

IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0144/016/002

Case No: 2024587

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

Stiefel Labs (U.K.) Ltd.

Holtspur Lane, Wooburn Green, Bucks HP10 0AU, England

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

Stiemycin 2% w/w 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 **25/09/2006**.

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

Stiemycin 2% w/w Gel

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Erythromycin 2% w/w.

For full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Gel
Clear, colourless gel

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Stiemycin Gel is indicated for the topical treatment of mild to moderate acne vulgaris.

4.2 Posology and method of administration

Adults:

Apply Stiemycin Gel to the whole of the affected area twice daily after washing with soap and water. Patients should be advised that a therapeutic effect may not be seen until after 6-8 weeks of treatment. Treatment should be continued for at least 12 weeks.

Elderly Patients:

There are no specific recommendations. Acne vulgaris does not present in the elderly.

Paediatric use:

The safety and efficacy of Stiemycin Gel has not been established in children since acne vulgaris rarely presents in this age group.

4.3 Contraindications

Stiemycin Gel is contra-indicated in patients with known hypersensitivity to any of the ingredients.

4.4 Special warnings and precautions for use

Avoid contact with the eyes, mouth and other mucous membranes.

4.5 Interaction with other medicinal products and other forms of interaction

Concomitant topical acne therapy should be used with caution, because a cumulative irritant effect may occur.

4.6 Pregnancy and lactation

There is no evidence of hazard from erythromycin in human pregnancy. It has been in wide use for many years without ill consequence. There is no restriction on the use of Stiemycin Gel in pregnancy.

Use during Lactation

There is no restriction on the use of Stiemycin Gel during lactation.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Dryness, reddening of the skin and a burning sensation can occur. Such reactions are normally mild and do not necessitate discontinuation of treatment.

4.9 Overdose

Acute overdose of Stiemycin Gel has not been reported to date. Systemic ingestion of erythromycin resulting in overdose has been associated with hearing loss, severe nausea, vomiting and diarrhoea. Treatment by gastric lavage and general supporting therapy is recommended.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Erythromycin is a macrolide antibiotic which acts by interfering with bacterial protein synthesis. Its spectrum of activity includes *Propionibacterium acnes*, the organism implicated in acne vulgaris. Erythromycin also has anti-inflammatory properties.

5.2 Pharmacokinetic properties

The evaluation of erythromycin absorption into the blood stream following topical use in acne vulgaris, has been reported in the literature. No erythromycin was detected in the serum even after extensive application.

A study of percutaneous absorption of erythromycin following topical application of Stiemycin Solution to acne patients showed no detectable absorption. Stiemycin Solution contains 2% erythromycin in an alcohol/propylene glycol vehicle. The product was applied topically twice daily over two weeks and serum levels were measure by bioassay.

5.3 Preclinical safety data

The clinical and preclinical safety of erythromycin is well established. The compound has been in wide use for many years.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ethanol
Hyprollose

6.2 Incompatibilities

Not applicable

6.3 Shelf Life

2 years

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and contents of container

Internally lacquered aluminium tubes with polypropylene screw caps.
Pack contents: 25g.

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

Stiefel Laboratories (UK) Limited
Holtspur Lane
Wooburn Green
High Wycombe
Bucks HP10 0AU
UK

8 MARKETING AUTHORISATION NUMBER

PA 144/16/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 25th September 1996

Date of last renewal: 25th September 2006

10 DATE OF REVISION OF THE TEXT

November 2006