IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0030/030/001
Case No: 2061350

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

Novartis Consumer Health UK Ltd

Wimblehurst Road, **Horsham**, **West Sussex RH12 5AB**, **England**

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

Lypsyl Cold Sore Gel.

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 **12/06/2009** until **01/08/2010**.

Signed on behalf of the Irish Medicines Board this

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A person authorised in that behalf by the said Board.

Part II

Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Lypsyl Cold Sore Gel.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Lidocaine hydrochloride	2.0 % w/w
Zinc sulphate	1.0 % w/w
Cetrimide	0.5 % w/w

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Gel.

A colourless, viscous gel with a characteristic menthol odour.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of cold sores.

Route of administration: Topical.

4.2 Posology and method of administration

A small amount of Lypsyl Cold Sore Gel should be applied to the affected area with a clean finger tip at the first sign of infection, and then 3 – 4 times a day. The product should not be washed off.

4.3 Contraindications

Patients with a known hypersensitivity to lidocaine hydrochloride, zinc sulphate or cetrimide should not use the product.

Not recommended for children under 12 years.

4.4 Special warnings and precautions for use

For external use only.

Contact with the eyes should be avoided. In the event of aggravation discontinue use. Wash hands after use. If symptoms persist, consult your doctor.

Keep out of the reach and sight of children.

4.5 Interaction with other medicinal products and other forms of interaction

No known interactions with other drugs.

4.6 Pregnancy and lactation

No special warning stated.

4.7 Effects on ability to drive and use machines

None known.

4.8 Undesirable effects

Skin irritation and occasional sensitisation may occur.

4.9 Overdose

There are no known cases of overdose.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Lidocaine hydrochloride is a local anaesthetic of the amide type which is widely used for local application to mucous membranes. It produces surface anaesthesia by diminishing or preventing the conduction of sensory nerve impulses.

Cetrimide is a quaternary ammonium disinfectant. As well as having emulsifying and detergent properties, it is active against gram-positive and some gram-negative organisms.

Zinc sulphate has astringent properties.

5.2 Pharmacokinetic properties

Lidocaine hydrochloride is effectively absorbed from mucous membranes.

5.3 Preclinical safety data

Not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methylhydroxyethylcellulose 3000
Polysorbate 20
Nonoxinol 9
Propylene glycol
Levomenthol
Purified water

6.2 Incompatibilities

None known.

6.3 Shelf Life

3 years.

6.4 Special precautions for storage

Do not store above 30°C.

6.5 Nature and contents of container

Laminated tube consisting of aluminium foil coated internally and externally with low density polyethylene or high density polyethylene.

Pack size 3g or 5g.

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

Keep out of reach and sight of children.

7 MARKETING AUTHORISATION HOLDER

Novartis Consumer Health UK Ltd.,
Trading as: Novartis Consumer Health,
Wimblehurst Road,
Horsham,
West Sussex RH12 5AB
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 0030/030/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 2nd August 1990

Date of last renewal: 2nd August 2005

10 DATE OF REVISION OF THE TEXT

April 2007