

## Revised Package Insert

### 1. NAME OF THE MEDICINAL PRODUCT

Giona Easyhaler™ 100 micrograms/dose inhalation powder.  
Giona Easyhaler® 200 micrograms/dose inhalation powder.

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Giona Easyhaler™ 100 micrograms/dose inhalation powder : One metered dose contains 100 micrograms of budesonide.  
Giona Easyhaler™ 200 micrograms/dose inhalation powder: : One metered dose contains 200 micrograms of budesonide.

With the Easyhaler device the delivered dose (ex-actuator) contains the same quantity of active substance as the metered dose (ex-reservoir).

Excipient with known effect: Lactose monohydrate.

For a full list of excipients, see section 6.1.

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### 3. PHARMACEUTICAL FORM

Inhalation powder. White or almost white powder.

### 4. CLINICAL PARTICULARS

#### 4.1 Therapeutic indications

Bronchial asthma requiring maintenance treatment with glucocorticoids for control of underlying airway inflammation.

(Note: Giona Easyhaler is not suitable for the treatment of acute asthma attacks.)

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#### 4.2 Dosage and method of administration

Method of administration: For inhalation use. For optimum response, Giona Easyhaler® inhalation powder should be used regularly.

The therapeutic effect begins after a few days' treatment and reaches its maximum after some weeks of treatment.

When transferring a patient to Giona Easyhaler® from ~~any~~ other inhalation devices, the treatment should be individualised. The previous active substance, dose regimen, and method of delivery should be considered. The patients should be prescribed a starting dose of inhaled budesonide which is appropriate for the severity or level of control of their disease.

**The starting dose** for adults with mild asthma (Step 2) is 200-400 micrograms/day. If needed, the dose can be increased up to 800 micrograms/day. For adult patients with moderate (Step 3) and severe (Step 4) asthma the starting dose and the dose for periods of severe asthma can be up to 1600 micrograms/day.

For children 5 —7 years old, the starting dose and the dose for periods of severe asthma is 200 — 400 mcg daily. For children over 7 years old, the starting dose and the dose for periods of severe asthma is 200 — 800 mcg daily.

The maintenance dose should be adjusted to meet the requirements of an individual patient, taking into account the severity of the disease and the clinical response of the patient. The dose should be adjusted until control is achieved and then titrated to the lowest dose at which effective control of asthma is maintained.

#### Twice daily dosing

Adults with mild and moderate or severe asthma: The usual maintenance dose is 100-400 micrograms twice daily. During periods of severe asthma, the daily dose may be increased up to 1600 micrograms administered in divided (two) doses and subsequently reduced when asthma has stabilised.

Children over 7 ~~years~~ -years: The usual maintenance dose is 100-200 micrograms twice daily.

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#### Once daily dosing

Adults with mild and moderate asthmatics: In patients who have not previously received inhaled corticosteroids the usual maintenance dose is 200-400 micrograms once daily. In patients already controlled on inhaled corticosteroids (eg budesonide or beclometasone dipropionate) administered *twice* daily, once daily dosing up to 400 micrograms may be used.

Children over 7 years with mild to moderate asthma: In steroid naive patients or patients controlled on inhaled corticosteroids (eg budesonide or beclometasone dipropionate) administered twice daily the usual maintenance dose is 200-400 micrograms once daily.

The patient should be transferred to once daily dosing at the same equivalent total daily dose (with consideration of the drug and the method of delivery).The dose should be subsequently reduced to the minimum needed to maintain good asthma control. Patients should be instructed to take the once daily dose in the evening. It is important that the dose is taken consistently and at the same time each evening.

There are insufficient data to make recommendations for the transfer of patients from newer inhaled steroids to once daily Giona Easyhaler™@.

Patients, in particular those receiving once daily treatment, should be advised that if their asthma deteriorates (e.g. increased frequency of bronchodilator use or persistent respiratory symptoms) they should increase the frequency of dosing and the daily dose. They should be advised to contact their doctor as soon as possible.

There is no experience of treatment of patients with impaired hepatic or renal function. Since budesonide is predominantly eliminated through hepatic metabolism, increased exposure may be expected in patients with severe cirrhosis of the liver.

A rapid-acting inhaled bronchodilator should be available for the relief of acute symptoms of asthma at all times.

**Instruction for use and handling:**

Easyhaler™@ is an inspiratory flow-driven device. This means that when the patient inhales through the mouthpiece, the substance will follow the inspired air into the airways.

Note: It is important to instruct the patient

- To carefully read the instructions for use in the patient information leaflet which is packed together with each inhaler
- That it is recommended to keep the device in the protective cover after opening the laminate pouch to enhance the stability of the product during use and makes the inhaler more tamper proof
- To shake and actuate the device prior to each inhalation
- To breathe in forcefully and deeply through the mouthpiece to ensure that an optimal dose is delivered to the lungs
- Never to breathe out through the mouthpiece as this will result in a reduction in the delivered dose. Should this happen the patient is instructed to tap the mouthpiece onto a table top or the palm of a hand to empty the powder, and then to repeat the dosing procedure.
- Never to actuate the device more than once without inhalation of the powder. Should this happen the patient is instructed to tap the mouthpiece onto a table top or the palm of a hand to empty the powder, and then to repeat the dosing procedure.
- To always replace the dust cap and close the protective cover after use to prevent accidental actuation of the device (which could result in either overdosing or under dosing the patient when subsequently used).
- To rinse the mouth out with water or brush the teeth after inhaling the prescribed dose to minimise the risk of oropharyngeal candidiasis
- To clean the mouthpiece with a dry cloth at regular intervals. Water should never be used for cleaning because the powder is sensitive to moisture.
- To replace Giona Easyhaler when the counter reaches zero even though powder can still be observed within the device.

**4.3 Contra-indications**

Hypersensitivity to budesonide or to the excipient listed in section 6.1(lactose, which contains small amounts of milk protein). Hypersensitivity to budesonide or to lactose.

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

Giona Easyhaler™@ is not indicated for the treatment of acute dyspnoea or status asthmaticus. These conditions should be treated in the normal way.

Patients should be aware that Giona Easyhaler™@ inhalation powder is prophylactic therapy and therefore has to be used regularly even when asymptomatic for optimum benefit and should not be stopped abruptly.

The transfer of patients treated with oral corticosteroids to the inhaled steroid and their subsequent management requires special care. The patients should be in a reasonably stable state before initiating a high dose of inhaled corticosteroid through twice daily dosing in addition to their usual maintenance dose of systemic corticosteroid. After about 10 days, withdrawal of the systemic corticosteroid is started by reducing the daily dose gradually (by for example 2.5 milligrams prednisolone or the equivalent each month) to the lowest possible level. It may be possible to completely replace the oral corticosteroid with inhaled corticosteroid. Transferred patients whose adrenocortical function is impaired may need supplementary systemic corticosteroid during periods of stress e.g. surgery, infection or worsening asthma attacks. This applies also to patients who have received prolonged treatment with high doses of inhaled corticosteroids. They may also have impaired adrenocortical function which may result in clinically significant adrenal suppression and may need systemic corticosteroid cover during periods of stress.

During transfer from oral therapy to inhaled budesonide symptoms may appear that hbad previously been suppressed by systemic treatment with glucocorticosteroids, for example symptoms of allergic rhinitis, eczema, muscle and joint pain. In these cases a temporary increase of the oral steroid may sometimes be necessary. If it; in isolated cases, fatigue, headache,

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nausea, vomiting or similar symptoms occur, a generally unsatisfactory effect of the steroid should be suspected.

As with other inhalation therapies paradoxical bronchospasm may occur, manifested by an immediate increase in wheezing and shortness of breath after dosing. Paradoxical bronchospasm responds to a rapid-acting inhaled bronchodilator and should be treated straightaway. Budesonide should be discontinued immediately, the patient should be assessed and, if necessary, alternative treatment instituted.

When, despite a well monitored treatment, an acute episode of dyspnoea occurs, a rapid- acting inhaled bronchodilator should be used and medical reassessment should be considered. If, despite maximum doses of inhaled corticosteroids, asthma symptoms are not adequately controlled, patients may require short-term treatment with systemic corticosteroids. In such a case, it is necessary to maintain the inhaled corticosteroid therapy in association with treatment by the systemic route.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur than with oral corticosteroids. Possible systemic effects include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and glaucoma. It is important, therefore, that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is 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. In addition, consideration should be given to referring the patient to a paediatric respiratory specialist.

#### 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.

Patients who have previously been dependent on oral corticosteroids may, as a result of prolonged systemic corticosteroid therapy, experience effects of impaired adrenal function. Recovery may take a considerable amount of time after cessation of oral corticosteroid therapy and hence oral steroid-dependent patients transferred to budesonide may remain at risk from impaired adrenocortical function for some considerable time. In such circumstances hypothalamic pituitary adrenocortical (HPA) axis function should be monitored regularly.

To reduce the risk of oral candidiasis and hoarseness patients should be advised to rinse out the mouth properly or brush the teeth after each administration of inhaled corticosteroid. Oral candidiasis can be rapidly controlled by local antimycotic treatment, without the need to discontinue the treatment with inhaled budesonide.

Exacerbation of clinical symptoms of asthma may be due to acute respiratory tract bacterial infections and treatment with appropriate antibiotics may be required. Such patients may need to increase the dose of inhaled budesonide and a short course of oral corticosteroids may be required. A rapid-acting inhaled bronchodilator should be used as "rescue" medication to relieve acute asthma symptoms.

Special care and adequate specific therapeutic control of patients with active and quiescent tuberculosis is necessary before commencing treatment with Giona Easyhaler<sup>TM</sup>. Similarly patients with fungal, viral or other infections of the airways require close observation and special care and should use Giona Easyhaler<sup>TM</sup> only if they are also receiving adequate treatment for such infections. Special care is needed in patients with lung tuberculosis and fungal and viral infections in the airways. In patients with excessive mucous secretion in the respiratory tract, short-term therapy with oral corticosteroid may be necessary.

In patients with severe hepatic dysfunction, treatment with inhaled budesonide can result in a reduced elimination rate and thus enhanced systemic availability. Possible systemic effects may then result and therefore HPA axis function in these patients should be monitored at regular intervals.

Concomitant treatment with ketoconazole or other potent CYP3A4 inhibitors should be avoided (see Section 4.5 Interaction with other medicinal products and other forms of interaction). If this is not possible the time interval between administration of the interacting drugs should be as long as possible (see section 4.5).

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine.

Lactose, the excipient in the product, contains small amounts of milk proteins and can therefore cause allergic reactions.

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#### 4.5 Interaction with other medicinal products and other forms of interaction

Ketoconazole 200 mg once daily increased plasma levels of concomitantly administered oral budesonide (single dose of 3 mg on average six-fold. When ketoconazole was administered 12 hours after budesonide the concentration was on average increased three-fold. Information about this interaction is lacking for inhaled budesonide, but marked increases in plasma levels could be expected. Since data to give dosage recommendations are lacking, the combination should be avoided. If this is not possible the time interval between administration of ketoconazole and budesonide should be as long as possible. A reduction in the dose of budesonide should also be considered. Other potent inhibitors of CYP3A4 are also likely to markedly increase plasma levels of budesonide.

#### 4.6 Pregnancy and lactation

Data on approximately 2000 exposed pregnancies indicate no increased teratogenic risk associated with the use of inhaled budesonide. In animal studies glucocorticosteroids have been shown to induce malformations. This is not likely to be relevant for humans given recommended doses.

Animal studies have also identified an involvement of excess prenatal glucocorticoids in increased risks for intrauterine growth retardation, adult cardiovascular disease and permanent changes in glucocorticoid receptor density, neurotransmitter turnover and behaviour at exposures below the teratogenic dose range.

During pregnancy, inhaled budesonide should only be used when the benefits outweigh the potential risks. The lowest effective dose of budesonide needed to maintain adequate asthma control should be used.

It is not known whether budesonide passes into human breast milk. Administration of inhaled budesonide to women who are breast-feeding should only be considered if the expected benefit to the mother is greater than any possible risk to the child.

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

No effects on ability to drive and use machines have been observed.

#### 4.8 Undesirable effects

Frequency of reported adverse reactions:

##### Common (>1/100, <1/10)

Respiratory system disorders:	hoarseness, cough and throat irritation.
Resistance mechanism disorders:	oropharyngeal candidiasis.
Gastrointestinal disorders:	difficulty in swallowing.

##### Rare (>1/10,000, <1/1000)

Skin and appendages disorders:	easy bruising, skin thinning, urticaria, rash, dermatitis, pruritus, erythema.
Psychiatric disorders:	depression, aggressive reactions, irritability, anxiety, psychosis, behavioural changes in children, restlessness, increased motorial activity.
Endocrine disorders:	hypocorticism, hypercorticism.
Respiratory system disorders:	bronchospasm (see Section 4.4 Special warnings and precautions for use).
Body as a whole - general disorders:	anaphylactic shock, angioedema, immediate and delayed hypersensitivity reactions.
Musculoskeletal, connective tissue and bone disorders:	growth retardation.

##### Very rare including isolated cases (<1/10,000)

Psychiatric disorders:	nervousness.
Endocrine disorders:	adrenal suppression.
Eye disorders:	cataract, glaucoma.
Musculoskeletal, connective tissue and bone disorders:	decreased bone density.

##### Unknown

Eye disorders:	vision, blurred.
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Treatment with inhaled budesonide may result in candida infection in the oropharynx. Experience has shown that candida infection occurs less often when inhalation is performed before meals and/or when the mouth is rinsed after inhalation. In most cases this condition responds to topical anti-fungal therapy without discontinuing treatment with inhaled budesonide.

Systemic effects of inhaled corticosteroids may occur, particularly at high doses prescribed for prolonged periods. These may include adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract and

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glaucoma, and susceptibility to infections. The ability to adapt to stress may be impaired. The systemic effects described, however, are much less likely to occur with inhaled budesonide than with oral corticosteroids.

#### 4.9 Overdose and treatment

Symptoms of overdose

The acute toxicity of budesonide is low. Chronic use in excessive doses can result in systemic glucocorticosteroid effects, such as increased susceptibility to infection, hypercorticism and adrenal suppression. Atrophy of the adrenal cortex can occur and the ability to adapt to stress can be impaired.

Therapeutic management of overdose

For acute overdosage, no special emergency action needs to be taken.

In stress situations, it may be necessary to administer corticosteroids as a precaution (eg high doses of hydrocortisone). Patients with adrenocortical atrophy are regarded as being steroid- dependent and must be adjusted to the adequate maintenance therapy of a systemic corticosteroid until the condition has stabilised.

### 5. PHARMACOLOGICAL PROPERTIES

#### 5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Glucocorticoids. ATC code: R03BA02.

Budesonide is a non-halogenated corticosteroid. It has local anti-inflammatory effects on respiratory mucosa when administered topically.

Improvement in asthma control following inhalation of budesonide can occur within 24 hours of commencing the treatment although maximum benefit is achieved after a few weeks of continuous treatment.

The precise mechanism of corticosteroid actions on inflammation in asthma is not known. Budesonide has been shown to have a wide range of inhibitory effects against several cell types (e.g., eosinophils, macrophages, mast cells, lymphocytes, and neutrophils) and mediators (e.g., cytokines, leukotrienes, eicosanoids, and histamine) involved in allergic and non-allergic respiratory inflammation. These actions of corticosteroids may contribute to their efficacy in asthma.

#### 5.2 Pharmacokinetic properties

The activity of Giona Easyhaler<sup>®</sup> is due to the parent active substance, budesonide, which is provided as a mixture of two epimers (22R and 22S). In glucocorticoid receptor affinity studies, the 22R form is twice as active as the 22S epimer. These two forms of budesonide do not interconvert. The terminal half-life is the same for both epimers (2-3 hours). In asthmatic patients, approximately 15-25% of the inhaled budesonide dose from Easyhaler<sup>®</sup> reaches the lungs. The largest fraction of the inhaled dose is retained in the oropharynx and swallowed if not rinsed out.

Absorption: After oral administration of budesonide, peak plasma concentration is achieved in about 1-2 hours; and the absolute systemic availability is 6-13%. In plasma, 85-95% of budesonide is bound to proteins. In contrast, peak plasma concentration is reached approximately 30 minutes after inhalation. Most of budesonide delivered to the lungs is systemically absorbed.

#### Metabolism:

Budesonide is mainly eliminated by metabolism. Budesonide is rapidly and extensively metabolised in liver via cytochrome P4503A4 to two major metabolites. The *in vitro* glucocorticoid activity of these metabolites is less than 1% of that of the parent compound. Negligible metabolic inactivation has been observed in human lung and serum preparations.

#### Excretion:

Budesonide is excreted in urine and faeces in the form of conjugated and non-conjugated metabolites.

#### Special patient populations

The exposure to budesonide may be increased in patients with liver disease. In children the elimination half-life from plasma is markedly lower than in adults.

### 6. PHARMACEUTICAL PARTICULARS

#### 6.1 List of excipients

Lactose monohydrate (which contains small amounts of milk proteins).

#### 6.2 Incompatibilities

Not applicable.

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#### **6.32 Shelf life**

Shelf life of the medicinal product as packaged for sale: 3 years.

Shelf life after first opening the laminate pouch: 6 months

#### **6.43 Special precautions for storage**

Do not store above 30°C. When in use, Giona Easyhaler<sup>TM</sup> should be stored protected from moisture.

#### **6.54 Nature and contents of container**

The multidose powder inhaler consists of seven plastic parts and a stainless steel spring. The plastic materials of the inhaler are: overcap -polyester; bulk chamber cover -LDPE; bulk chamber polycarbonate; metering cylinder and counter wheel -acetal; mouthpiece -styrene butadiene; dust cap polypropylene. The plastic materials of the protective cover are polypropylene and thermoplastic elastomer. The inhaler is sealed in a laminate pouch and packed with or without a protective cover in a cardboard box.

Packages:

Giona Easyhaler<sup>TM</sup> 100 micrograms/dose inhalation powder:

- 200 doses + protective cover
- 200 doses

Giona Easyhaler<sup>TM</sup> 200 micrograms/dose inhalation powder:

- 200 doses + protective cover
- 200 doses

#### **6.56 Instructions for use and handling**

See Patient Information Leaflet

Manufactured by:

Orion Corporation,

Orion Pharma

Espoo, Finland, Finland

Date of Revision of Text: ~~October 2004-02~~ October 2020

## PATIENT INFORMATION LEAFLET

### A GUIDE TO USING YOUR INHALER

Read this whole leaflet carefully before you start using this inhaler

- Keep this leaflet. You may need to read it again.
- This medicine has been prescribed by your doctor for you personally and you should not pass it on to other people. It may harm them, even if their symptoms are the same as yours.
- If you have further questions, please ask your doctor or your pharmacist

#### In this leaflet:

1. What's in Giona Easyhaler<sup>®</sup>
2. Before you use Giona Easyhaler<sup>®</sup>
3. Using Giona Easyhaler<sup>®</sup>
4. Possible side effects
5. Keeping Giona Easyhaler<sup>®</sup> safe

#### GIONA EASYHALER<sup>®</sup> 100 MICROGRAMS/DOSE INHALATION POWDER

#### GIONA EASYHALER<sup>®</sup> 200 MICROGRAMS/DOSE INHALATION POWDER

The active substance in Giona Easyhaler<sup>®</sup> is budesonide.

Giona Easyhaler<sup>®</sup> 100 mcg/dose also contains a small amount of lactose (4 mg/dose).

Giona Easyhaler<sup>®</sup> 200 mcg/dose also contains a small amount of lactose (8 mg/dose).

Giona Easyhaler<sup>®</sup> comes in packs containing one inhalers with or without a protective cover.

The manufacturer this product is Orion Corporation, Orionintie 1, P.O.Box 65, FIN-02101 Espoo, Finland.

#### 1. WHAT'S IN GIONA EASYHALER<sup>®</sup>

and what it does

Your medicine — Giona — comes in an inhaler — the Easyhaler<sup>®</sup>. The medicine comes as a ~~th~~dry powder for you to breathe in. There is enough powder in the Easyhaler<sup>®</sup> for 200 puffs (or inhalations). For Giona Easyhaler<sup>®</sup> 100 mcg/dose, each puff contains 100 micrograms of budesonide. For Giona Easyhaler<sup>®</sup> 200 mcg/dose, each puff contains 200 micrograms of budesonide.

**Treating asthma:** Budesonide is one of a family of medicines called corticosteroids, which are used to treat asthma and other breathing problems. Corticosteroids are versions of natural chemicals produced by the body. They work by gradually reducing the swelling and irritation in the lungs which are often the cause of asthma attacks.

**Use it regularly:** This type of inhaler is a “preventer” and you need to use it regularly for it to work properly — even when your asthma is not giving you problems. If you stop using the inhaler altogether, it may make your asthma worse.

Giona Easyhaler<sup>®</sup> is not the same as a “reliever” inhaler: it won't stop an asthma attack that has already started. Make sure you have a reliever inhaler (usually blue) always handy.

#### 2. BEFORE YOU USE GIONA EASYHALER<sup>®</sup>

points to check

#### People who shouldn't take Giona Easyhaler<sup>®</sup>

There are some people who shouldn't take this medicine. Don't use Giona Easyhaler<sup>®</sup>:

- If you are allergic to budesonide (the main ingredient) or to lactose. If you are, or think you may be, talk to your doctor before you use the inhaler.

#### People who should take special care with Giona Easyhaler<sup>®</sup>

Some people need to take special care when taking Giona Easyhaler<sup>®</sup>. You may be asked to keep a regular check on your asthma using something called a peak flow meter. If your asthma, wheezing or tightness in the chest get worse, **tell your doctor**.

Like other corticosteroids at high doses budesonide may have an effect on the adrenal gland. Your doctor may ask for a blood sample from time to time.

#### Take special care:

- If you have ever had a reaction to budesonide or lactose
- If you have tuberculosis, or have ever been treated for it
- If you have liver disease
- If you have anything else wrong with your eyes, nose, throat or lung.

If any of these applies to you, and you haven't already talked it over with your doctor, talk to your doctor **before** you use Giona Easyhaler<sup>®</sup>. She/he may need to prescribe a different medicine.

**Women who are pregnant or breast-feeding:** Talk to your doctor before you use Giona Easyhaler<sup>®</sup>. Ask your doctor or pharmacist for advice before taking any medicine.

**You can drive or use machines:** Giona Easyhaler<sup>®</sup> won't make you drowsy.

**Important information about the excipient:** The small amount of lactose in Giona Easyhaler is unlikely to cause problems in patients with lactose intolerance. If you have been told by your doctor that you have an intolerance to some other sugars, contact your doctor before taking this medicinal product.

**Using other medicines and Giona Easyhaler<sup>®</sup>:** Giona Easyhaler<sup>®</sup> usually causes no problems with other medicines. But you do need to take care:

- If you take an antifungal medicine containing ketoconazole
- If you use a nose spray with corticosteroid in it
- If you take steroid tablets (pills containing corticosteroids).

If so, tell your doctor. Your dose may need to be altered to take this into account.

Tell your doctor also about all other medicines you are using. This may also include medicines you can buy without a doctor's prescription and medicinal products used some time ago.

Make sure your doctor knows what other illnesses or allergies you have.

If you have to consult a doctor because of any other medical problem in the future, let your doctor know that you have been given Giona Easyhaler<sup>®</sup> treatment.

### **3. USING GIONA EASYHALER<sup>®</sup>** the usual dose and instructions

#### **How much to take:**

*Your doctor has worked out the correct dose for you. From time to time, your doctor may adjust the dose to find the lowest dose needed to control your asthma. Follow your doctor's advice and the pharmacist's label on the package.*

The usual dose is one to two inhalations twice a day, once in the morning and once in the evening. You may only need to take Giona Easyhaler<sup>®</sup> once a day in the evening but you must only do this if your doctor has specifically told you to. It is important that you take it at the same time each evening.

*If Giona Easyhaler<sup>®</sup> is to be used by your child, make sure that it is used correctly, as your doctor has told you.*

Giona Easyhaler<sup>®</sup> is intended for oral inhalation.

You should notice that your breathing gets easier over time, although Giona Easyhaler<sup>®</sup> will usually take a few weeks to have its full effect. You must use it regularly. If you find that your asthma is getting worse, or not getting any better, talk to your doctor.

If you have been taking steroid tablets for your asthma, your doctor may have told you to reduce the number of tablets gradually once you start to use Giona Easyhaler<sup>®</sup>. As a result of this, you may have symptoms like stuffy or runny nose, rash (eczema), muscle and joint pain, or you may feel generally unwell, if so, continue using Giona Easyhaler and tell your doctor.

**If your wheezing or chest tightness is worse than usual**, or come back more quickly than usual, tell your doctor as soon as possible; your asthma may be getting worse and you may need extra treatment.

#### **If you have taken too much**

If you take too much Giona Easyhaler<sup>®</sup> talk to your doctor. Always use your inhaler as your doctor has told you.

#### **If you forget to use Giona Easyhaler<sup>®</sup>**

If you miss a puff, don't worry: just take one as soon as you remember. If it is already time for your next puff; take the next one as usual. Do not take double dose to make up.



## How to use your Easyhaler™

Giona Easyhaler™ is easy to use. Read through these instructions first: they tell you what you should do and what to look out for.

### UNPACK THE INHALER

Take the inhaler out of its packaging. It comes in a laminate pouch to keep the powder dry. **Only take it out of the pouch when you are ready to start using it.**

Make sure you have all the bits (Figure 1):

- An inhaler, with a dust cap on the mouthpiece
- Possibly a protective cover.

If you **do not use the protective cover** move on to section **“TO TAKE A DOSE FROM GIONA EASYHALER™”**.

### Fit the inhaler into its protective cover:

Open up the protective cover (Figure 2). Make sure the dust cap covers the mouthpiece of the inhaler (this stops the inhaler going off by accident). Insert the inhaler into the protective cover to improve durability of the Product. If you are not using the device immediately, close the protective cover.

### TO TAKE A DOSE FROM GIONA EASYHALER™

If you are also using a reliever inhaler, use that first.

If you use the protective cover with your Giona Easyhaler™, open it.

#### Remove the dust cap.

##### A. Shake

- **Shake the device** vigorously up and down three to five times (Figure 3a or 3b). This is to make sure the powder flows properly and gives the correct dose.

##### Make sure...

- You shake it up and down
- You don't click it while you shake it.

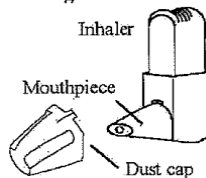
##### B. Click

- Hold the device upright, gripping it between your finger and thumb (Figure 4a or 4b).
- Squeeze until you hear a click, and let it click back again. This delivers powder into the inhalation channel inside the mouthpiece.

##### Make sure...

- The dust cap is not on the inhaler, it will stop you clicking it
- You only click down once, just before you take the medicine.  
If you click it more than once, see section *“If you have problems using the inhale?”*.
- You keep the inhaler upright as you click it and inhale the dose.

Figure 1



Protective cover



Figure 2

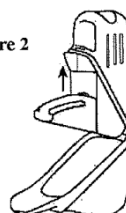


Figure 3a.

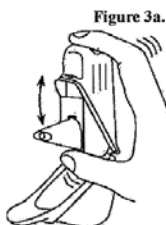


Figure 3b.

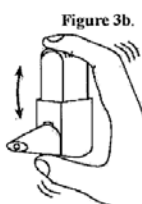


Figure 4a.

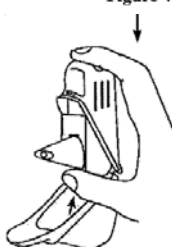


Figure 4b.

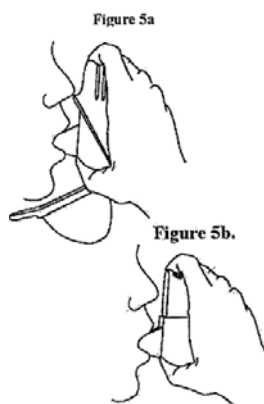


### C. Inhale

- Breathe out normally
- Place the mouthpiece in your mouth between your teeth and close your lips tightly around the mouthpiece
- **Take a strong and deep breath in** (Figure 5a or 5b)
- Take the inhaler out of your mouth
- Hold your breath for at least 5 seconds, then breathe normally.
- You may feel a sweet taste in your mouth. This indicates that you have received the dose.

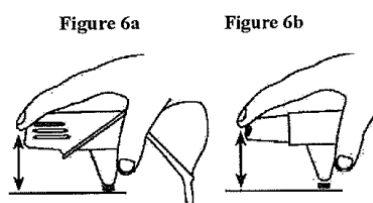
### Make sure...

- The whole mouthpiece is well inside your mouth, so the powder doesn't go on your teeth
- Your lips make a good seal around the mouthpiece
- You **don't** breathe out into the inhaler. This is important: it could clog up the inhaler. If you breathed out into the inhaler, see section "*If you have problems using the inhaler*".



### If you have problems using the inhaler

- **Don't rush things.** It's important to breathe normally. Practice a few times, in front of the mirror if this helps.
- **If you click it by accident**, or if you might have clicked it **more than once**, or if you **breathe out** into it, tap the mouthpiece to empty the powder onto a table top, or the palm of your hand (Figure 6a or 6b). This ensures proper dosing. Then start again with steps A, B and C.



### If you're taking a second puff, because your doctor prescribed it

- Start again with steps A, B and C (Note that you need to shake the device again to get another dose).

### After you've used the inhaler

- **Put the dust cap back on the mouthpiece.** If you are using the protective cover, close it.
- **Rinse out your mouth** with water, or **brush your teeth**. This is to get rid of any traces of powder left in your mouth. If you leave them, there may be a risk of fungal infection.

## 34. POSSIBLE SIDE EFFECTS

what to look for, what to do

Budesonide can cause side effects in some people.

*Common side effects (more than 1 out of 100)*

Sometimes inhaled budesonide causes a sore throat, hoarse voice or a cough. It can also cause thrush (a candida infection) in the mouth. Rinsing out your mouth with water or brushing your teeth after a puff can help to prevent these effects, which are not serious. If you get any of these, don't stop taking Giona Easyhaler<sup>®</sup>. Talk to a doctor as soon as possible.

*Rare side effects (less than 1 out of 1000):* Depression, irritability, anxiety, growth and behaviour problems in children, easy bruising, thinning of the skin, rash and other skin symptoms

*Very rare side effects (less than 1 out of 10 000):* Nervousness, suppression of the adrenal gland, cataract (which can interfere with your sight), glaucoma (high pressure in the eye), decrease in bone mineral density.

If you think you might have any of these rare or very rare side effects, or if you're worried about any of them, talk to your doctor as soon as possible.

Very rarely, some people get an **allergic reaction** to inhaled budesonide. In the most serious cases it cause reactions called anaphylaxis or angioedema. These are the signs, which come on soon after using the drug: sudden large drop in blood pressure, itching, rash, reddened skin, swelling of the eyes, lips, face or throat. If you get any of these, **don't take any more Giona Easyhaler<sup>®</sup>. Talk to a doctor straight away.**

Very rarely, inhaled drugs can cause increase in wheezing and shortness of breath immediately after dosing. If this occurs, **stop taking Giona Easyhaler** and use your reliever inhaler (usually blue). **Talk to a doctor straight away.**

If you notice any effects not mentioned in this leaflet, whether or not you think they're linked with Giona Easyhaler<sup>®</sup>, please tell your doctor or pharmacist.

## 5. KEEPING GIONA EASYHALER<sup>TM</sup>

### SAFE cleaning, replacing and storing

#### Cleaning the Easyhaler<sup>TM</sup>

Clean the Easyhaler<sup>TM</sup>'s mouthpiece at least once a week with a **dry cloth**. **Do not use water: the powder in the**

**Easyhaler<sup>TM</sup> is sensitive to moisture.**

If you use the protective cover, you can take the Easyhaler<sup>TM</sup> out of it to wipe it. When you are putting it back into its protective cover, put the dust cap on the mouthpiece to stop it going off accidentally.

#### Getting a new Easyhaler<sup>TM</sup>

The inhaler has a dose counter which shows how many doses are left (Figure 7a or 7b). The counter turns after every fifth actuation. When the numbers go red, there are 20 doses left. If you don't already have a new Easyhaler<sup>TM</sup>, contact your doctor for a new prescription. When the counter reaches 0, you need to replace the Easyhaler<sup>TM</sup> even though you can still observe the powder in the clear window on the back of the inhaler (Figure 8).

- Take the new inhaler out of the pouch. Insert the new inhaler into the protective cover, with the dust cap on. Now you can use the new inhaler as usual. See section 3 for more details.

#### Storing the Easyhaler<sup>TM</sup>

Do not store above 30°C. **Giona Easyhaler<sup>TM</sup> is affected by damp and moisture.** Therefore, it is recommended to keep the Easyhaler<sup>TM</sup> in its protective cover.

**If your Giona Easyhaler<sup>TM</sup> gets damp**, you need to replace it with a new one.

Replace Giona Easyhaler<sup>TM</sup> 6 months after you opened the laminate pouch. Write down the date you opened the pouch here to help you remember:

If the Easyhaler<sup>TM</sup> has passed the expiry date marked on the box, don't use it. Keep the Easyhaler<sup>TM</sup> out of the reach of children.

Figure 7a      Figure 7b

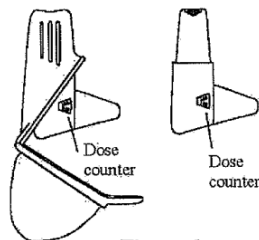


Figure 8

