SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE MEDICINAL PRODUCT

Budesonide 64 micrograms/actuation, Aqueous Nasal Spray

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

The delivered (metered) dose of 0.05 ml nasal spray, suspension contains 64 micrograms of budesonide.

Excipient (s) with known effect:

0.06 mg of potassium sorbate / 0.05 ml nasal spray, suspension

For the full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Nasal spray, suspension.

White to almost white, homogeneous suspension

4 CLINICAL PARTICULARS

4.1 Therapeutic indications

Treatment and prevention of signs and symptoms of seasonal and perennial allergic rhinitis in adults and children over 6 years of age.

Treatment of signs and symptoms of nasal polyps in adults.

4.2 Posology and method of administration

Posology

For nasal use only.

The dosage should be determined individually. The dose should be titrated to the lowest dose at which effective control of symptoms is maintained.

The duration of the therapy with Budesonide nasal spray should be restricted to the period of allergen exposure and depends on the nature and the characteristics of the allergen. For a full therapeutic benefit regular use is essential.

Allergic rhinitis

Initial dose

Adults, adolescents and children from 6 years of age:

The recommended initial dose of 256 micrograms may be administered once daily in the morning or divided into two administrations, in the morning and in the evening.

2 actuations into each nostril once daily in the morning or 1 actuation into each nostril in the morning and in the evening

Children should be treated under guidance of an adult.

The advice of a doctor is required for any treatment in children for more than 2 months over one year.

Concomitant therapy may sometimes be necessary to treat the symptoms affecting the eye caused by the allergy.

Maintenance dose

The desired clinical effect appears within about 1-2 weeks.

Afterwards, the lowest dose should be chosen that keeps the patient just without symptoms. No better efficacy is to be expected with a dose greater than 256 micrograms.

Nasal polyps

Symptomatic treatment of nasal polyps in adults:

The recommended dose for the treatment of nasal polyps is 256 micrograms. The dose may be administered once daily in the morning or divided into two administrations, in the morning and in the evening.

2 actuations into each nostril once daily in the morning or

1 actuation into each nostril in the morning and in the evening

After the desired clinical effect has appeared, the lowest dose should be chosen that keeps the patient without symptoms.

Method of administration

1. Gently blow your nose to clean the nostrils, if necessary.
2. Shake the bottle (figure 1). Remove the protective cap.

Figure 1.

3. Hold the bottle as shown in figure 2. Before using Budesonide nasal spray suspension for the first time you must prime the nozzle (i.e. fill it with medicine). Pump the nozzle up and down several times (5-10 times), spraying into the air until an even mist is seen. The priming effect remains for approximately 24 hours. If a longer period of time passes before the next dose is taken, the nozzle must be primed (filled with medicine) again. If Budesonide nasal spray suspension is used at shorter intervals it is sufficient to spray just once into the air.

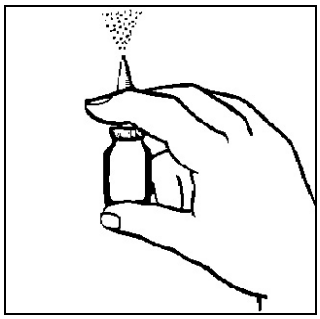

Figure 2.

4. Insert the tip of the nozzle into your nostril as shown in figure 3 and spray once (or more if your doctor has told you to). Use the spray into the other nostril in the same way. Note, it is not necessary to breathe in at the same time as you spray.

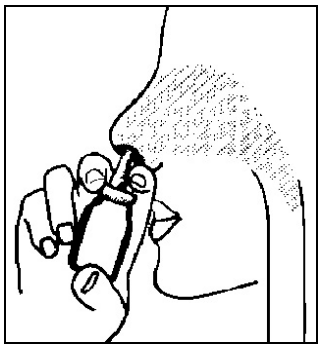

Figure 3.

5. Wipe the nozzle with a clean tissue and replace the protective cap.
6. Store the bottle in an upright position.

Cleaning your Budesonide nasal spray pump

You should clean the plastic nozzle of Budesonide nasal spray pump regularly, and at any time the spray of medicine is not coming out as it should. If this happens, first check if the nozzle is primed with medicine (see earlier). If after priming the nozzle again the pump is still not working, clean the nozzle by using the following instructions:

- Remove the plastic nozzle with a clean tissue and wash in warm – not hot – water.
- Rinse the nozzle thoroughly, dry it and then replace onto the top of the bottle.
- Never try to unblock the nozzle by using a pin or other sharp object.
After cleaning the nozzle must be primed (filled with medicine) again before use.

4.3 Contraindications

- Hypersensitivity to the active substance or to any of the excipients listed in section 6.1.
- Disorders of haemostasis, or epistaxis.
- Oro-nasal and ophthalmic herpes virus infection.

4.4 Special warnings and precautions for use

The risk of systemic effects, adrenal cortical slowing and impact on growth is increased in case of concomitant administration of inhaled or systemic corticosteroid therapy.

Systemic effects of nasal corticosteroids may occur, particularly at high doses, when prescribed for prolonged periods, together with additional or previous therapy with corticoids and due to individual factors. These effects are much

less likely to occur than with oral corticosteroids and may vary in individual patients and between different corticosteroid preparations. Potential systemic effects may include Cushing's syndrome, Cushingoid features, skin thinning, subcutaneous haematomas, adrenal suppression, growth retardation in children and adolescents, decreased bone 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).

Treatment with higher than recommended doses of nasal corticosteroids may result in clinically significant adrenal suppression. If there is evidence of higher than recommended doses being used then additional systemic corticosteroid cover should be considered during period of stress or elective surgery.

Glucocorticoids may increase blood glucose levels. This must be taken into account when prescribing to diabetic patients.

In case of infections of the nose caused by bacteria or fungi, Budesonide nasal spray suspension should be used only if concomitant antibacterial or antifungal treatment is carried out.

In continuous long-term treatment, the nasal mucosa should be inspected regularly e.g. every 6 months. If mucosal atrophy is observed, the doses of local corticosteroids should be reduced.

Impaired liver function influences the pharmacokinetics of corticosteroids. Severe impairment of hepatic function influences the pharmacokinetics, including the elimination, of orally administered budesonide resulting in increased systemic availability and reduced elimination capacity. However, the intravenous pharmacokinetic of budesonide in healthy volunteers and patients with liver cirrhosis is approximately the same. Consideration of potential systemic effects may be needed in severe impairment of hepatic function. However, this is of limited clinical relevance for budesonide nasal spray since only a relatively low oral content is systemically available after nasal administration.

Budesonide nasal spray is not recommended in patients with epistaxis and in patients, with herpetic infection of oral, nasal or ophthalmic region.

Budesonide nasal spray is not recommended in patients with nasal ulcerations, in cases of recent surgery or nasal trauma until it is fully recovered.

Permeability of the nasal cavity must be ensured for optimal diffusion of budesonide into the nasal cavity. The patient should be advised to blow his or her nose before each instillation.

Special caution is necessary in patients with active or quiescent pulmonary tuberculosis, and in patients with fungal or viral infections of the airways.

Any contact with a person who has contracted tuberculosis, measles or chickenpox should be taken into account when initiating treatment.

The patient should be informed that the full effect is not achieved until after a few days of treatment. Treatment of seasonal rhinitis should, if possible, start before exposure to the allergens.

Glucocorticoids may increase intraocular pressure. Patients with glaucoma or a family history of glaucoma should therefore be closely monitored while taking this drug.

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.

Ophthalmologic examination is also required for ocular infections.

This medicinal product contains potassium sorbate and may cause skin reactions (e.g. contact dermatitis).

The co-administration of nasal corticosteroids in patients undergoing long-term oral corticosteroid therapy does not dispense with the precautions necessary when reducing oral corticosteroid doses. These should be reduced very gradually and weaning should be carried out under careful medical supervision (looking for the appearance of signs of acute or subacute adrenal insufficiency) lasting beyond the end of general corticosteroid therapy.

Paediatric population

The long-term effects of nasal glucocorticosteroids in children are not fully known. Physicians should closely follow the growth of children taking glucocorticosteroids for longer term by any route, and weigh the benefits of the glucocorticosteroid therapy against the possibility of growth suppression.

Growth retardation has been reported in children receiving nasal corticosteroids at licensed doses. It is recommended that the height of children receiving prolonged treatment with nasal corticosteroids is regularly monitored. If growth is slowed, therapy should be reviewed with the aim of reducing the dose of nasal corticosteroid if possible, to the lowest dose at which effective control of symptoms is maintained. In addition, consideration should be given to referring the patient to the paediatric specialist.

Switching from systemic administration route

Care must be taken while transferring patients from systemic steroid treatment to Budesonide Nasal Spray if there is any reason to suppose that their adrenal function is impaired.

Athletes

Anti-Doping Warning: Athletes must be aware that this medicinal product may cause a positive reaction to sports doping control tests. Use of Budesonide as a doping agent may become a health hazard.

4.5 Interaction with other medicinal products and other forms of interaction

Budesonide has not been observed to interact with any drug used for the treatment of rhinitis.

The metabolism of budesonide is primarily mediated by CYP3A4, a subfamily of cytochrome P450. Significant increases in blood levels of budesonide may be observed with potent CYP3A4 inhibitors (e.g. cobicistat-containing products, ketoconazole, itraconazole, voriconazole, posaconazole, clarithromycin, telithromycin, nefazodone, and HIV protease inhibitors such as saquinavir, nelfinavir, indinavir, atazanavir, ritonavir, boceprevir) cyclosporin, ethinyl estradiol and troleandomycin, can therefore increase systemic exposure to budesonide several times. Since there is no data to support a dosage recommendation, the combination should be avoided. If this is not possible, the time between therapies should be as long as possible and a reduction of the budesonide dose may also be considered. In the context of short-term treatment, this is of limited clinical significance.

In case of prolonged oral or inhaled use: increase in plasma concentrations of budesonide by decrease of its hepatic metabolism by the inhibitor, with risk of appearance of a Cushing's syndrome or even adrenal insufficiency. A non metabolised corticosteroid is preferred.

The concomitant administration of cimetidine and budesonide may result in a slight elevation of the budesonide plasma level, which, however, has no clinical significance.

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.

Co-treatment with CYP3A inhibitors, including cobicistat-containing products, is expected to increase the risk of systemic side-effects. The combination should be avoided unless the benefit outweighs the increased risk of systemic corticosteroid side-effects, in which case patients should be monitored for systemic corticosteroid side-effects.

Because adrenal function may be suppressed, an ACTH stimulation test for diagnosing pituitary insufficiency might show false results (low values).

Combinations to be taken into account

+ Acetylsalicylic acid

Increased risk of bleeding. Association to be taken into account with analgesic or antipyretic doses (>=500 mg per dose and/or <3 g per day).

+ Nonsteroidal anti-inflammatory drugs

Increased risk of ulceration and gastrointestinal bleeding.

+ Fluoroquinolones

Possible increased risk of tendinopathy or even tendon rupture (exceptional), especially in patients receiving prolonged corticosteroid therapy.

+ Heparins

Increased risk of bleeding.

Precaution of use

+ Oral anticoagulants

Glucocorticoids (systemic and rectal routes): possible impact of corticosteroid therapy on the metabolism of antivitamin K and coagulation factors. Risk of bleeding specific to corticosteroid therapy (digestive mucosa, vascular fragility) at high doses or in prolonged treatment exceeding 10 days.

When combination is justified, reinforce monitoring: if necessary, with antivitamins K, biological control on the 8th day, then every 15 days during and after the end of corticosteroid therapy.

+ Enzyme-inducing anticonvulsants

Decrease in plasma concentrations and efficacy of corticosteroids due to increased hepatic metabolism by the inducer: the consequences are particularly important in addisonian patients treated with hydrocortisone and in cases of transplantation.

Clinical and biological monitoring; adjustment of corticosteroid dosage during treatment with the inducer and after its discontinuation.

+ Cobimetinib

Increased risk of bleeding. Clinical monitoring.

+ Enzyme inducers

Decreased plasma concentrations and efficacy of corticosteroids due to increased hepatic metabolism by the inducer; consequences are particularly important in addisonian patients treated with hydrocortisone and in cases of transplantation.

Clinical and biological monitoring; adjustment of corticosteroid dosage during and after inducer therapy.

+ Gastrointestinal topical agents, antacids and adsorbents

Decreased absorption of budesonide.

As a precautionary measure, these topical agents or antacids should be taken at a distance from any other medication (more than 2 hours, if possible)

4.6 Fertility, pregnancy and lactation

Pregnancy

Results from prospective epidemiological studies and from worldwide post marketing experience indicate no increased risk for overall congenital malformations from the use of inhaled or intranasal budesonide during early pregnancy. Animal studies have shown reproductive toxicity (see section 5.3). The potential risk for humans is unknown. As with other drugs the administration of budesonide during pregnancy requires that the benefits for the mother are weighed against the risks for the foetus. The use of budesonide should be as short as possible.

In chronic diseases requiring treatment throughout pregnancy, mild intrauterine growth retardation is possible. Neonatal adrenal insufficiency has been observed exceptionally after high-dose corticosteroid therapy. A period of clinical (weight, diuresis) and biological (blood glucose) monitoring of the newborn may be warranted.

Breast-feeding

Budesonide is excreted in breast milk. At therapeutic doses of budesonide no effects on the suckling child are anticipated (see section 5.2).

However, the biological or clinical impact of long-term maternal treatment has not been evaluated to date.

Therefore, breast-feeding is possible in case of brief treatment. In case of chronic treatment, breast-feeding should be avoided as a precautionary measure.

Fertility

There is no evidence that intranasal budesonide affects fertility.

4.7 Effects on ability to drive and use machines

Budesonide nasal spray suspension has no influence on the ability to drive or use machines.

4.8 Undesirable effects

When patients are transferred from systemic corticosteroid (oral or parenteral) to Budesonide nasal spray suspension, undesirable effects outside the nasal area which were previously under control by systemic therapy e.g. allergic conjunctivitis or dermatitis, may become unmasked. They should be treated additionally if needed.

In rare cases, signs or symptoms of systemic glucocorticosteroid-side effects may occur with nasal glucocorticosteroids, probably depending on dose, exposure time, concomitant and previous corticosteroid exposure, and individual sensitivity

Undesirable effects frequencies were defined as follows:

- 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)

Undesirable effects are presented by frequency category based on 1) Undesirable effects reported in clinical trials or epidemiological studies, if available, or 2) when the frequency cannot be estimated, the frequency category listed is "frequency not known".

System Organ Class	Frequency	Adverse drug reaction
Immune system disorders	Uncommon	immediate or delayed hypersensitivity reaction (erythema, urticaria, rash, itching, dermatitis, angioedema)
	Rare	anaphylactic reaction
Endocrine disorders	Rare	signs and symptoms of systemic corticosteroid effects, including adrenal suppression and growth retardation in children (see section 4.4)
Nervous system disorders	Not known	headache

Eye disorders	Rare	vision, blurred (see also section 4.4), increased eye pressure
	Not known	glaucoma, cataract (with long-term treatment)
Respiratory, thoracic and mediastinal disorders	Common	local symptoms like nasal mucosa irritation, slight haemorrhagic secretion, epistaxis (immediately after application), dryness of the nasal mucosa, oropharyngeal pain
	Rare	nasal ulcer, nasal septum perforation, dysphonia
Skin and subcutaneous tissue disorders	Rare	Bruising
Musculoskeletal and connective tissue disorders	Uncommon	muscle spasm
	Rare	osteoporosis (with long-term treatment)
Infections and infestations	Not known	Nasal and oropharyngeal candidiasis

Candida albicans infections

Cases of nasal and pharyngeal Candida albicans infections have been described during treatment with local corticosteroids. In such cases, it is preferable to discontinue nasal corticosteroid therapy and to consider starting an appropriate treatment.

Systemic effects

Occasionally, signs and symptoms of systemic glucocorticoid side effects may occur with the use of nasal glucocorticoids (see section 4.4).

The risk of latent adrenal insufficiency after prolonged administration should be considered (see section 4.4).

Paediatric population

Growth retardation has been reported in children receiving intranasal steroids. 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 the Yellow Card Scheme (www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

4.9 Overdose

An acute overdose with Budesonide nasal spray suspension is unlikely even if all the sprays contained in the bottle are administered all at once. Acute overdose with budesonide is not expected to be clinically relevant. Administration of doses higher than recommended (see section 4.2) for a longer period (over months) may result in adverse effects.

Long-term overdose could lead to pituitary-adrenal suppression and, if prolonged, to clinical signs of hypercorticism. These symptoms will disappear after discontinuation of treatment, which should be gradual.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Decongestants and other nasal preparations for topical use, Corticosteroids

ATC Code: R01AD05

Budesonide is a glucocorticosteroid with a strong topical anti-inflammatory effect on the nasal mucosa and weak systemic effects after topical administration.

Nasal instillation of budesonide in nasal polyps improves symptoms and reduces polyp volume but has not been shown to reduce the need for nasal polypectomy or prevent recurrence of polyps).

Corticosteroids have been shown to have a wide range of inhibitory activities against multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in allergic mediated inflammation. They also reduce cytokines, leukotrienes and chemokines (e.g. IL-1 to IL-6,

RANTES, TNF-α, IFN-γ and GM-CSF) which are secreted by inflammatory cells. Budesonide binds to glucocorticoid receptors resulting in a complex which acts as a transcription factor by either down-regulating proinflammatory mediators or up-regulating anti-inflammatory mediators. There are believed to be approximately 10 – 100 steroid-responsive genes per cell.

Paediatric population

Clinical efficacy

The therapeutic efficacy of budesonide Nasal Spray has been evaluated in several thousand adults and children. Most studies were conducted with delivered doses of budesonide of 32 to 256 μg intranasal once daily. Examples of representative studies evaluating the use of budesonide for the treatment of children with seasonal and perennial allergic rhinitis studies are provided below. The primary efficacy variable was the combined nasal symptoms score (CNSS), which is the sum of the individual nasal symptom scores for three nasal symptoms (congestion, runny nose and sneezing, each rated on a scale of 0-3).

Seasonal allergic rhinitis

A 2-week randomized double-blind, placebo-controlled, parallel-group study evaluated the efficacy and safety of budesonide nasal spray 16, 32 and 64 μg once daily in 400 children (aged 2 to 5 years) with allergic rhinitis (seasonal or perennial). There was a marked reduction from baseline CNSS in all treatment groups, including placebo. The difference between budesonide nasal spray 64 μg and placebo treatment was not statistically significant.

Perennial allergic rhinitis

A 6-week randomized double-blind, placebo-controlled, parallel-group study evaluated the efficacy and safety of budesonide nasal spray 128 μg once daily in 202 children (aged 6-16 years) with perennial allergic rhinitis. Primary efficacy variables were CNSS and values of peak nasal inspiratory flow (PNIF) measurements. Budesonide nasal spray improved the CNSS and PNIF statistically significantly more than placebo. Onset of action for budesonide nasal spray was 12 hours after first dose for CNSS and 48 hours for PNIF.

Clinical safety

In a randomized, double-blind, placebo-controlled growth study, 229 pre-pubertal children ages 4 years to 8 years received budesonide nasal spray 64 mcg once daily or placebo for 12 months after a 6-month baseline period. In this study, growth velocity was similar between budesonide nasal spray and placebo treatment groups after 12 months of therapy: the mean difference in growth velocity (placebo- budesonide nasal spray) was 0.27 cm/year (95% confidence interval: –0.07 to 0.62).

Influence on plasma cortisol concentration:

In the recommended dosages budesonide nasal spray does not cause clinical relevant changes in basal plasma cortisol concentrations or to ACTH stimulation. In healthy volunteers a dose dependent suppression of plasma cortisol- and urinary cortisol concentrations were seen after short term administration of budesonide nasal spray.

5.2 Pharmacokinetic properties

Absorption

The nasal administration of budesonide in seasonal and chronic rhinitis leads not only to the absorption through the nasal mucosa but also to a gastrointestinal absorption of the active substance, since the active ingredients are swallowed with increased production of mucus in the nose. The swallowed fraction leads to very low plasma levels due to the high first-pass effect for budesonide.

The systemic availability of budesonide from budesonide nasal spray, with reference to the metered dose, is 33%. In adults, the maximal plasma concentration after administration of 256 micrograms budesonide from budesonide nasal spray is 0.64 nmol/L and is reached within 0.7 hours. The Area Under Curve (AUC) after administration of 256 micrograms budesonide from budesonide nasal spray is 2.7 nmol*h/L in adults.

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 and 16α-hydroxyprednisolone, is less than 1 % of that of budesonide. The metabolism of budesonide is primarily mediated by CYP3A, a subfamily of cytochrome P450. Budesonide does not undergo local metabolic inactivation in the nose.

Elimination

The metabolites are excreted as such or in conjugated form mainly via the kidneys. No intact budesonide has been detected in the urine. Budesonide has a high systemic clearance (approximately 1.2 L/min) and the plasma half-life after i.v dosing averages 2-3 hours, and 1.5 hours in children.

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. The Area Under Curve (AUC) after administration of 256 micrograms budesonide from budesonide nasal spray is 5.5 nmol*h/L in children, indicating a higher systemic glucocorticosteroid exposure in children than in adults. At clinically recommended doses, the pharmacokinetics of budesonide are dose-proportional and plasma exposure is correlated to the weight of the patient. Therefore this should be taken into account when establishing paediatric doses.

Special populations (breast-feeding)

Maintenance treatment with inhaled budesonide (200 or 400 mcg 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.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans at therapeutic doses based on studies of chronic toxicity, genotoxicity and carcinogenicity.

Oral budesonide has been shown to increase the incidence of liver tumours in male rats at doses of 25 micrograms/kg/day. These effects were also observed in a long-term follow-up study with other corticosteroids (prednisolone and triamcinolone acetonide) and are therefore considered to be class effects of corticosteroid administration.

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.

Budesonide had no effect on fertility in rats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Dispersible cellulose (Microcrystalline cellulose and carboxymethylcellulose sodium, (89:11, w/w))
Polysorbate 80
Potassium sorbate E 202
Glucose, anhydrous

Disodium edetate
Hydrochloric acid, concentrated
Ascorbic acid E 300
Water for injection

6.2 Incompatibilities

Not applicable.

6.3 Shelf life

18 months

After first opening: 3 months

6.4 Special precautions for storage and other handling

Do not store above 30°C

Do not freeze.

6.5 Nature and contents of container

Amber type III glass bottle fitted with a plastic nasal spray pump and polypropylene nasal applicator: pack size of 1 x120 (1 x 10 ml) doses, 3 x 120 (3 x 10 ml) doses, 10 x 120 (10 x 10 ml) doses

Not all pack sizes may be marketed.

6.6 Special precautions for disposal

No special requirements for disposal.

Any unused medicinal product or waste material should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Sandoz Limited
Park View, Riverside Way
Watchmoor Park
Camberley, Surrey
GU15 3YL
United Kingdom

8 MARKETING AUTHORISATION NUMBER(S)

PL 04416/0784

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30/01/2011

10 DATE OF REVISION OF THE TEXT

18/02/2025