

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use NASONEX safely and effectively. See full prescribing information for NASONEX.

NASONEX® (mometasone furoate monohydrate) nasal spray
Initial U.S. Approval: 1997

INDICATIONS AND USAGE

NASONEX is a corticosteroid indicated for:

- Treatment of Nasal Symptoms of Allergic Rhinitis in patients ≥ 2 years of age (1.1)
- Treatment of Nasal Congestion Associated with Seasonal Allergic Rhinitis in patients ≥ 2 years of age (1.2)
- Prophylaxis of Seasonal Allergic Rhinitis in patients ≥ 12 years of age (1.3)
- Treatment of Nasal Polyps in patients ≥ 18 years of age (1.4)

DOSAGE AND ADMINISTRATION

For Nasal Use Only

- Recommended Dosage for Treatment of Nasal Symptoms of Allergic Rhinitis (2.2)
Adults & Adolescents (12 yrs. and older): 2 sprays in each nostril once daily
Children (2-11 yrs.): 1 spray in each nostril once daily
- Recommended Dosage for Treatment of Nasal Congestion Associated with Seasonal Allergic Rhinitis (2.3)
Adults & Adolescents (12 yrs. and older): 2 sprays in each nostril once daily
Children (2-11 yrs.): 1 spray in each nostril once daily
- Recommended Dosage for Prophylaxis of Seasonal Allergic Rhinitis (2.4)
Adults & Adolescents (12 yrs. and older): 2 sprays in each nostril once daily
- Recommended Dosage for Treatment of Nasal Polyps (2.5)
Adults (18 yrs. and older): 2 sprays in each nostril twice daily. 2 sprays in each nostril once daily may also be effective in some patients.

DOSAGE FORMS AND STRENGTHS

Nasal spray: 50 mcg of mometasone furoate in each spray (3)

CONTRAINDICATIONS

Patients with known hypersensitivity to mometasone furoate or any of the ingredients of NASONEX. (4)

WARNINGS AND PRECAUTIONS

- Epistaxis, nasal ulceration, *Candida albicans* infection, nasal septal perforation, impaired wound healing. Monitor patients periodically for signs of adverse effects on the nasal mucosa. Avoid use in patients with recent nasal ulcers, nasal surgery, or nasal trauma. (5.1)
- Glaucoma and cataracts. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use NASONEX long term. (5.2)
- Potential worsening of existing tuberculosis; fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex. More serious or even fatal course of chickenpox or measles in susceptible patients. Use caution in patients with the above because of the potential for worsening of these infections. (5.4)
- Hypercorticism and adrenal suppression with higher than recommended dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue NASONEX slowly. (5.5)
- Potential reduction in growth velocity in children. Monitor growth routinely in pediatric patients receiving NASONEX. (5.6, 8.4)

ADVERSE REACTIONS

The most common adverse reactions ($\geq 5\%$) included headache, viral infection, pharyngitis, epistaxis and cough. (6)

To report SUSPECTED ADVERSE REACTIONS, contact Organon LLC, a subsidiary of Organon & Co., at 1-844-674-3200 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling.

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Treatment of Allergic Rhinitis

NASONEX[®] is indicated for the treatment of the nasal symptoms of seasonal allergic and perennial allergic rhinitis, in adults and pediatric patients 2 years of age and older.

1.2 Treatment of Nasal Congestion Associated with Seasonal Allergic Rhinitis

NASONEX is indicated for the relief of nasal congestion associated with seasonal allergic rhinitis, in adults and pediatric patients 2 years of age and older.

1.3 Prophylaxis of Seasonal Allergic Rhinitis

NASONEX is indicated for the prophylaxis of the nasal symptoms of seasonal allergic rhinitis in adult and adolescent patients 12 years and older.

1.4 Treatment of Nasal Polyps

NASONEX is indicated for the treatment of nasal polyps in patients 18 years of age and older.

2 DOSAGE AND ADMINISTRATION

2.1 Preparation and Administration

Administer NASONEX by the nasal route only.

Initial Priming

Prior to initial use of NASONEX, the pump must be primed by actuating ten times or until a fine spray appears. The pump may be stored unused for up to 1 week without repriming.

Repriming (as needed)

If unused for more than 1 week, reprime by actuating two times, or until a fine spray appears.

2.2 Recommended Dosage for Treatment of Allergic Rhinitis

Adults and Adolescents 12 Years of Age and Older:

The recommended dosage for treatment of the nasal symptoms of seasonal allergic and perennial allergic rhinitis is mometasone furoate 200 mcg (administer as 2 sprays into each nostril, each spray containing 50 mcg of mometasone furoate) once daily (total daily dose of 200 mcg).

Children 2 to 11 Years of Age:

The recommended dosage for treatment of the nasal symptoms of seasonal allergic and perennial allergic rhinitis is mometasone furoate 100 mcg (administer as 1 spray into each nostril, each spray containing 50 mcg of mometasone furoate) once daily (total daily dose of 100 mcg).

2.3 Recommended Dosage for Treatment of Nasal Congestion Associated with Seasonal Allergic Rhinitis

Adults and Adolescents 12 Years of Age and Older:

The recommended dosage for treatment of nasal congestion associated with seasonal allergic rhinitis is mometasone furoate 200 mcg (administer as 2 sprays into each nostril, each spray containing 50 mcg of mometasone furoate) once daily (total daily dose of 200 mcg).

Children 2 to 11 Years of Age:

The recommended dosage for treatment of nasal congestion associated with seasonal allergic rhinitis is mometasone furoate 100 mcg (administer as 1 spray into each nostril, each spray containing 50 mcg of mometasone furoate) once daily (total daily dose of 100 mcg).

2.4 Recommended Dosage for Prophylaxis of Seasonal Allergic Rhinitis

Adults and Adolescents 12 Years of Age and Older:

The recommended dosage for prophylaxis treatment of nasal symptoms of seasonal allergic rhinitis is mometasone furoate 200 mcg (administer as 2 sprays into each nostril, each spray containing 50 mcg of mometasone furoate) once daily (total daily dose of 200 mcg).

In patients with a known seasonal allergen that precipitates nasal symptoms of seasonal allergic rhinitis, prophylaxis with 2 sprays in each nostril once daily (200 mcg/day) is recommended 2 to 4 weeks prior to the anticipated start of the pollen season.

2.5 Recommended Dosage for Treatment of Nasal Polyps

Adults 18 Years of Age and Older:

The recommended dosage for the treatment of nasal polyps is 2 sprays (50 mcg of mometasone furoate in each spray) in each nostril twice daily (total daily dose of 400 mcg). A dose of 2 sprays (50 mcg of mometasone furoate in each spray) in each nostril once daily (total daily dose of 200 mcg) is also effective in some patients.

3 DOSAGE FORMS AND STRENGTHS

Nasal spray: 50 mcg, metered-dose, manual pump spray.

After initial priming (10 actuations), each actuation of the pump delivers a metered spray containing 50 mcg of mometasone furoate.

4 CONTRAINDICATIONS

NASONEX is contraindicated in patients with known hypersensitivity to mometasone furoate or any of its ingredients.

5 WARNINGS AND PRECAUTIONS

5.1 Local Nasal Effects

Epistaxis

In clinical studies, epistaxis was observed more frequently in patients with allergic rhinitis with NASONEX than those who received placebo [see *Adverse Reactions (6)*].

Candida Infection

In clinical studies with NASONEX, the development of localized infections of the nose and pharynx with *Candida albicans* has occurred. When such an infection develops, use of NASONEX should be discontinued and appropriate local or systemic therapy instituted, if needed.

Nasal Septum Perforation

Instances of nasal septum perforation have been reported following the nasal application of corticosteroids. As with any long-term topical treatment of the nasal cavity, patients using NASONEX over several months or longer should be examined periodically for possible changes in the nasal mucosa.

Impaired Wound Healing

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

5.2 Glaucoma and Cataracts

Glaucoma and cataracts may be reported with systemic and topical (including nasal, inhaled and ophthalmic) corticosteroid use. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use NASONEX long term [see *Adverse Reactions (6)*].

5.3 Hypersensitivity Reactions

Hypersensitivity reactions including instances of wheezing may occur after the nasal administration of mometasone furoate monohydrate. Discontinue NASONEX if such reactions occur [see *Contraindications (4)*].

5.4 Immunosuppression and Risk of Infections

Persons who are on drugs which suppress the immune system are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can have a more serious or even fatal course in nonimmune children or adults on corticosteroids. In such children or adults who have not had these diseases, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affect the risk of developing a disseminated infection is not known. The contribution of the underlying disease and/or prior corticosteroid treatment to the risk is also not known. If exposed to chickenpox, prophylaxis with varicella zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective Prescribing Information for VZIG and IG.) If chickenpox develops, treatment with antiviral agents may be considered.

Corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculous infection of the respiratory tract, or in untreated fungal, bacterial, systemic viral infections, or ocular herpes simplex because of the potential for worsening of these infections.

5.5 Hypercorticism and Adrenal Suppression

When nasal steroids are used at higher than recommended dosages or in susceptible individuals at recommended dosages, systemic corticosteroid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, the dosage of NASONEX should be discontinued slowly, consistent with accepted procedures for discontinuing oral corticosteroid therapy.

5.6 Effect on Growth

Corticosteroids may cause a reduction in growth velocity when administered to pediatric patients. Monitor the growth routinely of pediatric patients receiving NASONEX. To minimize the systemic effects of nasal corticosteroids, including NASONEX, titrate each patient's dose to the lowest dosage that effectively controls his/her symptoms [see *Use in Specific Populations (8.4)*].

6 ADVERSE REACTIONS

Systemic and local corticosteroid use may result in the following:

- Epistaxis, ulcerations, *Candida albicans* infection, impaired wound healing [see *Warnings and Precautions (5.1)*]
- Glaucoma and cataracts [see *Warnings and Precautions (5.2)*]
- Immunosuppression and Risk of Infections [see *Warnings and Precautions (5.4)*]
- Hypercorticism and Adrenal Suppression, including growth reduction [see *Warnings and Precautions (5.5, 5.6), Use in Specific Populations (8.4)*]

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

Allergic Rhinitis

Adults and adolescents 12 years of age and older

In controlled US and international clinical studies, a total of 3210 adult and adolescent patients 12 years and older with allergic rhinitis received treatment with NASONEX at doses of 50 to 800 mcg/day. The majority of patients (n=2103) were treated with 200 mcg/day. A total of 350 adult and adolescent patients have been treated for one year or longer. Adverse reactions did not differ significantly based on age, sex, or race. Four percent or less of patients in clinical trials discontinued treatment because of adverse events and the discontinuation rate was similar for the vehicle and active comparators.

All adverse reactions (regardless of relationship to treatment) reported by 5% or more of adult and adolescent patients ages 12 years and older who received NASONEX, 200 mcg/day vs. placebo and that were more common with NASONEX than placebo, are displayed in Table 1 below.

Table 1: Adult and Adolescent Patients 12 Years and Older – Adverse Reactions from Controlled Clinical Trials in Seasonal Allergic and Perennial Allergic Rhinitis (Percent of Patients Reporting)

	NASONEX 200 mcg (n=2103)	VEHICLE PLACEBO (n=1671)
Headache	26	22
Viral Infection	14	11
Pharyngitis	12	10
Epistaxis/Blood-Tinged Mucus	11	6
Coughing	7	6
Upper Respiratory Tract Infection	6	2
Dysmenorrhea	5	3
Musculoskeletal Pain	5	3
Sinusitis	5	3

Other adverse reactions which occurred in less than 5% but greater than or equal to 2% of adult and adolescent patients (ages 12 years and older) treated with NASONEX 200-mcg/day (regardless of relationship to treatment), and more frequently than in the placebo group included: arthralgia, asthma, bronchitis, chest pain, conjunctivitis, diarrhea, dyspepsia, earache, flu-like symptoms, myalgia, nausea, and rhinitis.

Pediatric patients <12 years of age

In controlled US and international studies, a total of 990 pediatric patients (ages 3 to 11 years) with allergic rhinitis received treatment with NASONEX at doses of 25 to 200 mcg/day. The majority of pediatric patients (n=720) were treated with 100 mcg/day. A total of 163 pediatric patients have been treated for one year or longer. Two percent or less of patients in clinical trials who received NASONEX discontinued treatment because of adverse events and the discontinuation rate was similar for the placebo and active comparators.

Adverse events which occurred in ≥5% of pediatric patients (ages 3 to 11 years) treated with NASONEX 100 mcg/day vs. placebo (regardless of relationship to treatment) and more frequently than in the placebo group included upper respiratory tract infection (5% in NASONEX group vs. 4% in placebo) and vomiting (5% in NASONEX group vs. 4% in placebo).

Other adverse reactions which occurred in less than 5% but greater than or equal to 2% of pediatric patients (ages 3 to 11 years) treated with NASONEX 100 mcg/day vs. placebo (regardless of relationship to treatment) and more frequently than in the placebo group included: diarrhea, nasal irritation, otitis media, and wheezing.

The adverse reaction (regardless of relationship to treatment) reported by 5% of pediatric patients ages 2 to 5 years who received NASONEX 100 mcg/day in a clinical trial vs. placebo including 56 subjects (28 each NASONEX and placebo) and that was more common with NASONEX than placebo, included: upper respiratory tract infection (7% vs. 0%, respectively). The other adverse event which occurred in less than 5% but greater than or equal to 2% of pediatric patients ages 2 to 5 years treated with NASONEX 100 mcg/day vs. placebo (regardless of relationship to treatment) and more frequently than in the placebo group included: skin trauma.

Nasal Congestion Associated with Seasonal Allergic Rhinitis

A total of 1008 patients aged 12 years and older received NASONEX 200 mcg/day (n=506) or placebo (n=502) for 15 days. Adverse reactions that occurred more frequently in patients treated with NASONEX than in patients with the placebo included sinus headache (1.2% in NASONEX group vs. 0.2% in placebo) and epistaxis (1% in NASONEX group vs. 0.2% in placebo) and the overall adverse reaction profile was similar to that observed in the other allergic rhinitis trials.

Nasal Polyps

Adults 18 years of age and older

In controlled clinical studies, the types of adverse reactions observed in patients with nasal polyps were similar to those observed in patients with allergic rhinitis. A total of 594 adult patients (ages 18 to 86 years) received NASONEX at doses of 200 mcg once or twice daily for up to 4 months for treatment of nasal polyps. The overall incidence of adverse reactions for patients treated with NASONEX was comparable to patients with the placebo except for epistaxis, which was 9% for 200 mcg once daily, 13% for 200 mcg twice daily, and 5% for the placebo.

Nasal ulcers and nasal and oral candidiasis were also reported in patients treated with NASONEX primarily in patients treated for longer than 4 weeks.

6.2 Post-Marketing Experience

The following adverse reactions have been identified during the post-marketing period for NASONEX: nasal burning and irritation, anaphylaxis and angioedema, disturbances in taste and smell, nasal septal perforation, and vision blurred. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

7 DRUG INTERACTIONS

No formal drug-drug interaction studies have been conducted with NASONEX.

Inhibitors of Cytochrome P450 3A4:

Studies have shown that mometasone furoate is primarily and extensively metabolized in the liver of all species investigated and undergoes extensive metabolism to multiple metabolites. *In vitro* studies have confirmed the primary role of cytochrome CYP3A4 in the metabolism of this compound.

Concomitant administration of CYP3A4 inhibitors may inhibit the metabolism of, and increase the systemic exposure to, mometasone furoate and potentially increase the risk for systemic corticosteroid side effects. Caution should be exercised when considering the coadministration of NASONEX with long-term ketoconazole and other known strong CYP3A4 inhibitors (e.g., ritonavir, cobicistat-containing products, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin) [see *Clinical Pharmacology* (12.3)]. Consider the benefit of coadministration versus the potential risk of systemic corticosteroid effects, in which case patients should be monitored for systemic corticosteroid side effects.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no adequate and well-controlled clinical studies of NASONEX in pregnant women. In animal reproduction studies with pregnant mice, rats, or rabbits, mometasone furoate caused increased fetal malformations and decreased fetal survival and growth following administration of doses that produced exposures approximately 1/3 to 8 times the maximum recommended human dose (MRHD) on a mcg/m² or AUC basis [see *Data*]. However, experience with oral corticosteroids suggests that rodents are more prone to teratogenic effects from corticosteroid exposure than humans.

The estimated background risk of major birth defects and miscarriage for the indicated population is unknown. All pregnancies have a background risk of birth defect, loss, or other adverse outcomes. In the U.S. general population, the estimated risk of major birth defects and miscarriage in clinically recognized pregnancies is 2 to 4% and 15 to 20%, respectively.

Data

Animal Data

In an embryofetal development study with pregnant mice dosed throughout the period of organogenesis, mometasone furoate produced cleft palate at a dose less than the maximum recommended daily nasal dose (MRDID) (on a mcg/m² basis with maternal subcutaneous doses of 60 mcg/kg and above) and decreased fetal survival at approximately 2 times the MRDID (on a mcg/m² basis with a maternal subcutaneous dose of 180 mcg/kg). No toxicity was observed with a dose that produced an exposure less than the MRDID (on a mcg/m² basis with maternal topical dermal doses of 20 mcg/kg and above).

In an embryofetal development study with pregnant rats dosed throughout the period of organogenesis, mometasone furoate produced fetal umbilical hernia at exposures approximately 10 times the MRDID (on a mcg/m² basis with maternal topical dermal doses of 600 mcg/kg and above) and delays in fetal ossification at a dose approximately 6 times the MRDID (on a mcg/m² basis with maternal topical dermal doses of 300 mcg/kg and above).

In another reproductive toxicity study, pregnant rats were dosed with mometasone furoate throughout pregnancy or late in gestation. Treated animals had prolonged and difficult labor, fewer live births, lower birth weight, and reduced early pup survival at a dose less than the MRDID (on a mcg/m² basis with a maternal subcutaneous dose of 15 mcg/kg). There were no findings at a dose less than the MRDID (on a mcg/m² basis with a maternal subcutaneous dose of 7.5 mcg/kg).

Embryofetal development studies were conducted with pregnant rabbits dosed with mometasone furoate by either the topical dermal route or oral route throughout the period of organogenesis. In the study using the topical dermal route, mometasone furoate caused multiple malformations in fetuses (e.g., flexed front paws, gallbladder agenesis, umbilical hernia, hydrocephaly) at doses approximately 6 times the MRDID (on a mcg/m² basis with maternal topical dermal doses of 150 mcg/kg and above). In the study using the oral route, mometasone furoate caused increased fetal resorptions and cleft palate and/or head malformations (hydrocephaly and domed head) at a dose approximately 30 times of the MRDID (on a mcg/m² basis with a maternal oral dose of 700 mcg/kg). At approximately 110 times the MRDID (on a mcg/m² basis with a maternal oral dose of 2800 mcg/kg), most litters were aborted or resorbed. No effects were observed at a dose approximately 6 times the MRDID (on a mcg/m² basis with a maternal oral dose of 140 mcg/kg).

8.2 Lactation

Risk Summary

There are no available data on the presence of NASONEX in human milk, the effects on the breastfed child, or the effects on milk production. Other corticosteroids are excreted in human milk. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for NASONEX and any potential adverse effects on the breastfed infant from NASONEX or from the underlying maternal condition.

8.4 Pediatric Use

The safety and effectiveness of NASONEX for allergic rhinitis in children 12 years of age and older have been established [see *Adverse Reactions* (6.1) and *Clinical Studies* (14.1)]. Use of NASONEX for allergic rhinitis in pediatric patients 2 to 11 years of age is supported by safety and efficacy data from clinical studies. Seven hundred and twenty (720) patients 3 to 11 years of age with allergic rhinitis were treated with mometasone furoate nasal spray 50 mcg (100 mcg total daily dose) in controlled clinical trials [see *Adverse Reactions* (6.1) and *Clinical Studies* (14.2)]. Twenty-eight (28) patients 2 to 5 years of age with allergic rhinitis were treated with mometasone furoate nasal spray 50 mcg (100 mcg total daily dose) in a controlled trial to evaluate safety [see *Adverse Reactions* (6.1)]. Safety and effectiveness of NASONEX for allergic rhinitis in children less than 2 years of age have not been established.

The safety and effectiveness of NASONEX for the treatment of nasal polyps in children less than 18 years of age have not been established. One 4-month trial was conducted to evaluate the safety and efficacy of NASONEX in the treatment of nasal polyps in pediatric patients 6 to 17 years of age. The primary objective of the study was to evaluate safety; efficacy parameters were collected as secondary endpoints. A total of 127 patients with nasal polyps were randomized to placebo or NASONEX 100 mcg once or twice daily (patients 6 to 11 years of age) or 200 mcg once or twice daily (patients 12 to 17 years of age). The results of this trial did not support the efficacy of NASONEX in the treatment of nasal polyps in pediatric patients. The adverse reactions reported in this trial were similar to the adverse reactions reported in patients 18 years of age and older with nasal polyps.

Controlled clinical studies have shown nasal corticosteroids may cause a reduction in growth velocity in pediatric patients. This effect has been observed in the absence of laboratory evidence of hypothalamic-pituitary-adrenal (HPA) axis suppression, suggesting that growth velocity is a more sensitive indicator of systemic corticosteroid exposure in pediatric patients than some commonly used tests of HPA axis function. The long-term effects of this reduction in growth velocity associated with nasal corticosteroids, including the impact on final adult height, are unknown. The potential for "catch up" growth following discontinuation of treatment with nasal corticosteroids has not been adequately studied. The growth of pediatric patients receiving nasal corticosteroids, including NASONEX, should be monitored routinely (e.g., via stadiometry). The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the availability of safe and effective noncorticosteroid treatment alternatives. To minimize the systemic effects of nasal corticosteroids, including NASONEX, each patient should be titrated to his/her lowest effective dose.

A clinical study to assess the effect of NASONEX (100 mcg total daily dose) on growth velocity has been conducted in pediatric patients 3 to 9 years of age with allergic rhinitis. No statistically significant effect on growth velocity was observed for NASONEX compared to placebo following one year of treatment. No evidence of clinically relevant HPA axis suppression was observed following a 30-minute cosyntropin infusion.

The potential of NASONEX to cause growth suppression in susceptible patients or when given at higher doses cannot be ruled out.

8.5 Geriatric Use

A total of 280 patients above 64 years of age with allergic rhinitis or nasal polyps (age range 64 to 86 years) have been treated with NASONEX for up to 3 or 4 months, respectively. The adverse reactions reported in this population were similar in type and incidence to those reported by younger patients.

8.6 Hepatic Impairment

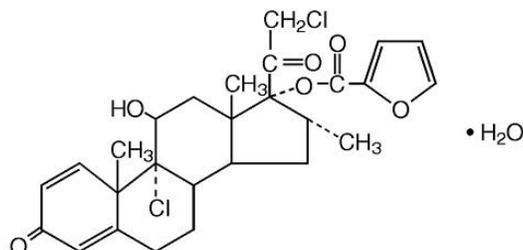
Concentrations of mometasone furoate appear to increase with severity of hepatic impairment [see *Clinical Pharmacology* (12.3)].

10 OVERDOSAGE

There are no data available on the effects of acute or chronic overdosage with NASONEX. Because of low systemic bioavailability, and an absence of acute drug-related systemic findings in clinical studies, overdose is unlikely to require any therapy other than observation. Chronic overdosage with any corticosteroid may result in signs or symptoms of hypercorticism [see *Warnings and Precautions* (5.5)].

11 DESCRIPTION

Mometasone furoate monohydrate, the active component of NASONEX Nasal Spray, 50 mcg, is an anti-inflammatory corticosteroid having the chemical name, 9,21-Dichloro-11 β ,17-dihydroxy-16 α -methylpregna-1,4-diene-3,20-dione 17-(2 furoate) monohydrate, and the following chemical structure:



Mometasone furoate monohydrate is a white powder, with an empirical formula of $C_{27}H_{30}Cl_2O_6 \cdot H_2O$, and a molecular weight of 539.45. It is practically insoluble in water; slightly soluble in methanol, ethanol, and isopropanol; soluble in acetone and chloroform; and freely soluble in tetrahydrofuran. Its partition coefficient between octanol and water is greater than 5000.

NASONEX is a metered-dose, manual pump spray. After initial priming (10 actuations), each actuation of the pump delivers a metered spray containing 100 mcg or 100 microliter of aqueous suspension of mometasone furoate monohydrate equivalent to 50 mcg (0.05% w/w) mometasone furoate calculated on the anhydrous basis; in an aqueous medium containing glycerin, microcrystalline cellulose and carboxymethylcellulose sodium, sodium citrate, citric acid, benzalkonium chloride, and polysorbate 80. The pH is between 4.3 and 4.9.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

NASONEX is a corticosteroid demonstrating potent anti-inflammatory properties. The precise mechanism of corticosteroid action on allergic rhinitis is not known. Corticosteroids have been shown to have a wide range of effects on multiple cell types (e.g., mast cells, eosinophils, neutrophils, macrophages, and lymphocytes) and mediators (e.g., histamine, eicosanoids, leukotrienes, and cytokines) involved in inflammation.

In two clinical studies utilizing nasal antigen challenge, NASONEX decreased some markers of the early- and late-phase allergic response. These observations included decreases (vs. placebo) in histamine and eosinophil cationic protein levels, and reductions (vs. baseline) in eosinophils, neutrophils, and epithelial cell adhesion proteins. The clinical significance of these findings is not known.

The effect of NASONEX on nasal mucosa following 12 months of treatment was examined in 46 patients with allergic rhinitis. There was no evidence of atrophy and there was a marked reduction in intraepithelial eosinophilia and inflammatory cell infiltration (e.g., eosinophils, lymphocytes, monocytes, neutrophils, and plasma cells).

12.2 Pharmacodynamics

Adrenal Function in Adults: Four clinical pharmacology studies have been conducted in humans to assess the effect of NASONEX at various doses on adrenal function. In one study, daily doses of 200 and 400 mcg of NASONEX and 10 mg of prednisone were compared to placebo in 64 patients (22 to 44 years of age) with allergic rhinitis. Adrenal function before and after 36 consecutive days of treatment was assessed by measuring plasma cortisol levels following a 6-hour Cortrosyn (ACTH) infusion and by measuring 24-hour urinary free cortisol levels. NASONEX at both the 200- and 400-mcg dose, was not associated with a statistically significant decrease in mean plasma cortisol levels post-Cortrosyn infusion or a statistically significant decrease in the 24-hour urinary free cortisol levels compared to placebo. A statistically significant decrease in the mean plasma cortisol levels post-Cortrosyn infusion and 24-hour urinary free cortisol levels was detected in the prednisone treatment group compared to placebo.

A second study assessed adrenal response to NASONEX (400 and 1600 mcg/day), prednisone (10 mg/day), and placebo, administered for 29 days in 48 male volunteers (21 to 40 years of age). The 24-hour plasma cortisol area under the curve (AUC_{0-24}), during and after an 8-hour Cortrosyn infusion and 24-hour urinary free cortisol levels were determined at baseline and after 29 days of treatment. No statistically significant differences in adrenal function were observed with NASONEX compared to placebo.

A third study evaluated single, rising doses of NASONEX (1000, 2000, and 4000 mcg/day), orally administered mometasone furoate (2000, 4000, and 8000 mcg/day), orally administered dexamethasone (200, 400, and 800 mcg/day), and placebo (administered at the end of each series of doses) in 24 male volunteers (22 to 39 years of age). Dose administrations were separated by at least 72 hours. Determination of serial plasma cortisol levels at 8 AM and for the 24-hour period following each treatment were used to calculate the plasma cortisol area under the curve (AUC_{0-24}). In addition, 24-hour urinary free cortisol levels were collected prior to initial treatment administration and during the period immediately following each dose. No statistically significant decreases in the plasma cortisol AUC, 8 AM cortisol levels, or 24-hour urinary free cortisol levels were observed in volunteers treated with either NASONEX or oral mometasone, as compared with placebo treatment. Conversely, nearly all volunteers treated with the three doses of dexamethasone demonstrated abnormal 8 AM cortisol levels (defined as a cortisol level <10 mcg/dL), reduced 24-hour plasma AUC values, and decreased 24-hour urinary free cortisol levels, as compared to placebo treatment.

In a fourth study, adrenal function was assessed in 213 patients (18 to 81 years of age) with nasal polyps before and after 4 months of treatment with either NASONEX (200 mcg once or twice daily) or placebo by measuring 24-hour urinary free cortisol levels. NASONEX at both doses (200 and 400 mcg/day), was not associated with statistically significant decreases in the 24-hour urinary free cortisol levels compared to placebo.

Three clinical pharmacology studies have been conducted in pediatric patients to assess the effect of mometasone furoate nasal spray on the adrenal function at daily doses of 50, 100, and 200 mcg vs. placebo. In one study, adrenal function before and after 7 consecutive days of treatment was assessed in 48 pediatric patients with allergic rhinitis (ages 6 to 11 years) by measuring morning plasma cortisol and 24-hour urinary free cortisol levels. Mometasone furoate nasal spray, at all three doses, was not associated with a statistically significant decrease in mean plasma cortisol levels or a statistically significant decrease in the 24-hour urinary free cortisol levels compared to placebo. In the second study, adrenal function before and after 14 consecutive days of treatment was assessed in 48 pediatric patients (ages 3 to 5 years) with allergic rhinitis by measuring plasma cortisol levels following a 30-minute Cortrosyn infusion. Mometasone furoate nasal spray, 50 mcg, at all three doses (50, 100, and 200 mcg/day), was not associated with a statistically significant decrease in mean plasma cortisol levels post-Cortrosyn infusion compared to placebo. All patients had a normal response to Cortrosyn. In the third study, adrenal function before and after up to 42 consecutive days of once-daily treatment was assessed in 52 patients with allergic rhinitis (ages 2 to 5 years), 28 of whom received mometasone furoate nasal spray, 50 mcg per nostril (total daily dose 100 mcg), by measuring morning plasma cortisol and 24-hour urinary free cortisol levels. Mometasone furoate nasal spray was not associated with a statistically significant decrease in mean plasma cortisol levels or a statistically significant decrease in the 24-hour urinary free cortisol levels compared to placebo.

12.3 Pharmacokinetics

Absorption:

Mometasone furoate monohydrate administered as a nasal spray suspension has very low bioavailability ($<1\%$) in plasma using a sensitive assay with a lower quantitation limit (LOQ) of 0.25 pcg/mL.

Distribution:

The *in vitro* protein binding for mometasone furoate was reported to be 98% to 99% in concentration range of 5 to 500 ng/mL.

Elimination:

Following intravenous administration, the effective plasma elimination half-life of mometasone furoate is 5.8 hours. Any absorbed drug is excreted as metabolites mostly via the bile, and to a limited extent, into the urine.

Metabolism:

Studies have shown that any portion of a mometasone furoate dose which is swallowed and absorbed undergoes extensive metabolism to multiple metabolites. There are no major metabolites detectable in plasma. Upon *in vitro* incubation, one of the minor metabolites formed is 6 β -hydroxy-mometasone furoate. In human liver microsomes, the formation of the metabolite is regulated by cytochrome P-450 3A4 (CYP3A4).

Specific Populations:

Patients with Hepatic Impairment: Administration of a single inhaled dose of 400 mcg mometasone furoate to subjects with mild (n=4), moderate (n=4), and severe (n=4) hepatic impairment resulted in only 1 or 2 subjects in each group having detectable peak plasma concentrations of mometasone furoate (ranging from 50 to 105 pcg/mL). The observed peak plasma concentrations appear to increase with severity of hepatic impairment, however, the numbers of detectable levels were few.

Patients with Renal Impairment: The effects of renal impairment on mometasone furoate pharmacokinetics have not been adequately investigated.

Pediatric Patients: Mometasone furoate pharmacokinetics have not been investigated in the pediatric population [see *Use in Specific Populations* (8.4)].

Male and Female Patients: The effects of gender on mometasone furoate pharmacokinetics have not been adequately investigated.

Racial or Ethnic Groups: The effects of race on mometasone furoate pharmacokinetics have not been adequately investigated.

Drug Interactions:

Inhibitors of Cytochrome P450 3A4: In a drug interaction study, an inhaled dose of mometasone furoate 400 mcg was given to 24 healthy subjects twice daily for 9 days and ketoconazole 200 mg (as well as placebo) were given twice daily concomitantly on Days 4 to 9. Mometasone furoate plasma concentrations were <150 pcg/mL on Day 3 prior to coadministration of ketoconazole or placebo. Following concomitant administration of ketoconazole, 4 out of 12 subjects in the ketoconazole treatment group (n=12) had peak plasma concentrations of mometasone furoate >200 pcg/mL on Day 9 (211-324 pcg/mL).

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

In a 2-year carcinogenicity study in Sprague Dawley rats, mometasone furoate demonstrated no statistically significant increase in the incidence of tumors at inhalation doses up to 67 mcg/kg (approximately 1 and 2 times the maximum recommended daily nasal dose [MRDID] in adults [400 mcg] and children [100 mcg], respectively, on a mcg/m² basis). In a 19-month carcinogenicity study in Swiss CD-1 mice, mometasone furoate demonstrated no statistically significant increase in the incidence of tumors at inhalation doses up to 160 mcg/kg (approximately 2 times the MRDID in adults and children, respectively, on a mcg/m² basis).

Mometasone furoate increased chromosomal aberrations in an *in vitro* Chinese hamster ovary-cell assay, but did not increase chromosomal aberrations in an *in vitro* Chinese hamster lung cell assay. Mometasone furoate was not mutagenic in the Ames test or mouse-lymphoma assay, and was not clastogenic in an *in vivo* mouse micronucleus assay and a rat bone marrow chromosomal aberration assay or a mouse male germ-cell chromosomal aberration assay. Mometasone furoate also did not induce unscheduled DNA synthesis *in vivo* in rat hepatocytes.

In reproductive studies in rats, impairment of fertility was not produced by subcutaneous doses up to 15 mcg/kg (less than the MRDID in adults on a mcg/m² basis).

13.2 Animal Toxicology and/or Pharmacology

Reproduction Toxicology Studies

In mice, mometasone furoate caused cleft palate at subcutaneous doses of 60 mcg/kg and above (less than the MRDID in adults on a mcg/m² basis). Fetal survival was reduced at 180 mcg/kg (approximately 2 times the MRDID in adults on a mcg/m² basis). No toxicity was observed at 20 mcg/kg (less than the MRDID in adults on a mcg/m² basis).

In rats, mometasone furoate produced umbilical hernia at topical dermal doses of 600 mcg/kg and above (approximately 10 times the MRDID in adults on a mcg/m² basis). A dose of 300 mcg/kg (approximately 6 times the MRDID in adults on a mcg/m² basis) produced delays in ossification, but no malformations. In rabbits, mometasone furoate caused multiple malformations (e.g., flexed front paws, gallbladder agenesis, umbilical hernia, hydrocephaly) at topical dermal doses of 150 mcg/kg and above (approximately 6 times the MRDID in adults on a mcg/m² basis). In an oral study, mometasone furoate increased resorptions and caused cleft palate and/or head malformations (hydrocephaly or domed head) at 700 mcg/kg (approximately 30 times the MRDID in adults on a mcg/m² basis). At 2800 mcg/kg (approximately 110 times the MRDID in adults on a mcg/m² basis), most litters were aborted or resorbed. No toxicity was observed at 140 mcg/kg (approximately 6 times the MRDID in adults on a mcg/m² basis).

When rats received subcutaneous doses of mometasone furoate throughout pregnancy or during the later stages of pregnancy, 15 mcg/kg (less than the MRDID in adults on a mcg/m² basis) caused prolonged and difficult labor and reduced the number of live births, birth weight, and early pup survival. Similar effects were not observed at 7.5 mcg/kg (less than the MRDID in adults on a mcg/m² basis).

14 CLINICAL STUDIES

14.1 Allergic Rhinitis in Adults and Adolescents

The efficacy and safety of NASONEX in the prophylaxis and treatment of seasonal allergic rhinitis and the treatment of perennial allergic rhinitis have been evaluated in 18 controlled trials, and one uncontrolled clinical trial, in approximately 3000 adults (ages 17 to 85 years) and adolescents (ages 12 to 16 years). Of the total number of patients, there were 1757 males and 1453 females, including a total of 283 adolescents (182 boys and 101 girls) with seasonal allergic or perennial allergic rhinitis. Patients were treated with NASONEX at doses ranging from 50 to 800 mcg/day. The majority of patients were treated with 200 mcg/day. The allergic rhinitis trials evaluated the total nasal symptom scores that included stuffiness, rhinorrhea, itching, and sneezing. Patients treated with NASONEX 200 mcg/day had a statistically significant decrease in total nasal symptom scores compared to placebo-treated patients. No additional benefit was observed for mometasone furoate doses greater than 200 mcg/day. A total of 350 patients have been treated with NASONEX for 1 year or longer.

In patients with seasonal allergic rhinitis, NASONEX demonstrated improvement in nasal symptoms (vs. placebo) within 11 hours after the first dose based on one single-dose, parallel-group study of patients in an outdoor "park" setting (park study) and one environmental exposure unit (EEU) study, and within 2 days in two randomized, double-blind, placebo-controlled, parallel-group seasonal allergic rhinitis studies. Maximum benefit is usually achieved within 1 to 2 weeks after initiation of dosing.

Prophylaxis of seasonal allergic rhinitis for patients 12 years of age and older with NASONEX given at a dose of 200 mcg/day, was evaluated in two clinical studies in 284 patients. These studies were designed such that patients received 4 weeks of prophylaxis with NASONEX prior to the anticipated onset of the pollen season; however, some patients received only 2 to 3 weeks of prophylaxis. Patients receiving 2 to 4 weeks of prophylaxis with NASONEX demonstrated a statistically significantly smaller mean increase in total nasal symptom scores with onset of the pollen season as compared to placebo patients.

14.2 Allergic Rhinitis in Pediatrics

The efficacy and safety of NASONEX in the treatment of seasonal allergic and perennial allergic rhinitis in pediatric patients (ages 3 to 11 years) have been evaluated in four controlled trials. This included approximately 990 pediatric patients ages 3 to 11 years (606 males and 384 females) with seasonal allergic or perennial allergic rhinitis treated with mometasone furoate nasal spray at doses ranging from 25 to 200 mcg/day. Pediatric patients treated with NASONEX (100 mcg total daily dose, 374 patients) had a significant decrease in total nasal symptom (nasal congestion, rhinorrhea, itching,

and sneezing) scores, compared to placebo-treated patients. No additional benefit was observed for the 200-mcg mometasone furoate total daily dose in pediatric patients (ages 3 to 11 years). A total of 163 pediatric patients have been treated for 1 year.

14.3 Nasal Polyps in Adults 18 Years of Age and Older

Two studies were performed to evaluate the efficacy and safety of NASONEX in the treatment of nasal polyps. These studies involved 664 patients with nasal polyps, 441 of whom received NASONEX. These studies were randomized, double-blind, placebo-controlled, parallel-group, multicenter studies in patients 18 to 86 years of age with bilateral nasal polyps. Patients were randomized to receive NASONEX 200 mcg once daily, 200 mcg twice daily or placebo for a period of 4 months. The co-primary efficacy endpoints were 1) change from baseline in nasal congestion/obstruction averaged over the first month of treatment; and 2) change from baseline to last assessment in bilateral polyp grade during the entire 4 months of treatment as assessed by endoscopy. Efficacy was demonstrated in both studies at a dose of 200 mcg twice daily and in one study at a dose of 200 mcg once a day (see Table 2 below).

Table 2: Effect of NASONEX in Two Randomized, Placebo-Controlled Trials in Patients with Nasal Polyps

	NASONEX 200 mcg qd	NASONEX 200 mcg bid	Placebo	P-value for NASONEX 200 mcg qd vs. placebo	P-value for NASONEX 200 mcg bid vs. placebo
Study 1	N=115	N=122	N=117		
Baseline bilateral polyp grade*	4.21	4.27	4.25		
Mean change from baseline in bilateral polyps grade	-1.15	-0.96	-0.50	<0.001	0.01
Baseline nasal congestion [†]	2.29	2.35	2.28		
Mean change from baseline in nasal congestion	-0.47	-0.61	-0.24	0.001	<0.001
Study 2	N=102	N=102	N=106		
Baseline bilateral polyp grade*	4.00	4.10	4.17		
Mean change from baseline in bilateral polyps grade	-0.78	-0.96	-0.62	0.33	0.04
Baseline nasal congestion [†]	2.23	2.20	2.18		
Mean change from baseline in nasal congestion	-0.42	-0.66	-0.23	0.01	<0.001

* polyps in each nasal fossa were graded by the investigator based on endoscopic visualization, using a scale of 0-3 where 0=no polyps; 1=polyps in the middle meatus, not reaching below the inferior border of the middle turbinate; 2=polyps reaching below the inferior border of the middle turbinate but not the inferior border of the inferior turbinate; 3=polyps reaching to or below the border of the inferior turbinate, or polyps medial to the middle turbinate (score reflects sum of left and right nasal fossa grades).

[†] nasal congestion/obstruction was scored daily by the patient using a 0-3 categorical scale where 0=no symptoms, 1=mild symptoms, 2=moderate symptoms and 3=severe symptoms.

There were no clinically relevant differences in the effectiveness of NASONEX in the studies evaluating treatment of nasal polyps across subgroups of patients defined by gender, age, or race.

14.4 Nasal Congestion Associated with Seasonal Allergic Rhinitis

The efficacy and safety of NASONEX for nasal congestion associated with seasonal allergic rhinitis were evaluated in three randomized, placebo-controlled, double blind clinical trials of 15 days duration. The three trials included a total of 1008 patients 12 years of age and older with nasal congestion associated with seasonal allergic rhinitis, of whom 506 received NASONEX 200 mcg daily and 502 received placebo. Of the 1008 patients, the majority 784 (78 %) were Caucasians. The majority of the patients were between 18 to < 65 years of age with a mean age of 38.8 years and were predominantly women (66%). The primary efficacy endpoint was the change from baseline in average morning and evening reflective nasal congestion score over treatment day 1 to day 15. The key secondary efficacy endpoint was the change from baseline in average morning and evening reflective total nasal symptom score (TNSS=rhinorrhea [nasal discharge/runny nose or postnasal drip], nasal congestion/stuffiness, nasal itching, sneezing) averaged over treatment day 1 to 15. Two out of three studies demonstrated that treatment with NASONEX significantly reduced the nasal congestion symptom score and the TNSS compared to placebo in patients 12 years of age and older with seasonal allergic rhinitis (see Tables 3 and 4 below).

Table 3: Effect of NASONEX in Two Randomized, Placebo-Controlled Trials on Nasal Congestion in Patients with Seasonal Allergic Rhinitis

Treatment (Patient Number)	Baseline * LS Mean †	Change from Baseline LS Mean †	Difference from Placebo LS Mean †	P-value for NASONEX 200 mcg qd vs. placebo
Study 1				
NASONEX 200 mcg qd (N=176)	2.63	-0.64	-0.15	0.006
Placebo (N=175)	2.62	-0.49		
Study 2				
NASONEX 200 mcg qd (N=168)	2.62	-0.71	-0.31	<0.001
Placebo (N=164)	2.60	-0.40		

* nasal congestion/obstruction was scored daily by the patient using a 0-3 categorical scale where 0=no symptoms, 1=mild symptoms, 2=moderate symptoms and 3=severe symptoms.

† LS Mean and p-value was from an ANCOVA model with treatment, baseline value, and center effects.

Table 4: Effect of NASONEX on TNSS in Two Randomized, Placebo-Controlled Trials in Patients with Seasonal Allergic Rhinitis

Treatment (Patient Number)	Baseline * LS Mean †	Change from Baseline LS Mean †	Difference from Placebo LS Mean †	P-value for NASONEX 200 mcg qd vs. placebo
Study 1				
NASONEX 200 mcg qd (N=176)	9.60	-2.68	-0.83	<0.001
Placebo (N=175)	9.66	-1.85		
Study 2				
NASONEX 200 mcg qd (N=168)	9.39	-3.00	-1.27	<0.001
Placebo (N=164)	9.50	-1.73		

* TNSS was the sum of four individual symptom scores: rhinorrhea, nasal congestion/stuffiness, nasal itching and sneezing. Each symptom was to be rated on a scale of 0=none, 1=mild, 2=moderate, 3=severe.

† LS Mean and p-value was from an ANCOVA model with treatment, baseline value, and center effects.

Based on results in other studies with NASONEX in pediatric patients, effects on nasal congestion associated with seasonal allergic rhinitis in patients below 12 years of age is similar to those seen in adults and adolescents [see *Clinical Studies (14.2)*].

16 HOW SUPPLIED/STORAGE AND HANDLING

NASONEX Nasal Spray:

- 50 mcg mometasone furoate monohydrate
- is supplied in a white, high-density, polyethylene bottle fitted with a white metered-dose, manual spray pump, and blue cap
- contains 17 g of product formulation (NDC 78206-144-01)
- 120 sprays, each delivering 50 mcg of mometasone furoate per actuation

Store at 25°C (77°F); excursions permitted to 15-30°C (59-86°F) [see USP Controlled Room Temperature]. Protect from light.

When NASONEX Nasal Spray, 50 mcg is removed from its cardboard container, prolonged exposure of the product to direct light should be avoided. Brief exposure to light, as with normal use, is acceptable.

SHAKE WELL BEFORE EACH USE.

Keep out of reach of children.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information).

17.1 Local Nasal Effect

Patients should be informed that treatment with NASONEX may be associated with adverse reactions which include epistaxis (nose bleed) and nasal septum perforation. *Candida* infection may also occur. Because of the inhibitory effect of corticosteroids on wound healing, patients who have experienced recent nasal septum ulcers, nasal surgery, or nasal trauma should not use a nasal corticosteroid until healing has occurred [see *Warnings and Precautions (5.1)*]. Patients should be cautioned not to spray NASONEX directly onto the nasal septum.

17.2 Glaucoma and Cataracts

Advise patients that long-term use of nasal and inhaled corticosteroids may increase the risk of some eye problems (glaucoma or cataracts); regular eye examinations should be considered. Patients should be cautioned not to spray NASONEX into the eyes [see *Warnings and Precautions (5.2)*].

17.3 Immunosuppression and Risk of Infections

Persons who are on immunosuppressant doses of corticosteroids should be warned to avoid exposure to chickenpox or measles, and patients should also be advised that if they are exposed, medical advice should be sought without delay [see *Warnings and Precautions (5.4)*].

17.4 Use Regularly for Best Effect

Patients should use NASONEX on a regular basis for optimal effect. Improvement in nasal symptoms of allergic rhinitis has been shown to occur within 1 to 2 days after initiation of dosing. Maximum benefit is usually achieved within 1 to 2 weeks after initiation of dosing. Patients should not increase the prescribed dosage but should contact their physician if symptoms do not improve, or if the condition worsens. Administration to young children should be aided by an adult.

If a patient missed a dose, the patient should be advised to take the dose as soon as they remember. The patient should not take more than the recommended dose for the day.

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For patent information: www.organon.com/our-solutions/patent/

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