IRISH MEDICINES BOARD ACT 1995

MEDICINAL PRODUCTS(LICENSING AND SALE)REGULATIONS, 1998

(S.I. No.142 of 1998)

PA0540/123/002
Case No: 2029151

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

sanofi-aventis Ireland Limited

Citywest Business Campus, **Dublin 24**, **Ireland**

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

RYNACROM 2% w/v Nasal 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 **26/10/2006** until **14/02/2010**.

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

Rynacrom 2 % w/v Nasal Spray, solution.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each metered dose contains 2.6 mg sodium cromoglicate.

For excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, solution.

A clear, colourless or pale yellow aqueous solution.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Rynacrom is indicated for the preventative treatment of allergic rhinitis (seasonal and perennial)

4.2 Posology and method of administration

For nasal use.

Adults and children:
One spray to each nostril four to six times daily at three to four hourly intervals (i.e. on average daily dosage between 10.4 mg and 15.6 mg).

4.3 Contraindications

Rynacrom is contraindicated in patients with known sensitivity to sodium cromoglicate or any of the other ingredients.

4.4 Special warnings and precautions for use

Since the treatment is primarily protective, it should be continued as directed by the physician.
The product is for nasal use only.

4.5 Interaction with other medicinal products and other forms of interaction

Not known.

4.6 Pregnancy and lactation

Cumulative experience with sodium cromoglicate suggests that it has no effects on foetal development. However, it should be used in pregnancy only if there is a clear need.

On the basis of animal studies and its physiochemical properties, sodium cromoglicate is considered unlikely to pass

into human breast milk. There is no information to suggest that use of sodium cromoglicate by nursing mothers has any undesirable effects on the baby.

4.7 Effects on ability to drive and use machines

Rynacrom has no known effect on the ability to drive or operate machinery.

4.8 Undesirable effects

Occasional irritation of the nasal mucosa may occur during the first days of use. There have been rare reports of alopecia, parosmia and epistaxis.

4.9 Overdose

No action other than medical supervision should be necessary

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

In vitro and in vivo animal studies have shown that sodium cromoglicate inhibits the degranulation of sensitised mast cells which occurs after exposure to specific antigens. Sodium cromoglicate acts by inhibiting the release of histamine and various membrane derived mediators of inflammation from mast cells. Sodium cromoglicate has no intrinsic vasoconstrictor or antihistamine activity.

5.2 Pharmacokinetic properties

After intranasal administration of sodium cromoglicate the drug is absorbed, mostly in the nose, to the extent of approximately 7% of the dose.

The absorbed fraction is cleared rapidly as sodium cromoglicate has a high systemic clearance (plasma clearance 7.9 ± 0.9 ml.min.kg) and accumulation, therefore, does not occur. The bulk of the nasal dose is expelled from the nose or swallowed and largely eliminated unchanged via the alimentary tract, as absorption from the gut is low (<1%).

Sodium cromoglicate is reversibly bound to plasma proteins (approximately 65%) and is not metabolised, being excreted unchanged in the bile and urine in approximately equal proportions.

5.3 Preclinical safety data

No relevant data.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium edetate
Benzalkonium chloride
Water, purified

6.2 Incompatibilities

None stated.

No other medicaments should be mixed with the solution.

6.3 Shelf Life

Unopened: 3 years
Opened: once opened, use within one month

6.4 Special precautions for storage

Do not store above 25°C. Keep the bottle in the outer carton.

6.5 Nature and contents of container

White HDPE bottle fitted with a polypropylene metered dose pump and cap and packaged in an outer box.
Pack sizes: 10 ml, 13 ml and 26 ml
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

If the nasal spray is new, it should be primed by pressing the nozzle downwards and releasing it at least 3 times until a fine spray of Rynacrom is produced.
Detailed instruction for use are contained in the Patient Information Leaflet supplied with each pack.

7 MARKETING AUTHORISATION HOLDER

sanofi-aventis Ireland Ltd.
Citywest Business Campus
Dublin 24.

8 MARKETING AUTHORISATION NUMBER

PA 540/123/2

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 20th July 1983
Date of last renewal: 15th February 2005

10 DATE OF REVISION OF THE TEXT

October 2006