1. Name of the Medicinal Product

1.1 Name of the Medicinal Product

ITCHNIL CREAM (Clotrimazole, Menthol, Ichthammol, Boric Acid & Zinc Oxide Cream)

1.2. Strength

Clotrimazole	USP	0.5%w/w
Menthol	USP	1.0%w/w
Ichthammol	USP	0.2%w/w
Boric Acid	BP	1.0%w/w
Zinc Oxide	BP	5.0%w/w

1.3. Pharmaceutical Dosage Form

Cream (Topical preparation)

2. Qualitative And Quantitative Composition

Qualitative Declaration

The **ITCHNIL CREAM** contains Clotrimazole USP, Menthol USP, Ichthammol USP, Boric Acid BP and Zinc Oxide BP.

Quantitative Declaration

Composition:

Clotrimazole	USP	0.5%w/w
Menthol	USP	1.0%w/w
Ichthammol	USP	0.2%w/w
Boric Acid	BP	1.0%w/w
Zinc Oxide	BP	5.0%w/w
Cream base		q.s.

3. Pharmaceutical Form

Cream

4. Clinical Particulars

4.1 Therapeutic Indications

For the treatment of skin infections due to dermatophytes (e.g. trycophyton species), yeasts (e.g. candida species), moulds and other fungi. These include ringworm (tinea) infections, paronychia, pityriasis versicolor, erythrasma and intertrigo.

4.2 Posology and Method of Administration

Posology

Apply the cream 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.

4.3 Contraindications

Known hypersensitivity to any of the components.

4.4 Special Warning and Precautions for Use

Do not use on the eyes or face. Do not use for other bites or stings or for other skin conditions.

Do not swallow or place in Nostrils. Keep away from Eyes.

4.5 Interaction with Other Medicinal Products and Other Forms of Interaction

There are no interactions with medicines

4.6 Pregnancy and lactation

Pregnancy

This product should not be used in pregnancy without medical advice.

Lactation

Contraindicated in breast feeding mothers.

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

In the event of accidental oral ingestion, gastric lavage is rarely required and should be considered only if a life-threatening amount of clotrimazole has been ingested within the preceding hour or if clinical symptoms of overdose become apparent (e.g. dizziness, nausea or vomiting). It should be carried out only if the airway can be protected adequately.

5.0 Pharmacological Properties

5.1 Pharmacodynamic properties

Pharmacotherapeutic group:

ATC code:

Clotrimazole D01AC01

Itchnil cream is a combination of Clotrimazole, Ichthammol, Zinc Oxide and Boric Acid 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 Itchnil Cream is fungistatic or fungicidal depending on the concentration of Clotrimazole at the site of infection.

5.2 Pharmacokinetic properties

Itchnil cream is minimally absorbed from the intact or inflamed skin into the human blood circulation.

5.3 Preclinical Safety Data

There is no pre-clinical safety data of relevance to the prescriber; therefore, none is presented in this section.

6.0 Pharmaceutical Particulars

6.1 List of Excipients

- Chlorocresol BP
- Bronopol BP
- Cetomacrogol Emulsifying wax BP
- Light liquid paraffin BP
- Petroleum Jelly (White) BP
- Propylene Glycol BP
- Cetostearyl Alcohol BP
- Citric Acid BP
- Purified water BP

6.2 Incompatibilities

None specific to this preparation.

6.3 Shelf Life

<36 Months>

6.4 Special Precautions for Storage

Store in a cool & dry place at a temperature not exceeding 30°C. Protect from light.

Do not freeze.

6.5 Nature and Contents of Container

ITCHNIL CREAM (Clotrimazole, Menthol, Ichthammol, Boric Acid & Zinc Oxide Cream) are available in 15gm lami tube.

6.6 Special Precautions for Disposal and Other Handling

None stated.

7. Registrant/Sole Agent

CHANNEL Pharmaceuticals Ltd.

Nigeria

8. Manufacturer

LABORATE PHARMACEUTICALS INDIA LIMITED

51, Industrial Area, Gondpur, Paonta Sahib, Himachal Pradesh (INDIA)

HO: E-11, Industrial Area, Panipat - 132103

9. Date of Revision of Text

To be given after approval of product

10. Dosimetry (If applicable)

Not applicable

11. Instructions for Preparation of Radiopharmaceuticals (If applicable)

Not applicable