

# New Zealand Data Sheet

## 1 PRODUCT NAME

Floair Inhaler – with dose counter

## 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Fluticasone propionate (equivalent to 50, 125 or 250 micrograms per metered actuation).  
Pressurised metered-dose inhaler (pMDI)

For the full list of excipients, see section 6.1.

## 3 PHARMACEUTICAL FORM

Floair Inhaler with a dose counter is a pressurised metered-dose inhaler that delivers fluticasone propionate equivalent to 50 micrograms per actuation into a specifically designed actuator.

Floair Inhaler with a dose counter is a pressurised metered-dose inhaler that delivers fluticasone propionate equivalent to 125 micrograms per actuation into a specifically designed actuator.

Floair Inhaler with a dose counter is a pressurised metered-dose inhaler that delivers fluticasone propionate equivalent to 250 micrograms per actuation into a specifically designed actuator.

Floair Inhaler consists of a pressurised aluminium canister filled with fluticasone propionate suspended in the non-CFC HFA-134a propellant (norflurane). The aluminium canister has a metering valve fitted within a plastic actuator. A dose counter is incorporated into the actuator, which shows how many actuations of medicine remain in the canister. One Floair Inhaler delivers 120 actuations of medicine. The actuator is fitted with a plastic dust cap.

## 4 CLINICAL PARTICULARS

### 4.1 Therapeutic indications

Floair Inhaler is indicated for the long-term prevention of bronchospasm in adults or children with mild, moderate or severe asthma.

Floair Inhaler is also indicated for adults or children with severe asthma dependent on oral corticosteroids for symptom control. Introduction of Floair Inhaler may allow the requirement for oral corticosteroids to be reduced or eliminated over time.

**Floair Inhaler is NOT indicated for the treatment of acute asthma symptoms, for which a fast-acting inhaled bronchodilator (e.g. salbutamol) should be used.**

Asthma:

Floair inhaler results in an anti-inflammatory effect within the lung tissue.

In individuals treated with other prophylactic treatment or treated with a bronchodilator previously, fluticasone propionate reduces exacerbations and asthma symptoms.

Regular medical evaluation is required in cases of severe asthma as it has the potential to cause death. Severe asthma patients experience numerous exacerbations and recurrent symptoms with physical capacity that is limited. PEF values are below 60% expected at baseline in patients with severe asthma with larger than 30% inconsistency, which usually

does not return completely to normal after the use of a bronchodilator. A high dose of fluticasone propionate will be required to be administered in these patients, or oral corticosteroid therapy (see section 4.2). Rapid deterioration of asthma symptoms may require an increase in corticosteroid dosage, which must be managed under urgent medical direction.

Management in:

- Adults with mild asthma – (>80% PEF values expected at baseline with <20% inconsistency), intermittent asthma medication or symptomatic bronchodilator is required more than occasionally.
- Adults with moderate asthma – (60-80% PEF values expected at baseline with 20-30% inconsistency), regular asthma medication is required. Asthma patients who are unstable or declining that are already on a bronchodilator alone or prophylactic treatment.
- Adults with severe chronic asthma – (<60% PEF values expected at baseline with 30% inconsistency), fluticasone propionate introduced to patients with severe asthma and who are reliant on systematic corticosteroids with the possibility to significantly decrease or eliminate their need for oral corticosteroids
- Children who are dependent on preventative asthma treatment, also includes children who are not already managed on current prophylactic medication.

## 4.2 Dose and method of administration

Floair Inhaler is for oral inhalation only. Babies, children or adults who find it difficult to synchronise actuation of a pressurised metered-dose inhaler with inspiration of breath may use a spacer device with Floair Inhaler.

Floair Inhaler is available in three dose strengths: 50 micrograms of fluticasone propionate per actuation; 125 micrograms of fluticasone propionate per actuation; and 250 micrograms of fluticasone propionate per actuation.

Regular review is required for the diagnosis and therapy of asthma.

The nature of prophylactic therapy should be discussed with the patient and advised that Floair Inhaler should be taken regardless of whether the patient is feeling an improvement or not. The therapeutic onset of the expected effect is between four to seven days, however some patients may notice a difference in 24 hours especially if inhaled steroids have not been administered previously.

The severity of an individual patient's disease should be used to determine the starting dose of Floair Inhaler. The response of the individual patient should be used to adjust the Floair Inhaler dosage until control is reached or to titrate the dosage to the minimum effective dose. Medical advice must be immediately sought if the patient believes that their short acting bronchodilator treatment is becoming less effective or they feel they are requiring additional doses than usual.

Recommended doses of Floair Inhaler are tabulated below:

	<b>Recommended starting dose</b>	<b>Approved dose range</b>
<b>Adults or adolescents aged <math>\geq</math> 16 years</b>		100–1000 micrograms twice a day
Mild asthma (previously treated with bronchodilators alone)	100–250 micrograms twice a day	
Moderate asthma (previously treated with prophylactic therapy)	250–500 micrograms twice a day	
Severe asthma (previously treated with oral corticosteroids)	500–1000 micrograms twice a day	
<b>Children aged 4 – 15 years</b>	50–100 micrograms twice a day	50–200 micrograms twice a day. Up to 200mcg can be administered twice a day in patients whose asthma is not adequately managed.
<b>Children aged &lt; 4 years</b>	100 micrograms twice a day administered via paediatric spacer with face mask	

Patients should be advised that Floair Inhaler is a preventative asthma treatment and should be taken consistently, irrespective of whether symptoms are present. Patients should be advised to take a short-acting inhaled  $\beta_2$  (beta-2) agonist to treat symptoms rather than additional doses of Floair Inhaler.

Half the daily beclomethasone dipropionate dosage can be used to estimate the starting dose of fluticasone propionate.

Fluticasone propionate benefits younger children by providing control over the persistent and frequent symptoms of asthma.

Studies have shown that prescribing fluticasone propionate 100mcg twice a day is the optimum dosage for the control of asthma symptoms in children aged between 1 and 4 years old. An elevated dosage is required in young children due to the decreased efficiency of the delivery of fluticasone propionate within smaller airways, increased nasal breathing and the use of a spacer device.

### **Special Patient Groups**

The dosage of Floair Inhaler does not require adjustment in the elderly or in individuals with renal or hepatic impairment.

### **4.3 Contraindications**

Floair Inhaler is contraindicated in individuals with hypersensitivity to any of its components.

### **4.4 Special warnings and precautions for use**

One of the features of the worsening control of asthma is the increased use of inhaled short-acting  $\beta_2$  (beta-2) agonists to alleviate symptoms. Patients should be instructed to seek medical attention if they find that their short-acting bronchodilator appears less effective or they need more inhalations than usual. Deterioration of control is indicated by the increase in

usage of short-acting bronchodilators. Daily monitoring of peak flow may be introduced in patients that are considered high risk.

To obtain optimum delivery of fluticasone propionate to the lungs, the inhaler technique of the patient should be monitored to make sure that the patient's inhalation is synchronised with the aerosol actuation.

### **Asthma management**

Floair Inhaler should not be used to treat acute asthma symptoms for which a fast and short-acting inhaled bronchodilator is required. Patients should be advised to have their short-acting inhaled bronchodilator for the relief of acute asthma symptoms available at all times. Treatment with Floair Inhaler should not be discontinued suddenly.

### **Asthma deterioration**

Asthma may deteriorate acutely over a period of hours or chronically over several days or longer and can be life-threatening. The patient should be advised to seek medical advice if their on-demand use of their short-acting  $\beta_2$  (beta-2) agonist increases or appears less effective. If patients do not respond to Floair Inhaler or have severe asthma attacks while treated with this medication, then the dosage of Floair Inhaler should be increased. Systemic corticosteroids should be considered to provide additional asthma control and antibiotics prescribed if an infection is present. Sudden worsening of symptoms may require increased corticosteroid dosage which should be administered under urgent medical supervision.

### **Paradoxical bronchospasm**

Similar to that seen with other inhalation therapy, potentially life-threatening paradoxical bronchospasm may occur immediately after using inhaled fluticasone propionate. If this occurs, the patient should be administered a short-acting bronchodilator. Floair Inhaler should be discontinued immediately and the patient should be treated with an alternative therapy.

### **Transfer from oral corticosteroids**

Regular adrenocortical function monitoring and special care should be exercised in patients switching from oral corticosteroids to Floair Inhaler because of the possibility of adrenal impairment or insufficiency. Systemic corticosteroids should be gradually tapered off after initiation of Floair Inhaler and patients are advised to have a warning card to alert if additional corticosteroids in times of stress maybe required.

Switching from oral corticosteroids to Floair Inhaler may also unmask eczema, allergic rhinitis, arthritis, conjunctivitis, or other allergies that have previously been managed by the systemic drug. These allergies should be symptomatically treated with antihistamines and/or topical preparations, including topical steroids.

### **Adrenal crisis**

When the recommended dosage of fluticasone propionate is administered, adrenal function generally remains within the normal range. However, prolonged treatment with high doses of inhaled corticosteroids may result in adrenal suppression and acute adrenal crisis. Rarely, acute adrenal crisis has been reported in children exposed to higher than approved doses (typically at least 1000 micrograms daily over several months or years); these individuals exhibit features including hypoglycaemia and sequelae of decreased consciousness and/or convulsions. Situations that could potentially trigger acute adrenal crisis include trauma, surgery, infection, or any rapid reduction in corticosteroid dosage. Presenting symptoms are typically vague and may include anorexia, abdominal pain, weight loss, tiredness, headache, nausea, and vomiting, decreased level of consciousness, hypoglycaemia, and seizures. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

**Systemic effects**

Some patients are more susceptible to the systemic effects of inhaled corticosteroids than others.

Any inhaled corticosteroid may be associated with systemic adverse effects that include Cushingoid features, Cushing's syndrome, adrenal suppression, decrease in bone mineral density, growth retardation in children and adolescents, cataract and glaucoma. Very rarely disturbances in the behaviour of children and adolescents have been recorded. These effects are more common when the inhaled corticosteroid is administered at high doses for long periods of time, although the risk is much less than oral corticosteroids. Due to this, Floair Inhaler is recommended to be titrated to the smallest effective dose.

**Paediatric use**

Children treated with inhaled corticosteroids for long periods of time should have their height regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of inhaled corticosteroid, if possible, to the lowest dose at which effective control of asthma is maintained.

**Infections**

Because of the potential for worsening infections, patients should exercise caution when taking Floair Inhaler if they have active or quiescent tuberculosis; respiratory tract infection; untreated systemic fungal, bacterial, viral or parasitic infections; or ocular herpes simplex virus infection.

In clinical studies, the development of localised infections of the mouth and pharynx with *Candida albicans* has occurred in patients treated with inhaled fluticasone propionate. Symptomatic candidiasis can be treated with a topical anti-fungal without discontinuing Floair Inhaler. It may be helpful for affected patients to rinse out their mouth with water immediately after inhalation.

**Increases in blood glucose levels**

When prescribing Floair Inhaler extra care should be taken if the patient has a history of diabetes mellitus. Increases of blood glucose levels with inhaled corticosteroids in patients with or without a history of diabetes mellitus have been reported, although this is very rare.

**Eosinophilic conditions**

In rare cases, patients on inhaled fluticasone propionate may present with systemic eosinophilic conditions, with some patients displaying clinical features of vasculitis consistent with Churg-Strauss syndrome, a condition that is often treated with systemic corticosteroid therapy. These events usually, but not always, have been linked with the decrease and/or withdrawal of oral corticosteroid therapy following the introduction of fluticasone propionate. Cases of serious eosinophilic conditions have also been reported with other inhaled corticosteroids in this clinical setting. Physicians should be alert to eosinophilia, vasculitic rash, worsening pulmonary symptoms, cardiac complications, and/or neuropathy presenting in their patients. A causal relationship between fluticasone propionate and these underlying conditions has not been established.

**Visual disturbance**

Visual disturbance may be reported with systemic and topical corticosteroid use. If a patient presents with symptoms such as blurred vision or other visual disturbances, the patient should be considered for referral to an ophthalmologist for evaluation of possible causes which may include cataract, glaucoma or rare diseases such as central serous chorioretinopathy (CSCR) which have been reported after use of systemic and topical corticosteroids.

## 4.5 Interaction with other medicines and other forms of interaction

High systemic clearance and extensive first-pass metabolism occurs after inhaled fluticasone propionate which is initiated by the cytochrome P450 3A4 within the liver and gut. Under physiological conditions, fluticasone propionate achieves low concentrations in the plasma after being orally inhaled; therefore, it is unlikely that fluticasone propionate mediates any clinically significant drug interactions.

In a study of drug interactions in healthy individuals receiving intranasal fluticasone propionate, drug plasma concentrations were greatly increased with concomitant administration of ritonavir (a powerful inhibitor of cytochrome P450 3A4), leading to markedly decreased serum cortisol concentrations. Clinically significant reports of drug interactions within patients treated with fluticasone propionate and ritonavir, leading to adrenal suppression, Cushing's syndrome, and other systemic corticosteroid effects. For this reason, Floair Inhaler should not be used concomitantly with ritonavir, unless the prospective benefit offsets the risk of the systemic corticosteroid adverse effects.

In a small study in healthy volunteers, the slightly less potent CYP3A inhibitor ketoconazole increased the exposure of a single inhalation of fluticasone propionate by 150%. This resulted in a greater reduction of plasma cortisol compared with fluticasone propionate alone. Co-treatment with other potent CYP3A inhibitors, such as itraconazole, is also expected to increase the systemic fluticasone propionate exposure and the risk of systemic side effects. Caution is recommended and long-term treatment with such drugs should, if possible, be avoided.

Other cytochrome P450 3A4 inhibitors have been administered concomitantly with fluticasone propionate in clinical studies: erythromycin produced negligible increases and ketoconazole produced minor increases after exposure systemically to fluticasone propionate with no significant reductions in the concentration of serum cortisol. Notwithstanding, care should be taken when co-administering ketoconazole and other potent cytochrome P450 3A4 inhibitors with Floair Inhaler, as increased systemic exposure to fluticasone propionate can potentially arise.

## 4.6 Fertility, pregnancy and lactation

### **Pregnancy**

The safety of fluticasone propionate has not been adequately established in human pregnancy.

Animal reproductive studies conducted have resulted in systemic exposure outcomes consistent with excess glucocorticosteroids compared to the outcomes seen with recommended therapeutic dose levels given by inhalation.

No mutagenic capability was shown in genotoxicity testing.

Floair Inhaler should only be considered during pregnancy if the potential benefit to the mother exceeds any possible risk to the foetus.

### **Breast feeding**

No investigation has been made on whether fluticasone propionate is excreted into breast milk.

Plasma levels of fluticasone propionate by inhalation are likely to be low in patients receiving the recommended dosages of the medicine. Floair Inhaler should only be considered in lactating women if the potential benefit to the mother exceeds any possible risk to the breastfeeding infant.

## **Fertility**

There are no fertility data in humans.

## **4.7 Effects on ability to drive and use machines**

Fluticasone propionate is not likely to generate an effect on the ability to drive or use machinery.

## **4.8 Undesirable effects**

### **Nervous system**

Headache (11%); dizziness (1% to 3%); aggression, agitation, anxiety, behavioural changes including irritability and hyperactivity, depression, sleep disorders and restlessness (post-marketing).

### **Gastrointestinal system**

Candidiasis (thrush) of the mouth and/or throat and non-site specific (5%); diarrhoea, dyspeptic symptoms, gastrointestinal discomfort and pain, gastrointestinal signs and symptoms, hyposalivation, viral gastrointestinal infections (1% to 3%).

### **Genitourinary system**

Urinary infections (1% to 3%)

### **Metabolic–nutritional**

Cushingoid features, growth velocity reduction in children and adolescents, hyperglycaemia, osteoporosis, Cushing's syndrome, adrenal suppression, minimised bone mineral density, weight gain (post-marketing).

### **Dermatological**

Viral skin infections (1% to 3%); contusions, cutaneous hypersensitivity reactions, ecchymosis, pruritus (post-marketing).

### **Eyes, ears, nose and throat**

Throat irritation (10%); sinusitis/sinus infection (7%); hoarseness/dysphonia (6%); laryngitis, nasal sinus disorder, oesophageal candidiasis, pharyngitis/throat infection, rhinitis, rhinorrhoea/postnasal drip (1% to 3%); aphonia, glaucoma, cataracts, facial and oropharyngeal oedema including angio-oedema and throat soreness and irritation (post-marketing).

### **Haematological–lymphatic system**

Eosinophilic conditions (post-marketing).

### **Respiratory system**

Upper respiratory tract infection (18%); bronchitis, cough (6%); upper respiratory inflammation (5%); asthma exacerbation, chest tightness, cough, dyspnoea, immediate and delayed bronchospasm, paradoxical bronchospasm, pneumonia, wheezing (post-marketing).

### **Musculoskeletal system**

Injuries, muscle injuries, muscle pain, muscle stiffness/tightness/rigidity, musculoskeletal pain, soft-tissue injuries (1% to 3%).

### **Miscellaneous**

Chest symptoms, fever, pain, viral infections (1% to 3%); anaphylactic reaction (post-marketing).

#### 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

Short-term inhibition of the hypothalamic-pituitary-adrenal axis may occur in the case of acute inhalation of fluticasone propionate in dosages exceeding those approved. However, normal adrenal function generally recovers within several days and emergency action is not usually necessary.

Significant adrenocortical inhibition is possible if fluticasone propionate dosages are continued over prolonged periods exceeding those approved. Patients receiving Floair Inhaler at dosages that exceed those approved should be monitored closely and have their Floair Inhaler dosage gradually reduced.

Very rarely, acute adrenal crisis has been reported in children that have been exposed to more than the approved doses (typically at least 1,000mcg daily over several months or years); these individuals exhibit features including sequelae of reduced consciousness and/or convulsions and hypoglycaemia. Surgery, infection, trauma or any rapid decrease in corticosteroid dosage can initiate acute adrenal crisis.

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: Glucocorticoid inhalants: ATC code: R03BA05

#### **Mechanism of Action**

Fluticasone propionate is a synthetic, trifluorinated corticosteroid with potent anti-inflammatory activity. *In vitro* assays have established fluticasone propionate as a human glucocorticoid-receptor agonist, with an affinity 18 times greater than dexamethasone, almost twice that of beclomethasone-17-monopropionate (BMP), the active metabolite of beclomethasone dipropionate, and over three times that of budesonide.

The precise mechanisms of fluticasone propionate action in asthma are unknown. Inflammation is an important component in the pathogenesis of asthma. Corticosteroids have been shown to inhibit multiple cell types (e.g. mast cells, eosinophils, basophils, lymphocytes, macrophages, and neutrophils) and mediator production or secretion (e.g. histamine, eicosanoids, leukotrienes, and cytokines) involved in the asthmatic response. These anti-inflammatory actions of corticosteroids contribute to their efficacy in asthma.

Fluticasone propionate is a potent glucocorticoid with anti-inflammatory activity. When inhaled at approved dosages, fluticasone propionate reduces asthma symptoms and exacerbations, with a lower incidence and severity of adverse effects than those observed when corticosteroids are administered systemically.

Though highly effective for the treatment of asthma, corticosteroids do not have an immediate effect on asthma symptoms. However, improvement following inhaled administration of fluticasone propionate can occur within 24 hours of beginning treatment, although maximum benefits may not be achieved for 1-2 weeks or longer thereafter. Even when corticosteroids are discontinued, asthma stability may persist for several days or longer.

## 5.2 Pharmacokinetic properties

### Absorption

Inhaled fluticasone propionate acts locally in the lungs; therefore, plasma levels do not predict therapeutic effect. Studies using oral dosing of labelled and unlabelled drug have demonstrated that the oral systemic bioavailability of fluticasone propionate is negligible (<1%), primarily due to incomplete absorption and pre-systemic metabolism in the gut and the liver. In contrast, the majority of the fluticasone propionate delivered to the lungs is systemically absorbed.

### Distribution

Following intravenous administration, the initial disposition phase for fluticasone propionate was rapid and consistent with its high lipid solubility and tissue binding. The volume of distribution averaged 4.2 L/kg. The percentage of fluticasone propionate bound to human plasma proteins averages 99%. Fluticasone propionate is weakly and reversibly bound to erythrocytes and is not significantly bound to human transcortin.

### Metabolism

The total clearance of fluticasone propionate is high (average: 1,093 mL/min), with renal clearance accounting for less than 0.02% of the total. The only circulating metabolite detected in humans is the 17- $\beta$ -carboxylic acid derivative of fluticasone propionate, which is formed through the cytochrome P450 3A4 pathway. This metabolite had less affinity (approximately 1/2,000) than the parent drug for the corticosteroid receptor of human lungs cytosol *in vitro* and negligible pharmacological activity in animal studies. Other metabolites detected *in vitro* using cultured human hepatoma cells have not been detected in humans.

### Elimination

Following intravenous dosing, fluticasone propionate showed polyexponential kinetics and had a terminal elimination half-life of approximately 7.8 hours. Less than 5% of a radiolabelled oral dose was excreted in the urine as metabolites, with the remainder excreted in the faeces as both parent drug and metabolites.

## 5.3 Preclinical safety data

No toxic effects have been shown in animals exposed daily for two years to the non-CFC propellant HFA-134a at very high vapour concentrations. These concentrations greatly exceeded any likely to be experienced by individuals treated with Floair Inhaler.

Repeat toxicity tests, teratology studies or reproductive studies resulted in no novel effects that were identified. Toxicology was only exposed in class effects characteristic of potent corticosteroids and those only at extreme doses that therapeutic use proposed. Floair Inhaler is absent of mutagenic activity *in-vivo* or *in-vitro* and resulted in no tumorigenic ability in rodents. Fluticasone propionate is both non-sensitising and non-irritant in animal models.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

HFA-134a, ethanol, soy lecithin.

### 6.2 Incompatibilities

None reported.

### 6.3 Shelf life

The shelf-life of Floair Inhaler is 24 months.

### 6.4 Special precautions for storage

Store Floair Inhaler below 25°C.

When the Floair Inhaler is not in use, the plastic dust cap should be securely placed back on the mouthpiece of the actuator.

Avoid direct sunlight or heat and do not refrigerate or freeze.

As the canister is pressurised, no attempt should be made to puncture, or dispose of it by burning.

As with other medication inhaled from aerosol canisters, the effect of the medication may be reduced if the canister is very cold. If this is the case, warm the inhaler between your hands before use. Do not use anything else to assist with warming up the inhaler.

#### **Instructions for Handling and Use**

Usage instructions can also be found in the package insert.

Correct operation of the Floair Inhaler is essential for successful therapy.

Prior to using the Floair Inhaler for the first time, remove the plastic dust cap from the mouthpiece of the inhaler, shake inhaler well and depress the canister twice into the air to prime the inhaler. If the inhaler has not been used for more than one week, remove the plastic dust cap from the mouthpiece of the inhaler, shake the inhaler well and depress the canister once into the air to prime the inhaler.

Technique for proper administration of the Floair Inhaler is described in the following steps:

1. Remove the plastic dust cap from the mouthpiece of the inhaler and check the mouthpiece is clean. Shake inhaler well and prime if necessary as described above.
2. Hold the inhaler, using either one or two fingers on the top of the canister and your thumb on the base. Breathe out deeply through your mouth. Place the mouthpiece of the actuator in your mouth taking care to not bite it and close your lips over the mouthpiece.
3. Start breathing in through your mouth. Then depress the canister to release one dose while continuing to breathe in deeply and steadily.
4. Remove the inhaler from your mouth and hold your breath for 10 seconds or as long as comfortable. Breathe out slowly.
5. If another dose is required, wait for at least one minute with the inhaler in an upright position, and then repeat steps 2 to 4.
6. Rinse your mouth with water after inhalation and spit it out.
7. After use, replace the mouthpiece cover, making sure the dust cap is secure.

#### **IMPORTANT:**

Do not rush steps 2, 3 and 4. It is essential that just before depressing the canister that you begin breathing in as slowly as possible.

It is useful to complete this exercise using a mirror for the initial few actuations. If you see “mist or vapour” appearing from the sides of your mouth or top of the inhaler, start again from step 2.

Provide feedback to your doctor if you have any concerns or issues when using your Floair Inhaler. If different directions have been provided by your doctor, please follow these instructions with care.

#### Children

An adult may be required to assist young children with operating their inhaler. The child should be instructed to breathe out then breathe in again slowly with the actuator in their mouth. As the child begins to breathe in, the adult should depress the canister. This technique may require practice. Older children or individuals with weak hands should use both hands to hold the inhaler, with two forefingers on top of the inhaler canister and two thumbs on the base of the actuator.

#### **Built-in dose counter**

The Floair Inhaler has a built-in dose counter to see how many actuations are left in the inhaler. After Floair Inhaler is primed for the first time, the dose counter should read 120. This means that there are 120 doses of medicine left in the inhaler. Each time the inhaler is used, the dose counter will count down by one number.

When there are 40 doses of medicine remaining in the Floair Inhaler, the colour on the dose counter will change from green to red. When the dose counter on the Floair Inhaler is red, the patient should ask their doctor for a new inhaler.

The dose counter will stop counting when it reaches 0. This means that there is no medication left in the inhaler and it should be discarded. The Floair Inhaler may not feel empty and may continue to operate; however, the right amount of medicine may not be dispensed if the inhaler is continued to be used once the dose counter has reached 0. The dose counter will continue to show 0 even if the inhaler is used again.

The dose counter cannot be reset and is permanently attached to the plastic actuator. Never try to change the numbers on the dose counter.

#### **Cleaning**

The Floair Inhaler plastic actuator should be cleaned at least once a week to ensure that it functions correctly.

#### **NEVER wash or soak any part of the inhaler in water.**

1. Remove the plastic dust cap from the mouthpiece of the inhaler. The metal canister should NOT be removed from the plastic actuator.
2. The plastic mouthpiece and the dust cap are to be wiped inside and outside with a clean dry cloth.
3. Replace the plastic dust cap on to the mouthpiece of the inhaler.

#### **6.5 Nature and contents of container**

Floair Inhaler is available in three strengths: 50 micrograms, 125 micrograms or 250 micrograms of fluticasone propionate per actuation, with 120 actuations per inhaler.

#### **6.6 Special precautions for disposal**

No special requirements

### **7 MEDICINE SCHEDULE**

Prescription Medicine

## **8 SPONSOR**

REX Medical Ltd  
PO Box 18-119  
AUCKLAND 1072

Ph (09) 574 6060  
Fax (09) 574 6070

## **9 DATE OF FIRST APPROVAL**

21 January 2012

## **10 DATE OF REVISION OF THE TEXT**

11 May 2018

## SUMMARY TABLE OF CHANGES

Section changed	Summary of new information
4.8	Addition of warning for visual disturbances