1.3 Product Information

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

1. NAME OF THE MEDICINAL PRODUCT

Name of product: KONIBION (Clotrimazole & Ichthammol Cream)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Label Claim:
Each gram contains
Clotrimazole BP ……..5 mg
Ichthammol BP ……2 mg
In Cream Base…….. QS

3. PHARMACEUTICAL FORM

Topical Cream

4. CLINICAL PARTICULARS

4.1 Therapeutic indications

KONIBION use For treatment of: All dermatomycoses due to moulds and other fungi (e.g. Trichophyton species). All dermatomycoses due to yeasts (Candida species). These include ringworm (tinea) infections (e.g. athlete's foot), paronychia, pityriasis versicolor, erythrasma and intertrigo. Skin diseases showing secondary infection with these fungi. iv. Candidal nappy rash, vulvitis and balanitis.

4.2 Posology and method of administration

Posology

KONIBION Apply twice daily to the affected skin. Treatment should be prolonged for 10 days after all skin diseases have disappeared to prevent relapse or as directed by the physician.

Method of administration

The **KONIBION** 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 candida infection.

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

KONIBION 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:

KONIBION has no interactions with medicines.

4.6 Fertility, pregnancy and lactation

KONIBION should not be used in pregnancy without medical advice.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Immune system disorders- Allergic reaction (syncope, hypotension, dyspnoea, urticaria). Skin and subcutaneous tissue disorder- Blisters, discomfort/pain, oedema, 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.

5.0 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Anti- Infective Agent.
ATC code: D01AC01

KONIBION is a combination of Clotrimazole & Ichthammol Cream, where Clotrimazole has a broad antimycotic spectrum of action in vitro and in vivo, which includes dermatophytes, yeasts, moulds, etc. The mode of action of KONIBION is fungistatic or fungicidal depending on the concentration of Clotrimazole at the site of infection.

Pharmacokinetic properties

Pharmacokinetic investigations after dermal application have shown that **KONIBION** 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.

5.2 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.

6.0 PHARMACEUTICAL PARTICULARS

6.1 List of Excipients

White soft Paraffin	BP
Cetosteryl Alcohol	BP
Cetamacrogal 1000	BP
Light Liquid Paraffin	BP
Para chloro meta cresol (Chlorocresol)	BP
Propylene Glycol	BP
Butylated Hydroxy Toluene	BP
Disodium EDTA	BP
Methyl Paraben	BP
Propyl Paraben	BP
Disodium hydrogen orthophosphate	BP
Sodium dihydrogen orthophosphate	BP
Perfume Ponds	BP
Purified Water	BP

6.2 Incompatibilities:

None reported

6.3 Shelf life:

36 months from the date of manufacture.

6.4 Special Precautions for Storage:

Do not freeze. Store below 30°C.
Keep all medicines out of reach of children.

6.5 Nature and Contents of Container

A 30 Gram Lami tube packed in Inner carton along with leaflet.

7. MARKETING AUTHORISATION HOLDER:

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8. MARKETING AUTHORISATION NUMBER:

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9. MANUFACTURER NAME:

Lesanto Laboratories,
Plot No. 9, 10, 11& 20, Survey No.53,
Palghar (E)-401404, Maharashtra India.

10. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION:
