SPONSOR'S NAME: MolendiiP Pharma Ltd

Product:

Dermalexin (5% topical cream)

Research Number:
DLX-412

Name(s):

Chemical Name: DLX-412

Generic Name: Dermalexiin (pending approval)

Trade Name(s):

Dermalexiin® *(fictional, included for sample purposes)*

INVESTIGATOR'S BROCHURE

Edition Number:
Version 1.0

Release Date:
22 April 2025

Replaces Previous Edition Number:
Not applicable (First Edition)

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1. Summary

Dermalexiin is a 5% topical cream developed for treating moderate-to-severe atopic dermatitis.

Nonclinical studies demonstrated local anti-inflammatory activity without systemic toxicity.

Phase I and IIa clinical trials support a favourable safety profile, with mild application-site reactions being the most common adverse events.

This brochure compiles the relevant nonclinical, pharmacological, and clinical data to guide investigators in the safe and effective use of Dermalexiin.

2. Introduction

Chemical Name: DLX-412

Pharmacological Class: Topical Anti-inflammatory Agent

Intended Use: Treatment of moderate-to-severe atopic dermatitis.

The investigational product offers a novel topical approach to modulate cytokine-driven inflammation in the skin without systemic immunosuppression.

The IB summarises the preclinical and clinical data, guiding investigators on the safe administration, monitoring, and management of Dermalexin.

3. Physical, Chemical, and Pharmaceutical Properties and Formulation

Description:

- White to an off-white, smooth cream.

Active Ingredient:

- DLX-412 (5% concentration).

Excipients:

- Purified water, glycerin, cetyl alcohol, emulsifying wax.

Solubility:

- Sparingly soluble in water; soluble in ethanol.

Storage Conditions:

- Store below 25°C. Protect from direct sunlight. Do not freeze.

There are no structural similarities to known mutagens or carcinogens.

4. Nonclinical Studies

4.1 Nonclinical Pharmacology

In murine models of allergic dermatitis, Dermalexin significantly reduced TNF-alpha and IL-6 levels at application sites. No behavioural changes, systemic signs of toxicity, or histological abnormalities were observed.

4.2 Pharmacokinetics and Product Metabolism in Animals

Topical application resulted in negligible systemic absorption (<0.2%).

No significant accumulation of DLX-412 or its metabolites was observed after repeated application.

4.3 Toxicology

- **Single-dose studies:** No adverse events up to 50x human equivalent dose.
- **Repeated dose studies (28 days):** No systemic toxicity detected.
- **Sensitisation studies:** No evidence of dermal sensitisation or irritation.

No studies indicated genotoxicity, carcinogenicity, or reproductive toxicity to date.

5. Effects in Humans

5.1 Pharmacokinetics and Metabolism

- Minimal systemic absorption after topical application.
- No evidence of systemic bioavailability based on plasma sampling.
- No effect on renal or hepatic clearance.

5.2 Safety and Efficacy

- **Phase I (N=24):** No serious adverse events. Mild transient burning in 8% of subjects.
- **Phase IIa (N=60):**
    - Application site burning (12%), mild erythema (9%), and pruritus (6%) were the most common adverse reactions.

- Statistically significant improvement in Eczema Area and Severity Index (EASI) scores at Week 4.

No dose-limiting toxicities identified.

5.3 Marketing Experience

Dermalexiin is not currently marketed in any country. No marketing authorisations have been granted or withdrawn.

6. Summary of Data and Guidance for Investigators

Investigators are advised:

- Apply Dermalexin once daily to affected areas for up to 12 weeks.
- Monitor participants at each visit for signs of skin irritation or hypersensitivity.
- Discontinue study treatment in cases of persistent or worsening local reactions.
- Report all adverse events per protocol, including documentation in the Case Report Form (CRF).
- Refer to the **Reference Safety Information (RSI)** for expected adverse reactions:
  - Application site burning
  - Mild erythema
  - Pruritus

Any serious and unexpected adverse events must be reported to MolendiiP Pharma Ltd immediately.

References

1. International Council for Harmonisation (ICH). *E6(R2) Guideline for Good Clinical Practice*. 2016. Available at: https://ichgcp.net
2. International Council for Harmonisation (ICH). *E3 Guideline: Structure and Content of Clinical Study Reports*. 1995.
3. EMA Guidelines for Good Clinical Practice. European Medicines Agency (EMA), 2021.

Disclaimer:

This sample Investigator's Brochure was created for educational purposes only. MolendiiP Pharma Ltd, Dermalexiin, and the study described are fictional.