Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Intal Spincaps 20mg Inhalation Powder Capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each hard capsule contains 20mg Sodium Cromoglicate.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Inhalation powder, hard capsule
Hard capsule with transparent yellow cap and clear body printed in black “Sodium Cromoglicate 20 mg” and intended for use with the SPINHALER inhalation device.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Intal is indicated for the preventative treatment of bronchial asthma in adults and children, including the prevention of exercise-induced asthma.

4.2 Posology and method of administration

Intal Spincaps must be administered via a SPINHALER. The capsules are not effective if swallowed. Since Intal therapy is essentially preventative, it is important that the patient is instructed to maintain regular dosage, as distinct from inhaling the drug intermittently to relieve symptoms.

Adults (including the elderly) and children: The recommended dosage is one capsule night and morning and at regular intervals of 3 to 6 hours during the day. The dose may be increased to one capsule 6 or 8 times daily in more severe cases or during periods of severe antigen challenge. Additional doses may be taken before exertion to prevent exercise-induced asthma or before exposure to other trigger factors.

When the asthmatic condition is stabilised it may be possible to reduce the dosage provided that adequate control of the asthma is maintained.

Concomitant bronchodilator therapy: Where a concomitant aerosol bronchodilator is prescribed it is recommended that this be administered prior to the Intal Spincaps.

If bronchodilators are used concomitantly, patients may find that the frequency of bronchodilator usage can be reduced as their asthma is stabilised with Intal.

Concomitant steroid therapy: In patients currently treated with steroids the addition of Intal to the regimen may make it possible to reduce the maintenance dose, or discontinue therapy completely. The patient must be carefully supervised while the steroid dose is reduced; a rate of reduction of 10% weekly is suggested. An increase in steroid dosage may be necessary if symptoms increase and at times of infection, severe antigen challenge or stress.

If reduction of a steroid dosage has been possible Intal should not be withdrawn until steroid cover has been re-instituted.

4.3 Contraindications

Intal is contraindicated in patients with known sensitivity to sodium cromoglicate or any of the excipients.

4.4 Special warnings and precautions for use

INTAL should be discontinued if an eosinophilic pneumonia appears (see section 4.8).

INTAL must not be used for relief of an acute attack of bronchospasm.

In those cases where reduction of steroid treatment is attempted in patients receiving sodium cromoglicate, the patient must be carefully supervised while steroid dose is reduced in a step-wise fashion. If possible, peak flow monitoring should be continued during such reductions and patients should be given instructions about what action to take if deterioration of asthma symptoms occurs.

Withdrawal of INTAL therapy: Since the therapy is prophylactic it is important to continue therapy in those patients who benefit. If it is necessary to withdraw treatment, it should be done progressively over a period of one week. Symptoms of asthma may recur, following withdrawal of treatment.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

As with all medication, caution should be exercised especially during the first trimester of pregnancy. There are no adequate and well-controlled studies in pregnant women. Cumulative experience with sodium cromoglicate does not suggest an association between the drug and congenital defects. It should be used in pregnancy only if the benefit to the mother outweighs the potential risk to the foetus.

It is unknown if this drug is excreted in human milk. Cumulative post-marketing experience with sodium cromoglicate used by nursing mothers does not suggest an adverse effect on the infant. It should be used in nursing mothers only if the benefit to the mother outweighs the potential risk to the infant.

4.7 Effects on ability to drive and use machines

None.

4.8 Undesirable effects

Mild throat irritation, coughing and transient bronchospasm may occur. Hypersensitivity reactions, including angioedema, bronchospasm, hypotension and collapse have been reported extremely rarely, in patients using inhaled sodium cromoglicate.

As with other inhalation therapy, paradoxical bronchospasm may occur immediately after administration: in such cases the product should be discontinued and alternative treatment instituted. Very rarely, severe bronchospasm associated with a marked fall in pulmonary function has been reported. In such cases treatment should be stopped and not reintroduced.

Very rare cases of eosinophilic pneumonia have been reported .

4.9 Overdose

Treatment should be supportive and directed to the control of the relevant symptoms.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Sodium cromoglicate is believed to act by inhibiting the release of chemical mediators from a range of inflammatory cells including mast cells, eosinophils and neutrophils, thereby preventing the allergic reaction in the lung. This anti-inflammatory effect prevents the symptoms of asthma.

5.2 Pharmacokinetic properties

After inhalation as a dry powder via the Spinhaler, around 5% to 15% of the dose of sodium cromoglicate enters the lung and is absorbed from the respiratory tract, from where it is excreted unchanged in the urine and bile. The proportion deposited in the lung depends on the inspiratory flow rate.

The majority of an inhaled dose is swallowed and excreted unchanged via the alimentary canal.

5.3 Preclinical safety data

Animal studies have shown that sodium cromoglicate has a very low order of local or systemic toxicity.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Gelatin
Quinoline yellow (E104)
Erythrosine (E127)
Black iron oxide (E172)
Shellac-pharmaceutical grade
Propylene glycol
Ammonium hydroxide
Potassium hydroxide

6.2 Incompatibilities

Not applicable

6.3 Shelf life

5 years.

6.4 Special precautions for storage

Store in the original package in a dry place, in order to protect from light and moisture.
Do not store above 25°C.
It is acceptable for up to four of the ‘Spincaps’ to be stored in the Spinhaler carrying case for up to 24 hours.

6.5 Nature and contents of container

HDPE bottle with a polypropylene screw cap. Bottles of 56 Spincap cartridges are available in packs of two.
AC/PVDC strip of 50, 100 or 120 Spincap cartridges in a laminated sachet packaged in an outer box.
Spinhaler insufflators are supplied in individual containers.

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

Refer to section 4.2.

7 MARKETING AUTHORISATION HOLDER

Sanofi-Aventis Ireland Ltd. T/A SANOFI
Citywest Business Campus
Dublin 24
Ireland.

8 MARKETING AUTHORISATION NUMBER

PA 540/104/1

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10 DATE OF REVISION OF THE TEXT

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