4.3 Contraindications

Elocon is contraindicated in facial rosacea, acne vulgaris, skin atrophy, perioral dermatitis, perianal and genital pruritus, napkin eruptions, bacterial (e.g. impetigo, pyodermas), viral (e.g. herpes simplex, herpes zoster, chickenpox, verrucae vulgaris, condylomata acuminate, molluscum contagiosum), parasitical and fungal (e.g. candida or dermatophyte) infections, varicella, tuberculosis, syphilis or post-vaccine reactions. Elocon should not be used on wounds or on skin which is ulcerated. Elocon should not be used in patients who are sensitive to mometasone furoate, to other corticosteroids, or to any ingredient in these preparations.

4.4 Special warnings and precautions for use

If irritation or sensitisation develop with the use of Elocon, treatment should be withdrawn and appropriate therapy instituted.

Should an infection develop, use of an appropriate antifungal or antibacterial agent should be instituted. If a favorable response does not occur promptly, the corticosteroid should be discontinued until the infection is adequately controlled.

Systemic absorption of topical corticosteroids can produce reversible hypothalamic-pituitary-adrenal (HPA) axis suppression with the potential for glucocorticosteroid insufficiency after withdrawal of treatment. Manifestations of Cushing's syndrome, hyperglycemia, and glucosuria can also be produced in some patients by systemic absorption of topical corticosteroids while on treatment. Patients applying a topical steroid to a large surface area or areas under occlusion should be evaluated periodically for evidence of HPA axis suppression.

Pediatric patients may be more susceptible to systemic toxicity from equivalent doses due to their larger skin surface to body mass ratios.

Local and systemic toxicity is common especially following long continued use on large areas of damaged skin, in flexures and with polythene occlusion. If used in childhood, or on the face, occlusion should not be used. If used on the face, courses should be limited to 5 days. Long term continuous therapy should be avoided in all patients irrespective of age.

Elocon may be used with caution in paediatric patients 2 years of age or older, although the safety and efficacy of the use of Elocon for greater longer than 3 weeks have not been established. As the safety and efficacy of Elocon in paediatric patients below 2 years of age have not been established, its use in this age group is not recommended.

There is not sufficient data if Elocon could be used in children under 2 years old.

Topical steroids may be hazardous in psoriasis for a number of reasons including rebound relapses following development of tolerance, risk of centralised pustular psoriasis and development of local or systemic toxicity due to impaired barrier function of the skin. If used in psoriasis careful patient supervision is important.

As with all potent topical glucocorticoids, avoid sudden discontinuation of treatment. When long term topical treatment with potent glucocorticoids is stopped, a rebound phenomenon can develop which takes the form of a dermatitis with intense redness, stinging and burning.
This can be prevented by slow reduction of the treatment, for instance continue treatment on an intermittent basis before discontinuing treatment.

Glucocorticoids can change the appearance of some lesions and make it difficult to establish an adequate diagnosis and can also delay the healing.

Elocon Cream and Lotion contain propylene glycol which may cause skin irritation.

Elocon Cream contains stearyl alcohol which may cause local skin reactions (e.g. contact dermatitis).

Elocon Ointment contains propylene glycol which may cause skin irritation.

Elocon topical preparations are not for ophthalmic use, including the eyelids, because of the very rare risk of glaucoma simplex or subcapsular cataract.

4.5 Interaction with other medicinal products and other forms of interaction (see also section 4.4)

None stated.

4.6 Pregnancy and lactation

During pregnancy and lactation treatment with Elocon should be performed only on the physician’s order. Then however, the application on large body surface areas or over a prolonged period should be avoided. There is inadequate evidence of safety in human pregnancy. Topical administration of corticosteroids to pregnant animals can cause abnormalities of foetal development including cleft palate and intra-uterine growth retardation. There are no adequate and well-controlled studies with Elocon in pregnant women and therefore the risk of such effects to the human foetus is unknown. However as with all topically applied glucocorticoids, the possibility that foetal growth may be affected by glucocorticoid passage through the placental barrier should be considered. Like other topically applied glucocorticoids, Elocon should be used in pregnant women only if the potential benefit justifies the potential risk to the mother or the foetus.

It is not known whether topical administration of corticosteroids could result in sufficient systemic absorption to produce detectable quantities in breast milk. Elocon should be administered to nursing mothers only after careful consideration of the benefit/risk relationship. If treatment with higher doses or long term application is indicated, breast-feeding should be discontinued.

4.7 Effects on ability to drive and use machines

None stated.

4.8 Undesirable effects

<table>
<thead>
<tr>
<th>Table 1: Treatment-related adverse reactions reported with Elocon by body system and frequency</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very common (≥1/10); common (≥1/100, &lt;1/10); uncommon (≥1/1,000, &lt;1/100); rare (≥1/10,000, &lt;1/1,000); very rare (&lt;1/10 000, including isolated reports); not known (cannot be estimated from the available data)</td>
</tr>
</tbody>
</table>


<table>
<thead>
<tr>
<th><strong>Infections and infestations</strong></th>
<th>Infection, furuncle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Not unknown</td>
<td></td>
</tr>
<tr>
<td>Very rare</td>
<td>Folliculitis</td>
</tr>
<tr>
<td><strong>Nervous system disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Not unknown</td>
<td></td>
</tr>
<tr>
<td>Very rare</td>
<td>Paraesthesia, Burning sensation</td>
</tr>
<tr>
<td><strong>Skin and subcutaneous tissue disorders</strong></td>
<td></td>
</tr>
<tr>
<td>Not unknown</td>
<td>Dermatitis contact, skin hypopigmentation, hypertrichosis, skin striae, dermatitis acneiform, skin atrophy</td>
</tr>
<tr>
<td><strong>Very rare</strong></td>
<td>Pruritus</td>
</tr>
<tr>
<td><strong>General disorders and administration site conditions</strong></td>
<td></td>
</tr>
<tr>
<td>Not unknown</td>
<td>Application site pain, application site reactions</td>
</tr>
</tbody>
</table>

Local adverse reactions reported infrequently with topical dermatologic corticosteroids include: dry skin, skin irritation, dermatitis, *perioral dermatitis*, skin maceration, heat rash *miliaria*, and telangiectasiae.

Paediatric patients may demonstrate greater susceptibility to topical corticosteroid-induced hypothalamic-pituitary-adrenal axis suppression and Cushing’s syndrome than mature patients because of a larger skin surface area to body weight ratio.

Chronic corticosteroids therapy may interfere with the growth and development of children.

### 4.9 Overdose

Excessive, prolonged use of topical corticosteroids can suppress hypothalamic-pituitary-adrenal function resulting in secondary adrenal insufficiency which is usually reversible.

If HPA axis suppression is noted, an attempt should be made to withdraw the drug, to reduce the frequency of application or to substitute a less potent steroid.

The steroid content of each container is so low as to have little or no toxic effect in the unlikely event of accidental oral ingestion.
4.3 Contraindications

Hypersensitivity to any ingredients of NASONEX Nasal Spray

NASONEX Nasal Spray should not be used in the presence of untreated localised infection involving the nasal mucosa.

Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal surgery or trauma should not use a nasal corticosteroid until healing has occurred.

4.4 Special warnings and precautions for use

NASONEX Nasal Spray should be used with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex.

Following 12 months of treatment with NASONEX Nasal Spray, there was no evidence of atrophy of the nasal mucosa; also, mometasone furoate tended to reverse the nasal mucosa closer to a normal histologic phenotype. As with any long-term treatment, patients using MFNS over several months or longer should be examined periodically for possible changes in the nasal mucosa, including the development of nasal ulcerations. If localized fungal infection of the nose or pharynx develops, discontinuation of MFNS therapy or appropriate treatment may be required. Persistence of nasopharyngeal irritation may be an indication for discontinuing NASONEX Nasal Spray.

Although NASONEX will control the nasal symptoms in most patients, the concomitant use of appropriate additional therapy may provide additional relief of other symptoms, particularly ocular symptoms.

There is no evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression following prolonged treatment with NASONEX Nasal Spray. However, patients who are transferred from long-term administration of systemically active corticosteroids to NASONEX Nasal Spray require careful attention. Systemic corticosteroid withdrawal in such patients may result in adrenal insufficiency for a number of months until recovery of HPA axis function. If these patients exhibit signs and symptoms of adrenal insufficiency, systemic corticosteroid administration should be resumed and other modes of therapy and appropriate measures should instituted.

During transfer from systemic corticosteroids to NASONEX Nasal Spray some patients may experience symptoms of withdrawal from systemically active corticosteroids (e.g., joint and/or muscular pain, lassitude, and depression initially) despite relief from nasal symptoms and will require encouragement to continue NASONEX Nasal Spray therapy. Such transfer may also unmask pre-existing allergic conditions, such as allergic conjunctivitis and eczema, previously suppressed by systemic corticosteroid therapy.

The safety and efficacy of Nasonex has not been studied for use in the treatment of unilateral polyps, polyps associated with cystic fibrosis, or polyps that completely obstruct the nasal cavities.

Unilateral polyps that are unusual or irregular in appearance, especially if ulcerating or bleeding, should be further evaluated.
Patients receiving corticosteroids who are potentially immunosuppressed should be warned of the risk of exposure to certain infections (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs.

Following the use of intranasal corticosteroids, instances of nasal septum perforation or increased intraocular pressure have been reported very rarely.

Systemic effects of nasal corticosteroids may occur, particularly at high doses prescribed for prolonged periods. 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 a paediatric specialist.

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

Safety and efficacy of NASONEX Nasal Spray for the treatment of nasal polyposis in children and adolescents less than 18 years of age have not been studied.

Acute Rhinosinusitis
If signs or symptoms of severe bacterial infection are observed (such as fever, persistent severe unilateral facial/tooth pain, orbital or peri-orbital facial swelling, or worsening of symptoms after an initial improvement), the patient should be advised to consult their physician immediately.

Safety and efficacy of NASONEX Nasal Spray for the treatment of symptoms of rhinosinusitis in children under 12 years of age have not been studied.

4.5 Interaction with other medicinal products and other forms of interaction (see 4.4 Special warnings and special precautions for use with systemic corticosteroids)

A clinical interaction study was conducted with loratadine. No interactions were observed.

4.6 Pregnancy and lactation

There are no adequate or well-controlled studies in pregnant women. Following intranasal administration of the maximal recommended clinical dose, mometasone plasma concentrations are not measurable; thus foetal exposure is expected to be negligible and the potential for reproductive toxicity, very low.

As with other nasal corticosteroid preparations NASONEX Nasal Spray should not be used in pregnancy or lactation unless the potential benefit to the mother justifies any potential risk to the mother, foetus or infant. Infants born of mothers who received corticosteroids during pregnancy should be observed carefully for hypoadrenalism.

4.7 Effects on ability to drive and use machines
None known.

4.8 Undesirable effects

Treatment-related adverse events reported in clinical studies for allergic rhinitis in adult and adolescent patients are shown below (Table 1).

<table>
<thead>
<tr>
<th>Table 1: Allergic Rhinitis-Treatment Related Undesirable Effects for Nasonex Nasal Spray</th>
</tr>
</thead>
<tbody>
<tr>
<td>very common (&gt; 1/10); common (&gt; 1/100, &lt; 1/10); uncommon (&gt; 1/1000, &lt; 1/100);</td>
</tr>
<tr>
<td>rare (&gt; 1/10,000, &lt; 1/1000); very rare (&lt; 1/10,000)</td>
</tr>
<tr>
<td><strong>Respiratory, thoracic and mediastinal disorders</strong></td>
</tr>
<tr>
<td>Common:</td>
</tr>
<tr>
<td><strong>General disorders and administration site conditions</strong></td>
</tr>
<tr>
<td>Common:</td>
</tr>
</tbody>
</table>

Epistaxis was generally self-limiting and mild in severity, and occurred at a higher incidence compared to placebo (5%), but at a comparable or lower incidence when compared to the active control nasal corticosteroids studied (up to 15%). The incidence of all other effects was comparable with that of placebo.

In the paediatric population, the incidence of adverse events, e.g., epistaxis (6%), headache (3%), nasal irritation (2%) and sneezing (2%) was comparable to placebo.

In patients treated for nasal polyposis, the overall incidence of adverse events was comparable to placebo and similar to that observed for patients with allergic rhinitis. Treatment-related adverse events reported in ≥ 1% of patients in clinical studies for polyposis are shown below (Table 2).

<table>
<thead>
<tr>
<th>Table 2: Polyposis-Treatment Related Undesirable Effects ≥ 1% for Nasonex Nasal Spray</th>
</tr>
</thead>
<tbody>
<tr>
<td>very common (&gt; 1/10); common (&gt; 1/100, &lt; 1/10); uncommon (&gt; 1/1000, &lt; 1/10);</td>
</tr>
<tr>
<td>rare (&gt; 1/10,000, &lt; 1/1000); very rare (&lt; 1/10,000)</td>
</tr>
<tr>
<td><strong>Respiratory, thoracic and mediastinal disorders</strong></td>
</tr>
<tr>
<td>(200 mcg once a day)</td>
</tr>
<tr>
<td>Upper respiratory tract infection</td>
</tr>
<tr>
<td>Epistaxis</td>
</tr>
<tr>
<td><strong>Gastrointestinal disorders</strong></td>
</tr>
<tr>
<td>Throat irritation</td>
</tr>
</tbody>
</table>
In patients treated for acute rhinosinusitis, the incidence of epistaxis for NASONEX was 3.3% vs. 2.6% for placebo and similar to that observed for patients treated with allergic rhinitis.

Rarely, immediate hypersensitivity reactions, including bronchospasm and dyspnoea, may occur after intranasal administration of mometasone furoate monohydrate. Very rarely, anaphylaxis and angioedema have been reported.

Disturbances of taste and smell have been reported very rarely.

As with other intranasal corticosteroids rare cases of nasal septum perforation have been reported.

Systemic effects of nasal corticosteroids may occur, particularly when prescribed at high doses for prolonged periods.

Rare cases of glaucoma, increased intraocular pressure and/or cataracts have been reported with the use of intranasal corticosteroids.

4.9 Overdose

Because of the very low (<0.1%) systemic bioavailability of NASONEX, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage. Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.
4.3 Contraindications

Patients with known hypersensitivity (allergy) to the active substance or to the excipient (see 6.1 List of excipients).

4.4 Special warnings and precautions for use

During clinical trials, oral candidiasis, which is associated with the use of this class of medicinal products, occurred in some patients. This infection may require treatment with appropriate antifungal therapy and in some patients discontinuance of Asmanex Twisthaler Inhalation Powder may be necessary.

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, cataracts and glaucoma.

Therefore, it is important that the dose of inhaled corticosteroid is titrated to the lowest dose at which effective control of asthma is maintained.

Particular care is needed for patients who are transferred from systemically active corticosteroids to inhaled mometasone furoate, because deaths due to adrenal insufficiency have occurred in asthmatic patients during and after transfer from systemic corticosteroids to less systemically available inhaled corticosteroids. After withdrawal from systemic corticosteroids, a number of months are required for recovery of hypothalamic-pituitary-adrenal (HPA) axis function.

During dose reduction some patients may experience symptoms of systemic corticosteroid withdrawal, e.g. joint and/or muscular pain, lassitude and depression, despite maintenance or even improvement in pulmonary function. Such patients are to be encouraged to continue with both Asmanex Twisthaler Inhalation Powder treatment and withdrawal of the systemic corticosteroids, unless objective signs of adrenal insufficiency are present. If evidence of adrenal insufficiency occurs, increase the systemic corticosteroid doses temporarily and thereafter continue withdrawal more slowly.

During periods of stress, including trauma, surgery, or infection, or a severe asthma attack, patients transferred from systemic corticosteroids will require supplementary treatment with a short course of systemic corticosteroids, which is gradually tapered as symptoms subside. It is recommended that such patients carry a supply of oral corticosteroids and a warning card indicating their need and recommended dosage of systemic corticosteroids during stressful periods. Periodic testing of adrenocortical function, particularly measurement of early morning plasma cortisol levels, is recommended.

Transfer of patients from systemic corticosteroid therapy to the mometasone furoate DPI may unmask pre-existing allergic conditions previously suppressed by systemic corticosteroid therapy. If this occurs, symptomatic treatment is recommended.

Mometasone furoate DPI is not to be regarded as a bronchodilator and is not indicated for rapid relief of bronchospasm or asthma attacks; thus, patients should be instructed to keep an appropriate short-acting bronchodilator inhaler on hand for use when needed.

Instruct patients to contact their physician immediately when asthmatic episodes are not responsive to bronchodilators or if peak-flow falls. This may indicate worsening asthma.
During such episodes, patients may require systemic corticosteroid therapy. In these patients, dose titration to the maximum recommended maintenance dose of inhaled mometasone furoate may be considered.

Use of Asmanex Twisthaler Inhalation Powder will often permit control of asthma symptoms with less suppression of HPA axis function than therapeutically equivalent oral doses of prednisone. Although mometasone furoate has demonstrated low systemic bioavailability at the recommended dosage, it is absorbed into the circulation and can be systemically active at higher doses. Thus, to maintain its profile of limited potential for HPA axis suppression, recommended doses of mometasone furoate DPI must not be exceeded, and must be titrated to the lowest effective dose for each individual patient.

As with other inhaled asthma medications, bronchospasm may occur with an immediate increase in wheezing after dosing. If bronchospasm occurs following dosing with the Asmanex Twischalher Inhalation Powder, immediate treatment with a fast-acting inhaled bronchodilator is recommended; thus, the patient should be told to keep an appropriate bronchodilator inhaler on hand at all times. In such cases, treatment with Asmanex Twischalher Inhalation Powder is then discontinued immediately and alternative therapy instituted.

No evidence supports that the administration of mometasone furoate DPI in amounts greater than recommended doses increases efficacy.

Use Asmanex Twischalher micrograms Inhalation Powder with caution, if at all, in patients with active or quiescent tuberculous infections of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections or ocular herpes simplex.

Advise patients who are receiving corticosteroids or other immunosuppressant medicines of the risk of exposure to certain infections (e.g., chickenpox, measles) and of the importance of obtaining medical advice if such exposure occurs. This is of particular importance in children. A reduction of growth velocity in children or adolescents may occur as a result of inadequate control of chronic diseases such as asthma or from use of corticosteroids for treatment. Physicians are advised to closely follow the growth of adolescents taking corticosteroids by any route and weigh the benefits of corticosteroid therapy and asthma control against the possibility of growth suppression if an adolescent’s growth appears slowed.

If growth is slowed, review therapy with the aim of reducing the dose of inhaled corticosteroids if possible, to the lowest dose at which effective control of symptoms is achieved. In addition, consideration should be given to referring the patient to a paediatric respiratory specialist.

When using inhaled corticosteroids, the possibility for clinically significant adrenal suppression may occur, especially after treatment with higher than recommended doses. This must be considered during periods of stress or elective surgery, when additional systemic corticosteroids may be needed. However, during clinical trials there was no evidence of HPA axis suppression after prolonged treatment with mometasone furoate DPI at doses \( \leq 800 \) micrograms per day.

Lack of response or severe exacerbations of asthma should be treated by increasing the maintenance dose of inhaled mometasone furoate, and if necessary, by giving a systemic corticosteroid and/or an antibiotic if infection is suspected, and by use of beta-agonist therapy.

The patient should be advised against abrupt discontinuation of therapy with Asmanex Twischalher Inhalation Powder.
Patients with lactose intolerance: The maximum recommended daily dose contains lactose 4.64 mg per day. This amount does not normally cause problems in lactose intolerant people.

4.5 Interaction with other medicinal products and other forms of interaction

Due to the very low plasma concentration achieved after inhaled dosing, clinically significant drug interactions are unlikely. However, there may be a potential for increased systemic exposure to mometasone furoate when strong CYP3A4 inhibitors (eg ketoconazole, itraconazole, nelfinavir, ritonavir) are co-administered. Co-administration of inhaled mometasone furoate with the potent CYP3A4 enzyme inhibitor ketoconazole causes small but marginally significant (p= 0.09) decreases in serum cortisol AUC (0-24) and resulted in approximately a 2-fold increase in plasma concentration of mometasone.

4.6 Pregnancy and lactation

There are no adequate studies in pregnant women. Studies in animals with mometasone furoate, like other glucocorticoids, have shown reproductive toxicity; however, the potential risk for humans is unknown.

As with other inhaled corticosteroid preparations, mometasone furoate is not to be used during pregnancy unless the potential benefit to the mother justifies the potential risk to the mother, fetus or infant. Infants born of mothers who received corticosteroids during pregnancy are to be observed carefully for hypoadrenalism.

It is known that mometasone furoate is excreted in low doses in the milk of suckling rats. It is not known if mometasone furoate is excreted in human milk, thus, caution should be used when Asmanex Twisthaler Inhalation Powder is administered to breast-feeding women.

4.7 Effects on ability to drive and use machines

Inhaled mometasone furoate has no or negligible influence on the ability to drive and use machines.

4.8 Undesirable effects

In placebo-controlled clinical trials, oral candidiasis was very common (> 10%) in the 400 micrograms twice daily treatment group; other common (1-10%), treatment-related undesirable effects were pharyngitis, headache and dysphonia (Table 1).

<table>
<thead>
<tr>
<th>Category</th>
<th>QD (Once Daily Dosing)</th>
<th>BID (Twice Daily Dosing)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>200 mcg</td>
<td>400 mcg</td>
</tr>
<tr>
<td>Infections and infestations</td>
<td>Candidiasis</td>
<td></td>
</tr>
<tr>
<td></td>
<td>common</td>
<td>common</td>
</tr>
</tbody>
</table>

Table 1. Treatment-related undesirable effects with Asmanex Twisthaler Inhalation Powder by treatment regimen by Severity, MedDRA System Organ Class and Preferred Term

[Very Common (> 1/10); Common (> 1/100, < 1/10); Uncommon (> 1/1,000, < 1/100)]
<table>
<thead>
<tr>
<th>Disorders</th>
<th>Uncommon</th>
<th>Common</th>
<th>Common</th>
<th>Common</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ear &amp; labyrinth disorders</td>
<td>Dysphonia</td>
<td>uncommon</td>
<td>common</td>
<td>common</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td>Pharyngitis</td>
<td>common</td>
<td>common</td>
<td>common</td>
</tr>
<tr>
<td>General disorders and administration site conditions</td>
<td>Headache</td>
<td>common</td>
<td>common</td>
<td>common</td>
</tr>
</tbody>
</table>

In patients dependent on oral corticosteroids, who were treated with Asmanex Twisthaler 400 micrograms twice daily for 12 weeks, oral candidiasis occurred in 20%, and dysphonia in 7%. These effects were considered treatment-related.

Uncommonly reported adverse events were dry mouth and throat, dyspepsia, weight increase and palpitations.

Rare cases of glaucoma, increased intraocular pressure and cataracts have been reported with the use of inhaled corticosteroids.

*There was no suggestion of an increased risk for undesirable effects in adolescents or patients 65 years of age or older.*

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

As with other glucocorticoid products, the potential for hypersensitivity reactions including rashes, urticaria, pruritus and erythema and oedema of the eyes, face, lips and throat should be considered.

### 4.9 Overdose

Because of the low systemic bioavailability of this product, overdose is unlikely to require any therapy other than observation, followed by initiation of the appropriate prescribed dosage. Inhalation or oral administration of excessive doses of corticosteroids may lead to suppression of HPA axis function.

Management of the inhalation of mometasone furoate in doses in excess of the recommended dose regimens should include monitoring of adrenal function. Mometasone furoate therapy in a dose sufficient to control asthma can be continued.