Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Novolizer Budesonide 400 micrograms inhalation powder

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Budesonide
One delivered dose contains 400 micrograms of budesonide.
Excipient with known effect:
10.5 mg of lactose monohydrate/delivered dose
The delivered dose is the dose which is available for the patient after passing the mouthpiece.

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Inhalation powder.

White powder.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

Regular treatment of persistent asthma.

Note: budesonide is not intended to be used as a reliever of acute asthma.

4.2 Posology and method of administration

Posology

If a patient is switched to Novolizer Budesonide 400 micrograms from an alternative inhalation device the dose should be reviewed and adjusted, as necessary, on an individual basis. The active substance, dose regimen and method of delivery should be considered.

Steroid naive patients and patients previously controlled on inhaled steroids:

Adults (including older people) and children/adolescents over 12 years of age:
Initial recommended dose: 200- 400 micrograms once or twice daily
Maximum recommended dose: 800 micrograms twice daily

Children 6 - 12 years:
Initial recommended dose: 200 micrograms twice or 200 –400 micrograms once daily
Maximum recommended dose: 400 micrograms twice daily

Children below 6 years of age:
Novolizer Budesonide 400 micrograms is not recommended for use in children below age 6 due to insufficient data on safety and efficacy.

Note: For the 200 micrograms doses a 200 micrograms strength is available.

The dose should be adapted to the requirements of each individual, the severity of the disease and the clinical response of the patient. The dose should be adjusted until control is achieved and then should be titrated to the lowest dose at which effective control of asthma is maintained.

Posology limits:

Adults (including older people) and children/adolescents over 12 years of age: 200 - 1600 micrograms daily

Children 6 - 12 years: 200 - 800 micrograms daily

Twice daily dosing in children and adults, including older people should be used when starting treatment, during periods of severe asthma and while reducing or discontinuing oral glucocorticosteroids.

Once daily dosing up to 800 micrograms may be used in adults, including older people and children/adolescents over 12 years of age with mild to moderate asthma already controlled on inhaled glucocorticosteroids (either budesonide or beclometasone dipropionate) administered twice daily.

Once daily dosing up to 400 micrograms may be used in children 6-12 years of age with mild to moderate asthma already controlled on inhaled glucocorticosteroids (either budesonide or beclometasone dipropionate) administered twice daily.

If a patient is transferred from twice daily dosing to once daily dosing this should be at the same equivalent total daily dose (with consideration of the active substance and the method of delivery) and this dose should then be reduced to the minimum dose needed to maintain effective control of asthma. The once daily regimen can be considered only when asthma symptoms are controlled.
In case of once daily dosing this dose should be taken in the evening.

In case of deterioration of asthma control (recognised by e.g. persistent respiratory symptoms, increased use of an inhaled bronchodilator) the dose of inhaled steroids should be increased. Those patients receiving the once daily dose regimen, should be advised to double their dose of inhaled corticosteroid, such that a once daily dose would be administered twice daily. In any case of deterioration of asthma control the patient should seek advice from amedical doctor as soon as possible.

A short acting inhaled beta-2-agonist should be available for the relief of acute symptoms of asthma at all times.

Asthma
Novolizer Budesonide 400 micrograms may permit replacement or significant reduction in dosage of oral glucocorticosteroids while maintaining asthma control. When transferral from oral steroids to Novolizer Budesonide4 00 micrograms is started, the patient should be in a relatively stable phase. A high dose of Novolizer Budesonide 400 micrograms is then given in combination with the previously used oral steroid dose for about 10 days.
After that, the oral steroid dose should be gradually reduced (by for example 2.5 milligrams prednisolone or the equivalent each month) to the lowest possible level. In many cases, it is possible to completely substitute the oral steroid with Novolizer Budesonide 400 micrograms. For further information on the withdrawal of corticosteroids, see section 4.4.

Mode and duration of treatment:
Novolizer Budesonide 400 micrograms is intended for long-term therapy. It should be administered regularly according to the recommended schedule even when the patient is asymptomatic.

The improvement in the control of asthma can appear in 24 hours, although 1 - 2 weeks additional treatment period may be necessary to reach a maximum benefit.

Method of Administration

Inhalation use

In order to ensure that the active substance optimally reaches the intended site of action it is necessary to inhale steadily, deeply and as rapidly as possible (to the maximum inhalation). A clearly audible click and a colour change in the control window from green to redindicates that inhalation has been performed correctly. If an audible click is not heard and there is no colour change in the control window, inhalation should be repeated. The inhaler remains locked until inhalation is performed correctly.

To reduce the risk of oral candidiasis and hoarseness it is recommended that inhalation be performed before meals and that the mouth is rinsed with water or the teeth brushed after each inhalation.

Usage and handling of the powder inhaler (=Novolizer)

Refilling
1. Lightly press together the ribbed surfaces on both sides of the lid, move the lid forwards and lift off.
2. Remove the protective aluminium foil from the cartridge container and take out the new cartridge.
3. Insert the cartridge into the powder inhaler (=Novolizer)with the dosage counter facing the mouthpiece.
4. Replace the lid into the side guides from above and push down flat towards the button until it snaps into place. The cartridge can be left in the powder inhaler (=Novolizer) until it has been used up, or for up to 6 months after insertion.
Note: Novolizer Budesonide 400 micrograms cartridges may only be used in the Novolizer powder inhaler

Usage
1. When using the powder inhaler (=Novolizer) always keep it horizontal. First remove the protective cap.
2. Completely depress the coloured button. A loud double click will be heard and the colour of the control window (lower) will change from red to green. Then release the coloured button. The colour green in the window indicates that the powder inhaler (=Novolizer)is ready for use.
3. Exhale as far as possible (but not into the powder inhaler).
4. Put the lips around the mouthpiece. Inhale the powder steadily, deeply and as rapidly as possible (to the maximum inhalation). During this breath a loud click should be heard, indicating correct inhalation. Hold the breath for a few seconds and then continue with normal breathing.
Note: If the patient needs to take more than 1 actuation at a time, steps 2 - 4 should be repeated.
5. Replace the protective cap on the mouth piece - the dosing procedure is now complete.
6. The number in the top window indicates the number of inhalations left.
Note: The coloured button should onlybe pressed immediately before inhalation.

A double inhalation in error is not possible with the powder inhaler (=Novolizer). The click sound and the change of colour in the control window indicate that inhalation has been performed correctly. If the colour of the control window does not change then inhalation should be repeated. If inhalation is not completed correctly after several attempts, then the patient should consult the doctor/physician.

Cleaning
The powder inhaler (=Novolizer) should be cleaned at regular intervals, but at least every time the cartridge is changed. Instructions on how to clean the powder inhaler (=Novolizer) can be found in the operating instructions attached.

Note: In order to ensure correct use of the inhaler, patients should receive thorough instructions on how to use the powder inhaler (=Novolizer) . Children should only use this product under the supervision of an adult.

4.3 Contraindications

Hypersensitivity to the active substance budesonide or to the excipient lactose monohydrate (which contains small amounts of milk proteins).

4.4 Special warnings and precautions for use

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

Treatment of acute exacerbations of asthma and asthma symptoms may need an increase in the dose of budesonide. The patient should be advised to use a short-acting inhaled bronchodilator as rescue medication to relieve acute asthma symptoms.

Close observation and special care is needed in patients with both active and quiescent pulmonary tuberculosis. Patients with active pulmonary tuberculosis may use budesonide only if they are treated simultaneously with effective tuberculostatics. Similarly patients with fungal, viral or other infections of the airways require close observation and special care and should use budesonide only if they are also receiving adequate treatment for such infections.

Patients who repeatedly fail to perform the inhalation correctly should consult their doctor.
In patients with severe hepatic dysfunction treatment with budesonide - similar to treatment with other glucocorticosteroids - may lead to a reduced elimination rate and an increase in systemic availability. Attention is to be paid to possible systemic effects. Therefore the hypothalamic pituitary adrenocortical (HPA) axis function of these patients should be checked at regular intervals.

Prolonged treatment with high doses of inhaled corticosteroids, particularly higher than the recommended doses, may result in clinically significant adrenal suppression. These patients may exhibit signs and symptoms of adrenal insufficiency when exposed to severe stress. Additional systemic corticosteroid cover should be considered during periods of stress or elective surgery.

Systemic effects may occur with any inhaled corticosteroids, particularly at high doses prescribed for prolonged periods. These effects are much less likely to occur with inhalation treatment than with oral corticosteroids. Possible systemic effects include Cushing's syndrome, Cushingoid features, adrenal suppression, growth retardation in children and adolescents, decrease in bone mineral density, cataract, glaucoma and more rarely, a range of psychological or behavioural effects including psychomotor hyperactivity, sleep disorders, anxiety, depression or aggression (particularly in children). It is important therefore that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.

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.

Concomitant use of ketoconazole, HIV protease inhibitors or other potent CYP3A4 inhibitors should be avoided. If this is not possible, the period between treatments should be as long as possible (see also section 4.5).

Oral candidiasis may occur during the therapy with inhaled corticosteroids. This infection may require treatment with appropriate antifungal therapy and in some patients discontinuation of treatment may be necessary (see also section 4.2).

As with other inhalation therapy paradoxical bronchospasm may occur with an immediate increase in wheezing after dosing. If this occurs, treatment with inhaled budesonide should be discontinued immediately, the patient assessed and alternative therapy instituted if necessary.

It is recommended that the height of children receiving prolonged treatment with inhaled corticosteroids is regularly monitored. If growth is slowed, therapy should be re-evaluated with the aim of reducing the dose of inhaled corticosteroid. The benefits of the corticosteroid therapy and the possible risks of growth suppression must be carefully weighed. In addition, consideration should be given to referring the patient to a paediatric respiratory specialist.

Precautions for patients not previously treated with corticosteroids:

When budesonide is used regularly as directed, patients who have previously never or only occasionally received brief treatment with corticosteroids, should experience an improvement in breathing after approximately 1 - 2 weeks. However, extreme mucous congestion and inflammatory processes may obstruct the bronchial passages to such an extent that budesonide cannot fully exert its local effects. In such cases, inhaled therapy with budesonide should be supplemented with a short course of systemic corticosteroids. Inhalation doses are continued after gradually reducing the dose of systemic corticosteroids.

Precautions for switching patients from systemically active corticosteroids to inhalation treatment:

Patients receiving systemic treatment with corticosteroids should be switched to Novolizer Budesonide 400 micrograms at a time when their symptoms are under control. In these patients, whose adrenocortical function is usually impaired, systemic treatment with corticosteroids must not be stopped abruptly. At the beginning of the switchover, a high dose of Novolizer Budesonide 400 micrograms should be given in addition to the systemic corticosteroids for about 7 to 10 days. Then, depending on the patient's response and depending on the original dose of the systemic steroid, the daily dose of the systemic corticosteroid can be reduced gradually (e.g. 1 milligram prednisolone or the equivalent each week or 2.5 milligram prednisolone or the equivalent each month).The oral steroid should be reduced to the lowest possible level and it may be possible to completely replace the oral steroid with inhaled budesonide.

Within the first few months of switching patients from systemic administration of

corticosteroids to inhalation treatment, it may be necessary to resume systemic administration of corticosteroids during periods of stress or in the case of emergencies (e.g. severe infections, injuries, surgery). This applies also to patients who have received prolonged treatment with high doses of inhaled corticosteroids. They may also have impaired adrenocortical function and may need systemic corticosteroid cover during periods of stress.

Recovery from impaired adrenal function may take some considerable time. Hypothalamic pituitary adrenocortical axis function should be monitored regularly.

The patient might feel generally unwell in a non specific way during the withdrawal of systemic corticosteroids despite maintenance or even improvement in respiratory function. The patient should be encouraged to continue with inhaled budesonide and withdrawal of oral steroids unless there are clinical signs which might indicate adrenal insufficiency.

After the patient has been switched to inhalation treatment, symptoms may become manifest that had been suppressed by the previous systemic treatment with glucocorticosteroids, e.g. allergic rhinitis, allergic eczema, muscle and joint pain. Suitable medicinal products should be co-administered to treat these symptoms.

Inhaled budesonide should not be stopped abruptly.

Exacerbation of clinical symptoms due to acute respiratory tract infections:

If clinical symptoms become exacerbated by acute respiratory tract infections, treatment with appropriate antibiotics should be considered. The dose of budesonide can be adjusted as required and, in certain situations, systemic treatment with glucocorticosteroids may be indicated.

If no improvement of symptoms or adequate asthma control is seen within 14 days of treatment, medical advice is sought for either adjusting the dose or clarifying correct inhalation procedure.

Precautions for switching patients from Novolizer Budesonide 200 micrograms to Novolizer Budesonide 400 micrograms:

Patients who are not able to produce flow rates above 60 l/min and children need careful monitoring when they begin treatment with the same dose but are switched from Novolizer Budesonide 200 micrograms to Novolizer Budesonide 400 micrograms.

Lactose may contain milk protein. The amount of lactose contained in Novolizer 400 micrograms does not normally cause problems in lactose intolerant people.

However, in patients with profound enzyme deficiency, lactose intolerance has been reported very rarely following inhalation of powder containing lactose.

4.5 Interaction with other medicinal products and other forms of interactions

The metabolism of budesonide is primarily mediated by CYP3A4. Inhibitors of this enzyme, e.g., ketoconazole, itraconazole, HIV protease inhibitors, cobicistat-containing products can therefore increase systemic exposure to budesonide several times, see section 4.4. Since there is no data to support a dosage recommendation, the combination should be avoidedunless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects . If this is not possible, the period between treatments should be as long as possible and a reduction of the budesonide dose could also be considered.
Limited data about this interaction for high-dose inhaled budesonide indicate that marked increases in plasma levels (on average four- fold) may occur if itraconazole, 200 mg once daily, is administered concomitantly with inhaled budesonide (single dose of 1000 microgram).
Raised plasma concentrations of and enhanced effects of corticosteroids have been observed in women also treated with oestrogens and contraceptive steroids, but no effect has been observed with budesonide and concomitant intake of low dose combination oral contraceptives.
Because adrenal function may be suppressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values).

4.6 Fertility, pregnancy and lactation

Pregnancy

Most results from prospective epidemiological studies and world-wide post-marketing data have not been able to detect an increased risk for adverse effects for the foetus and newborn child from the use of inhaled budesonide during pregnancy. It is important for both foetus and mother to maintain an adequate asthma treatment during pregnancy. As with other drugs administered during pregnancy, the benefit of the administration of budesonide for the mother should be weighed against the risks to the foetus.

Breast-feeding
Budesonide is excreted in breast milk. However, at therapeutic doses no effects on the suckling child are anticipated. Novolizer Budesonide 400 micrograms can be used during breast feeding.

Maintenance treatment with inhaled budesonide (200 or 400 microgram twice daily) in asthmatic nursing women results in negligible systemic exposure to budesonide in breast-fed infants.

In a pharmacokinetic study, the estimated daily infant dose was 0.3% of the daily maternal dose for both dose levels, and the average plasma concentration in infants was estimated to be 1/600th of the concentrations observed in maternal plasma, assuming complete infant oral bioavailability. Budesonide concentrations in infant plasma samples were all less than the limit of quantification.

Based on data from inhaled budesonide and the fact that budesonide exhibits linear PK properties within the therapeutic dosage intervals after nasal, inhaled, oral and rectal administrations, at therapeutic doses of budesonide, exposure to the suckling child is anticipated to be low.

4.7 Effects on ability to drive and use machines

Budesonide has no influence on the ability to drive and use machines.

4.8 Undesirable effects

Adverse events are listed below by system organ class and frequency. Frequencies are defined as:
Very common (≥ 1/10); Common (≥ 1/100 to < 1/10); Uncommon (≥ 1/1,000 to < 1/100);
Rare (≥ 1/10,000 to < 1/1,000); Very rare (< 1/10,000); Not known (cannot be estimated from the available data)

Table on Adverse Drug Reaction (ADR) by System Organ Class (SOC) and Frequency

SOC	Frequency	Adverse Drug Reaction
INFECTIONS AND INFESTATIONS	Common	Oropharyngeal candidiasis
IMMUNE SYSTEM DISORDERS	Rare	Immediate and delayed hypersensitivity reactions including: Angioneurotic oedema Anaphylactic reaction
ENDOCRINE DISORDERS	Rare	Signs and symptoms of systemic corticosteroid effects including: Adrenal suppression and Growth retardation*
PSYCHIATRIC DISORDERS	Uncommon	Depression
	Rare	Anxiety Restlessness Nervousness Behavioural changes (predominantly in children)
	Unknown	Sleep disorders Psychomotor hyperactivity Aggression
NERVOUS SYSTEM DISORDERS	Uncommon	Tremor

EYE DISORDERS	Uncommon	Cataract
	Unknown	Vision, blurred vision (see also section 4.4)
		Glaucoma
RESPIRATORY, THORACIC AND MEDIASTINAL DISORDERS	Common	Hoarseness
		Cough
		Throat irritation
	Rare	Bronchospasm
		Dysphonia
		Hoarseness**
GASTROINTESTINAL DISORDERS	Common	Oral mucosal irritation
SKIN AND SUBCUTANEOUS TISSUE DISORDERS	Rare	Urticaria
		Rash
		Dermatitis
		Pruritus
		Erythema
		Bruising
MUSCULOSKELETAL, CONNECTIVE TISSUE AND BONE DISORDERS	Uncommon	Muscle spasm
	Very rare	Bone density decreased

* refer to Paediatric population, below
** rare in children

Occasionally, signs or symptoms of systemic glucocorticosteroid-side effects may occur with inhaled glucocorticosteroids, probably depending on dose, exposure time, concomitant and previous corticosteroid exposure, and individual sensitivity.

Description of selected adverse reactions
Clinical trials with 13119 patients on inhaled budesonide and 7278 patients on placebo have been pooled. The frequency of anxiety was 0.52% on inhaled budesonide and 0.63% on placebo; that of depression was 0.67% on inhaled budesonide and 1.15% on placebo.

In placebo-controlled studies cataract was also uncommonly reported in the placebo group.

Mild mucosal irritations accompanied by throat irritation, hoarseness and cough may commonly occur.

The susceptibility to infection can be increased. The ability to adapt to stress can be impaired.

There is an increased risk of pneumonia in patients with newly diagnosed COPD starting treatment with inhaled corticosteroids. However a weighted assessment of 8 pooled clinical trials involving 4643 COPD patients treated with budesonide and 3643 patients randomized to non-ICS treatments did not demonstrate an increased risk for pneumonia. The results from the first 7 of these 8 trials have been published as a metaanalysis.

Lactose-monohydrate contains small amounts of milk proteins and can therefore cause allergic reactions.

Paediatric population
Due to the risk of growth retardation in the paediatric population, growth should be monitored as described in section 4.4.

Reporting of suspected adverse reactions
Reporting suspected adverse reactions after authorisation of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Healthcare professionals are asked to report any suspected adverse reactions via HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie.

4.9 Overdose

Acute overdose with Novolizer Budesonide 400 micrograms, even in excessive doses, is not expected to be a clinical problem.

In the longer term, atrophy of the adrenal cortex can occur. The effects which are usual for glucocorticosteroids, e.g. increased susceptibility to infection, can occur. The ability to adapt to stress can be impaired.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group**:** Other drugs for obstructive airway diseases, inhalants,Glucocorticoids; ATC-Code: R03BA02

Budesonide is a synthetic glucocorticoid. After oral inhalation, it has a local anti-inflammatory effect on the bronchial mucosa. Budesonide penetrates cellular membranes and binds to a cytoplasmic receptor protein. This complex enters the nucleus and induces there the biosynthesis of specific proteins, like macrocortin (lipocortin). The hormone-like effects occur after a certain latency period (30-60 min) and result in an inhibition of phospholipase A2. It is also possible that therapeutically effective doses of Budesonide (like other anti-inflammatory glucocorticosteroids) suppress cytokine-induced COX-2 expression.

Clinically, the anti-inflammatory effect results e.g. in improvement of the symptoms, such as dyspnoea. The hyperresponsiveness of the bronchial tract to exogenic challenges is reduced.

Clinical Safety

Paediatric population
Slit lamp examinations were performed in 157 children (5-16 years old), treated with an average daily dose of 504 µg for 3-6 years. Findings were compared with 111 age-matched asthmatic children. Inhaled budesonide was not associated with an increased occurrence of posterior subcapsular cataract.

Influence on plasma cortisol concentration
Studies in healthy volunteers with inhaled budesonide have shown dose-related effect on plasma and urinary cortisol. At recommended doses, inhaled budesonide causes significantly less effect on adrenal function than prednisone 10 mg, as shown by ACTH test.

5.2 Pharmacokinetic properties

Absorption
Peak plasma levels appear approximately 30 minutes after inhalation.
Systemic bioavailability after inhalation is up to 37% and the concentration in human plasma after inhalation of a single dose of 1600 micrograms is 0.63 nmol/L.

The trigger threshold of the Novolizer which must be overcome for successful inhalation is to be found at inspiratory flows through the inhaler of 35 - 50 l/min. Dose linearity for switching from Budesonide Novolizer 200 µg to Budesonide Novolizer 400 µg was shown at flow rates of 60 l/min upwards.
The fine particle dose (particles < 5 µm) measured in vitro in the clinically relevant range is approximately 30 – 50 % related to the nominal dose. In healthy subjects, approximately 20 – 30 % of the metered dose of budesonide pass into the lungs. The remainder deposits in mouth, nose and throat and a large part of it is swallowed.
Distribution
Budesonide has a volume of distribution of approximately 3 L/kg. Plasma protein binding averages 85-90%.

Biotransformation
Budesonide undergoes an extensive degree (≈90%) of biotransformation on first passage through the liver to metabolites of low glucocorticosteroid activity. The glucocorticosteroid activity of the major metabolites, 6β-hydroxybudesonide and16α-hydroxyprednisolone, is less than 1% of that of budesonide. The metabolism of budesonide is primarily mediated by CYP3A, a subfamily of cytochrome p450.

Elimination
The metabolites of budesonide are excreted as such or in conjugated form mainly via the kidneys. No unchanged budesonide has been detected in the urine. Budesonide has high systemic clearance (approximately 1.2 L/min) in healthy adults, and the terminal half-life of budesonide after iv dosing averages 2-3 hours.

Linearity
The kinetics of budesonide are dose-proportional at clinically relevant doses.

Paediatric population

Budesonide has a systemic clearance of approximately 0.5 L/min in 4-6 years old asthmatic children. Per kg body weight children have a clearance which is approximately 50% greater than in adults. The terminal half-life of budesonide after inhalation is approximately 2.3 hours in asthmatic children. This is about the same as in healthy adults.

5.3 Preclinical safety data

Preclinical data revealed no special hazard for humans at therapeutic doses based on studies of chronic toxicity, genotoxicity and carcinogenicity.

Glucocorticosteroids, including budesonide, have produced teratogenic effects in animals, including cleft palate and skeletal abnormalities. Similar effects are considered unlikely to occur in humans at therapeutic doses.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Lactose monohydrate.

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

Medicinal Product (Budesonide in the cartridge packed in a container)
Shelf life of the medicinal product as packaged for sale
3 years

Shelf life after first opening the cartridge container
6 months

Novolizer device
Shelf life before first use
3 years

In-use shelf life
1 year

To note: The functioning of the Novolizer device has been demonstrated in tests for 2000 metered doses. Therefore a maximum of 40 cartridges containing 50 metered doses or 20 cartridges containing 100 metered doses can be used with this device (within a single year) prior to replacement.

6.4 Special precautions for storage

Store in the original package. This medicinal product does not require any special temperature storage conditions
In-Use storage conditions: Keep the Novolizer device tightly closed, in order to protect from moisture.

6.5 Nature and contents of container

1 Acrylonitrile-butadiene-styrene/polypropylene cartridge containing 50 or 100 metered doses, equivalent to the filling amount of 0.545 or 1.09 g of powder packed in a polypropylene container sealed by aluminium foil.
1 Novolizer powder inhaler device (mouthpiece in polycarbonate and powder inhaler in acrylnitrilbutadienestyrol copolymer, polyoxymethylene).

Pack sizes:
Original sales packs:
1 cartridge containing 50/100 metered doses and 1Novolizer powder inhaler device
2 cartridges containing 100 metered doses each and 1Novolizer powder inhaler device

Refill packs:
1 cartridge containing 50/100 metered doses
2 cartridges containing 100 metered doses each
Hospital pack:
(1 cartridge containing 50 metered doses and 1Novolizer powder inhaler device) x 10
(1 cartridge containing 100 metered doses and 1Novolizer powder inhaler device) x 10
Sample pack:
1 cartridge containing 50 metered doses and 1Novolizer powder inhaler device
1 cartridge containing 100 metered doses and 1Novolizer powder inhaler device

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements.

7 MARKETING AUTHORISATION HOLDER

Mylan IRE Healthcare Limited
Unit 35/36
Grange Parade
Baldoyle Industrial Estate
Dublin 13
Ireland

8 MARKETING AUTHORISATION NUMBER

PA2010/032/002

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 22nd December 2005
Date of last renewal: 1 June 2008

10 DATE OF REVISION OF THE TEXT

June 2018