# DATA SHEET

## 1 INTAL FORTE (5MG AEROSOL INHALER, METERED DOSE)

Intal Forte 5 mg aerosol inhaler, metered dose

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The active component of INTAL FORTE 5 mg CFC-free is sodium cromoglycate 3.521% w/w. Each canister provides at least 112 actuations each containing 5 mg of sodium cromoglycate.

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

INTAL FORTE 5 mg CFC-free is presented as a metered dose inhaler containing sodium cromoglycate as a suspension in the non - CFC propellant HFA-227, for inhalation.

Sodium cromoglycate is a white crystalline odourless powder.

## 4 CLINICAL PARTICULARS

### 4.1 THERAPEUTIC INDICATIONS

INTAL FORTE 5 mg CFC-free is indicated for the preventive treatment of bronchial asthma (which may be due to allergy, exercise, cold air or chemical irritants) in adults and children.

### 4.2 DOSE AND METHOD OF ADMINISTRATION

#### Dose

INTAL FORTE 5 mg CFC-free therapy is preventative, it is therefore important that regular dosing should be maintained. The patient should be advised that because several doses may be needed to establish benefit, relief may not be apparent immediately, but may take some weeks to develop.

### Adults and children

The recommended dosage is 10 mg of sodium cromoglycate (as two 5 mg inhalations of the aerosol) four times daily. (The suggested dosage regimen is two inhalations at bedtime, and on waking in the morning, and at regular intervals of 3 to 6 hours during the day). The dose may be increased to two inhalations six or eight times daily in more severe cases or during periods of high antigen challenge.

When the asthmatic condition is stabilised, it is sometimes possible to reduce the dosage, but this must be carefully assessed for each individual patient, to ensure adequate control of asthma.

The addition of sodium cromoglycate in patients currently treated with oral or inhaled steroids, may allow reduction or discontinuation of the steroid dose.

For protection against bronchospasm induced by exercise or other known trigger factors, INTAL FORTE 5 mg CFC-free should be used 15 - 30 minutes before exposure to the factor concerned.

### Method of administration

The inhaler should be well shaken, the dust cap removed and after each actuation the aerosol inhaled slowly and deeply. To avoid condensation of moisture in the inhaler and blocking of the spray, exhalation through the inhaler should be avoided. The dust-cap should be replaced following use.

If the inhaler is new, it should be primed by actuating 4 times prior to inhalation. Re-priming of the inhaler is not required where periods of non-use are between zero and two days (ie. less than 48 hours). If there is a period of non-use of between 3 and 7 days, additional priming with 2 actuations is advised. If the inhaler is not used beyond seven days, additional priming with 4 actuations is advised.

It is essential to instruct the patient how to use the Inhaler correctly. Patients with difficulty coordinating inhalation may find a spacer device or a holding chamber helpful.

## 4.3 CONTRAINDICATIONS

INTAL FORTE 5 mg CFC-free is contraindicated in patients with known hypersensitivity to any of its constituents.

## 4.4 SPECIAL WARNINGS AND PRECAUTIONS FOR USE

INTAL FORTE 5 mg CFC-free should not be used for the relief of an acute attack of bronchospasm.

In those cases where reduction of steroid treatment is attempted in patients receiving sodium cromoglycate, the patient must be carefully supervised while the steroid dose is reduced in a

stepwise 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.

If it is necessary to withdraw treatment, it should normally be done progressively over a period of one week. Symptoms of asthma may recur, following withdrawal of treatment.

INTAL FORTE 5 mg CFC-free should be discontinued if an eosinophilic pneumonia appears.

To prevent excessive accumulation of powder the plastic body and mouthpiece cover should be washed twice a week and then thoroughly dried.

## 4.5 INTERACTION WITH OTHER MEDICINES AND OTHER FORMS OF INTERACTION

Sodium cromoglycate has been used for the treatment of a variety of indications for many years and no evidence of clinically significant drug interactions has been detected in post-marketing surveillance, nor is expected for sodium cromoglycate, due to its pharmacokinetic properties (no metabolism, moderate plasma protein binding, low plasma concentrations) and its high safety profile.

## 4.6 FERTILITY, PREGNANCY AND LACTATION

### Pregnancy

Category A

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 post-marketing experience with sodium cromoglycate 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 fetus.

### Breast-feeding

It is unknown if this drug is excreted in human milk. Cumulative post-marketing experience with sodium cromoglycate 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.

### Fertility

No data available.

### 4.7 EFFECTS ON ABILITY TO DRIVE AND USE MACHINES

INTAL FORTE 5 mg CFC-free has no known effect on ability to drive or operate machinery.

### 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 cromoglycate.

Very rare cases of eosinophilic pneumonia have been reported.

As with other inhalation therapy, paradoxical bronchospasm may occur immediately after administration: in such cases the product should be discontinued and alternative treatment instituted.

#### Reporting of suspected adverse reactions

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare professionals are asked to report any suspected adverse reactions https://nzphvc.otago.ac.nz/reporting/.

### 4.9 OVERDOSE

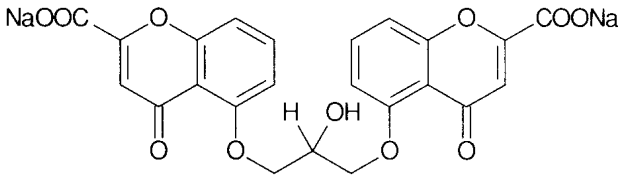
Animal studies have shown that sodium cromoglycate has a very low local or systemic toxicity and extended human studies have not revealed any safety hazard with products containing sodium cromoglycate. Overdosage is therefore unlikely to cause problems, but, if suspected, treatment should be supportive and directed to the control of the relevant symptoms.

For advice on the management of overdose please contact the National Poisons Centre on 0800 POISON (0800 764766).

## 5 PHARMACOLOGICAL PROPERTIES

### 5.1 PHARMACODYNAMIC PROPERTIES

Pharmacotherapeutic group: drugs for obstructive airway disease; Antiallergic agents, exclusive corticosteroids, ATC code: RO3BC01.



CAS No. [15826-37-6]

Chemically it is the disodium salt of 1, 3 bis (2 carboxychromon 5 yloxy) 2 hydroxypropane. It is soluble in 20 parts water at 20°C.

Sodium cromoglycate inhibits the activation of many of the cell types involved in the development and progression of asthma. Thus, sodium cromoglycate inhibits the release of inflammatory mediators including cytokines from mast cells and reduces the chemotactic activity of eosinophils and neutrophils. Activation of and mediator release from monocytes and macrophages in vitro is also reduced by sodium cromoglycate.

Sodium cromoglycate inhibits antigen-induced early and late phase airway obstruction in conscious animals and reduces the influx of inflammatory cells into the airways. The drug also inhibits sensory nerve (C fibre) activation in the dog lung and inflammatory responses induced by neuronal stimulation in the airways of animals.

This diverse range of activities of the drug may be explained by the ability of sodium cromoglycate to block chloride channels in different cell types which are important in cell activation.

In acute bronchial provocation tests in humans, sodium cromoglycate has been shown to inhibit or diminish the asthmatic reaction to antigen, exercise and to a range of non-specific triggers including cold air, sulphur dioxide, hypertonic saline and bradykinin. Antigen-induced increased bronchial hyperactivity to histamine is prevented and a reduction in bronchial mucus eosinophils and antigen-specific IgE occurs after 4 weeks treatment of asthmatic subjects with sodium cromoglycate.

## 5.2 PHARMACOKINETIC PROPERTIES

After inhalation via a metered dose inhaler approximately 10% of a dose of sodium cromoglycate is absorbed from the respiratory tract. The remainder is either exhaled or deposited in the oropharynx, or swallowed and eliminated via the gastrointestinal tract, as only a small amount (1%) of the dose is absorbed from the gastrointestinal tract. The rate of absorption of sodium cromoglycate from the respiratory tract is slower than the elimination rate (t1/2 of 1.5 - 2h). Hence, the drug remains effectively in the lungs to produce its local therapeutic effect and is then cleared rapidly from the systemic circulation. No substantial increase in plasma concentrations occurs during repeated dose therapy.

Sodium cromoglycate is moderately and reversibly bound to plasma proteins (≈ 65%) and is not metabolised in humans. It is excreted unchanged in both urine and bile in approximately equal proportions.

## 5.3 PRECLINICAL SAFETY DATA

Sodium cromoglycate is not carcinogenic, mutagenic or teratogenic in animals. No evidence of impaired fertility was shown in laboratory animal reproduction studies. By inhalation, even in

long-term studies, it proved impossible to achieve toxic dose levels of sodium cromoglycate in a range of mammalian species. Sodium cromoglycate is non-irritating to the eye and nasal mucosa in animal tests.

# 6 PHARMACEUTICAL PARTICULARS

## 6.1 LIST OF EXCIPIENTS

Povidone, macrogol 600, Apaflurane.

## 6.2 INCOMPATIBILITIES

None known.

## 6.3 SHELF LIFE

2 years

## 6.4 SPECIAL PRECAUTIONS FOR STORAGE

Store below 30°C. Do not refrigerate.

As the aerosol inhaler canister is pressurised it should be protected from heat or direct sunlight and should not be punctured or incinerated even when empty.

## 6.5 NATURE AND CONTENTS OF CONTAINER AND SPECIAL EQUIPMENT FOR USE

A metered dose of pressurised aerosol. The aluminium can is fitted with a metering valve which delivers 112 actuations (each containing 5 mg of sodium cromoglycate per shot), after initial priming.

The cartoned pack consists of an aerosol canister and a plastic mouthpiece, with a dust cap.

Each pack is individually supplied in a carton together with a patient information leaflet.

An additional mouthpiece has been supplied to assist in the cleaning and maintenance of INTAL FORTE 5mg CFC-free.

## 6.6 SPECIAL PRECAUTIONS FOR DISPOSAL

No special requirements for disposal. Do not incinerate.

# 7 MEDICINE SCHEDULE

Prescription Only Medicine

# 8 SPONSOR

Distributed by:
sanofi-aventis new zealand limited
Level 8, 56 Cawley Street
Ellerslie, Auckland
Phone:
Free Call: 0800 283 684

# 9 DATE OF FIRST APPROVAL

12 January 1999

# 10 DATE OF REVISION OF THE TEXT

25 September 2018

### Summary of changes

| Section changed | Summary of new information |
|---|---|
| All | Align with the Medsafe data sheet format including minor additions of text to meet requirements |
| 2 | Update to units of product strength |
| 3 | Delete 'new' |
| 4.4 | Add cleaning precaution |
| 4.5 | Added detail on clinically significant drug interactions |
| 6.6 | Addition of information regarding disposal |