**IRISH MEDICINES BOARD ACTS 1995 AND 2006**

**MEDICINAL PRODUCTS(CONTROL OF PLACING ON THE MARKET)REGULATIONS,2007**

**(S.I. No.540 of 2007)**

**PA0812/002/005**
Case No: 2072367

The Irish Medicines Board in exercise of the powers conferred on it by the above mentioned Regulations hereby grants to

**Recordati Pharmaceuticals Limited**

**Via Matteo Civitali**, **20148**, **Milan**, **Italy**

an authorisation, subject to the provisions of the said Regulations, in respect of the product

**Lomexin 2% w/v Cutaneous Spray, Solution**

The particulars of which are set out in Part I and Part II of the attached Schedule. The authorisation is also subject to the general conditions as may be specified in the said Regulations as listed on the reverse of this document.

This authorisation, unless previously revoked, shall continue in force from **28/01/2010**.

Signed on behalf of the Irish Medicines Board this

_____

A person authorised in that behalf by the said Board.

# Part II

# Summary of Product Characteristics

## 1 NAME OF THE MEDICINAL PRODUCT

Lomexin 2% w/v Cutaneous Spray, Solution

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fenticonazole nitrate 2.0% w/w

Excipients: contains propylene glycol (E1520) 31.0% w/v.

For a full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Cutaneous spray, solution. (cutaneous spray)

A clear, colourless solution.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic Indications

For the topical treatment of infections due to *C. albicans* or superficial dermatophytes sensitive to the drug, and the control of pityriasis versicolor. Imidazole derivatives have been used successfully in the treatment of onychomycosis and erythrasma.

### 4.2 Posology and method of administration

For cutaneous use.

Apply once or twice daily.

### 4.3 Contraindications

Lomexin should not be used in patients hypersensitive to imidazoles.

### 4.4 Special warnings and precautions for use

Treated areas should not be specifically exposed to sunlight.

Lomexin should only be applied to a limited area of skin.

If there is no improvement or there is aggravation of the condition, the physician should be consulted.

### 4.5 Interaction with other medicinal products and other forms of interaction

None known.

## 4.6 Pregnancy and lactation

Reproduction studies showed embryotoxic effects at high oral dosage in one species (rat) of two tested.

There is no experience of use during pregnancy or lactation in human beings. Although the results of oral dosage are unlikely to be relevant for topical application in man, use during pregnancy or lactation should be avoided unless deemed essential by the physician.

## 4.7 Effects on ability to drive and use machines

None known.

## 4.8 Undesirable effects

Lomexin is generally well tolerated, both on the skin and on the mucosa: mild and transient erythematous reactions or burning sensations at the site of application have been reported, but they normally disappear rapidly. In the event of more persistent irritations, hypersensitivity reactions or the development of resistant micro-organisms, treatment must be discontinued.

Lomexin is poorly absorbed in the recommended conditions of use; systemic consequences may therefore be excluded.

In the clinical study program, a total of 55 patients (3.3%) treated with Lomexin for superficial mycosis reported adverse events. In the table below, adverse reactions for which a reasonable causal relationship exists are listed by MedDRA system organ class and frequency: very common (≥ 1/10); common (≥ 1/100 to <1/10); uncommon (≥ 1/1,000 to <1/100); rare (≥ 1/10,000 to <1/1,000); very rare (<1/10,000), not known (frequency cannot be estimated from available data).

| | Uncommon | Not known |
|---|---|---|
| Nervous system disorders | Burning sensation | |
| Skin and subcutaneous tissue disorders | Eczema<br>Skin exfoliation<br>Skin irritation<br>Erythema<br>Pruritus | Rash |
| General disorders and administration site conditions | Oedema | |

From post-marketing experience the occurrence of adverse reactions (contact dermatitis, pruritus, skin irritation, rash erythematous, oedema) has been very rare.

## 4.9 Overdose

Due to the topical administration of this product overdosage has never been encountered.

# 5 PHARMACOLOGICAL PROPERTIES

## 5.1 Pharmacodynamic properties

ATC code: D01 A C12

An imidazole antimycotic.

## 5.2 Pharmacokinetic properties

Lomexin has low (0.5%) systemic absorption which may increase if applied to broken or inflamed skin.

## 5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to that already included in other sections of the SPC.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 List of excipients

Propylene glycol (E1520)
Ethanol
Purified water

## 6.2 Incompatibilities

Not applicable.

## 6.3 Shelf Life

3 years.

## 6.4 Special precautions for storage

Do not store above 25°C.

## 6.5 Nature and contents of container

Type III amber glass bottle with aluminium seal and plastic spray valve containing 30ml of spray.

Not all pack sizes may be marketed.

## 6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

# 7 MARKETING AUTHORISATION HOLDER

Recordati Industria Chimica e Farmaceutica SpA
Via Matteo Civitali
20148 Milan
Italy

# 8 MARKETING AUTHORISATION NUMBER

PA 812/2/5

## 9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first atuthorisation: 25 July 1988
Date of last renewal: 25 July 2008

## 10 DATE OF REVISION OF THE TEXT

January 2010