is seen as it is unlikely to occur following a single dermal application of an overdose (application over a large area under conditions favourable to absorption) or inadvertent oral ingestion. There is no specific antidote.

However, in the event of accidental oral ingestion, routine measures such as gastric lavage should be performed only if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). Gastric lavage should be carried out only if the airway can be protected adequately.

5. Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Antifungals for topical use – imidazole and triazole derivatives

ATC code: D01A C01

Mechanism of Action

Clotrimazole acts against fungi by inhibiting ergosterol synthesis. Inhibition of ergosterol synthesis leads to structural and functional impairment of the cytoplasmic membrane.

Pharmacodynamic Effects

Clotrimazole has a broad antimycotic spectrum of action *in vitro* and *in vivo*, which includes dermatophyte, yeasts, moulds, etc. Under appropriate test conditions, the MIC values for these types of fungi are in the region of less than 0.062-8.0 µg/ml substrate.

The mode of action of Clotrimazole is primarily fungi static or fungicidal depending on the concentration of Clotrimazole at the site of infection. *In vitro* activity is limited to proliferating fungal elements; fungal spores are only slightly sensitive.

In addition to its antimycotic action, Clotrimazole also acts on gram-positive microorganisms (Streptococci / Staphylococci / Gardnerellavaginalis), and gram-negative microorganisms (Bacteroides).

In vitro Clotrimazole inhibits the multiplication of Corynebacteria and gram-positive cocci - with the exception of Enterococcus - in concentrations of 0.5-10 µg/ml substrate.

Primarily resistant variants of sensitive fungal species are very rare; the development of secondary resistance by sensitive fungi has so far only been observed in very isolated cases under therapeutic conditions.

5.2 Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that Clotrimazole is minimally absorbed from the intact or inflamed skin into the human blood circulation. The resulting peak serum concentrations of Clotrimazole were below the detection limit of 0.001 mcg/ml, suggesting that Clotrimazole applied topically is unlikely to lead to measurable systemic effects or side effects.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on studies of repeated dose toxicity, genotoxicity and carcinogenicity.

Clotrimazole was not teratogenic in reproductive toxicity studies in mice, rats and rabbits. In rats high oral doses were associated with maternal toxicity, embryo toxicity, reduced fatal weights and decreased pup survival.

In rats Clotrimazole and/or its metabolites were secreted into milk at levels higher than in plasma by a factor of 10 to 20 at 4 hrs after administration, followed by a decline to a factor of 0.4

6. PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

Hard Paraffin Wax

Light Liquid Paraffin

Cetosteryl Alcohol

Cetamacrogal 1000

Micro crystalline Wax

Butylated Hydroxy Toluene

Propylene Glycol

Perfume Lavender

Parachlorometa cresol

6.2 Incompatibilities:

None Applicable

6.3 Shelf life:

36 months from the date of manufacture

6.4 Special Precautions for Storage:

Store below 30°C. Do not freeze.

6.5 Nature and Contents of Container

A **laminated tube** having respective over printed details, standard artwork, and standard colour scheme and containing white colour homogenous smooth cream **30 gm**.

6.6 Instructions for user handling

Carefully read the instructions before use. Consult your doctor for further information.

7.0 Marketing Authorization Holder:

IBU PHARMACY LTD.

8.0 Marketing Authorization Numbers:

Not Applicable

9.0 Date of the First Authorization or Renewal:

Not Applicable

10.0 Date of Revision of the Text:

Not Applicable