IRISH MEDICINES BOARD ACTS 1995 AND 2006

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

(S.I. No.540 of 2007)

PA0118/026/001
Case No: 2053248

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

Chauvin Pharmaceuticals Limited

106 London Road, **Kingston-upon-Thames**, **Surrey**, **KT2 6TN**, **United Kingdom**

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

Fluorets 1 mg

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 **25/07/2008**.

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

Fluorets 1mg

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Paper strips each impregnated with approximately 1mg Fluorescein Sodium.

3 PHARMACEUTICAL FORM

Ophthalmic strip.
Sterile, smooth narrow paper strip coloured orange contained in a sachet.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Fluorescein is a corneal stain and can be used in diagnostic examinations of the eye including Goldmann tonometry and in the fitting of contact lenses.

4.2 Posology and method of administration

One Fluorets moistened with tear fluid, sterile water or sterile ophthalmic solution applied topically to the eye should be sufficient to provide adequate corneal staining.

4.3 Contraindications

Not to be used with soft contact lenses.

Not for use in patients with a known hypersensitivity to fluorescein.

4.4 Special warnings and precautions for use

Care should be taken to handle the strip by the non-impregnated end. The applicator should be used once and discarded.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Pregnancy and lactation

Safety for use in pregnancy and lactation has not been established, therefore, use only when considered essential by a physician.

4.7 Effects on ability to drive and use machines

May cause transient blurring of vision when applied. Warn patients not to drive or operate hazardous machinery unless vision is clear.

4.8 Undesirable effects

ADRs are very rare (<1/10,000), including isolated reports.

Symptoms of allergic-type reactions and anaphylaxis have been reported following topical ophthalmic administration of Fluorescein sodium and may manifest as:

Eye disorders: allergic conjunctivitis, peri-orbital oedema

Immune system disorders: anaphylactic reaction

Skin and subcutaneous tissue disorders: urticaria, rash

4.9 Overdose

Not applicable.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Fluorescein sodium acts as a diagnostic stain.

5.2 Pharmacokinetic properties

Fluorescein will resist penetration of a normal cornea and most excess solution will, therefore, be carried with the tear film away from the conjunctival sac. The majority will be lost through the naso-lacrimal ducts and absorbed via the gastro-intestinal tract from where it is converted rapidly to its glucuronide and excreted via the urine.

If fluorescein crosses the cornea it will enter the Bowman’s membrane, stroma and possibly the anterior chamber. Aqueous flow and diffusion into the blood in the anterior chamber finally removes fluorescein from the eye and it is excreted unchanged in the urine.

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 this SPC.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

None.

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

5 years.

6.4 Special precautions for storage

Do not store above 25°C. Do not freeze. Store in the original package in order to protect from light.

6.5 Nature and contents of container

Sterile paper strips contained in sachets, supplied in cartons of 100 Flourets.

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

Each strip should be handled by the non-impregnated end. Strips should be used once and discarded.

7 MARKETING AUTHORISATION HOLDER

Chauvin Pharmaceuticals Ltd.
106 London Road
Kingston-upon-Thames
Surrey
United Kingdom

8 MARKETING AUTHORISATION NUMBER

PA 118/26/1

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st November 1982

Date of last renewal: 1st November 2007

10 DATE OF REVISION OF THE TEXT

July 2008