ASMANEX HFA- mometasone furoate aerosol
Organon LLC

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use ASMANEX HFA safely and effectively. See full prescribing information for ASMANEX HFA.

ASMANEX® HFA (mometasone furoate) inhalation aerosol, for oral inhalation use
Initial U.S. Approval: 1987

INDICATIONS AND USAGE

ASMANEX HFA is a corticosteroid indicated for:

- Maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older. (1.1)

Important limitations:

- Not indicated for the relief of acute bronchospasm. (1.1)

DOSAGE AND ADMINISTRATION

For oral inhalation only. (2.1)

- Treatment of asthma in patients 12 years of age and older: 2 inhalations twice daily of ASMANEX HFA 100 mcg or 200 mcg. Starting dosage is based on prior asthma therapy. (2.2)
- Treatment of asthma in patients aged 5 to less than 12 years: 2 inhalations twice daily of ASMANEX HFA 50 mcg. (2.2)

DOSAGE FORMS AND STRENGTHS

- Inhalation aerosol containing 50 mcg, 100 mcg, or 200 mcg of mometasone furoate per actuation. (3)

CONTRAINDICATIONS

- Primary treatment of status asthmaticus or acute episodes of asthma requiring intensive measures. (4.1)
- Hypersensitivity to any of the ingredients of ASMANEX HFA. (4.2)

WARNINGS AND PRECAUTIONS

- Deterioration of asthma and acute episodes: ASMANEX HFA should not be used for relief of acute symptoms. Patients require immediate re-evaluation during rapidly deteriorating asthma. (5.1)
- Localized infections: *Candida albicans* infection of the mouth and throat may occur. Monitor patients periodically for signs of adverse effects on the oral cavity. After dosing, advise patients to rinse their mouth with water and spit out contents without swallowing. (5.2)
- Immunosuppression: Potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infection; or ocular herpes simplex infections. More serious or even fatal course of chickenpox or measles can occur in susceptible patients. Use with caution in patients with these infections because of the potential for worsening of these infections. (5.3)
- Transferring patients from systemic corticosteroids: Risk of impaired adrenal function when transferring from oral steroids. Wean patients slowly from systemic corticosteroids if transferring to ASMANEX HFA. (5.4)
- Hypercorticism and adrenal suppression: May occur with very high dosages or at the regular dosage in susceptible individuals. If such changes occur, discontinue ASMANEX HFA slowly. (5.5)
- Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir): Risk of increased systemic corticosteroid effects. Exercise caution when used with ASMANEX HFA. (5.6)
- Paradoxical bronchospasm: Discontinue ASMANEX HFA and institute alternative therapy if paradoxical bronchospasm occurs. (5.7)
- Hypersensitivity reactions including anaphylaxis: Hypersensitivity reactions, such as urticaria, flushing, allergic dermatitis, bronchospasm, rash, pruritus, angioedema, and anaphylactic reaction may occur. Discontinue ASMANEX HFA if such reactions occur. (5.8)
- Decreases in bone mineral density: Monitor patients with major risk factors for decreased bone mineral content. (5.9)
- Effects on growth: Monitor growth of pediatric patients. (5.10)
- Glaucoma and cataracts: Consider referral to an ophthalmologist in patients who develop ocular

symptoms or use ASMANEX HFA long term. (5.11)

ADVERSE REACTIONS

Most common adverse reactions (reported in greater than or equal to 3% of patients) included:

- nasopharyngitis, headache, sinusitis, bronchitis, and influenza. (6.1)

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.

DRUG INTERACTIONS

- Strong cytochrome P450 3A4 inhibitors (e.g., ritonavir): Use with caution. May cause increased systemic corticosteroid effects. (7.1)

USE IN SPECIFIC POPULATIONS

- Hepatic impairment: Monitor patients for signs of increased drug exposure. (8.6)

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

Revised: 6/2025

FULL PRESCRIBING INFORMATION: CONTENTS*

* Sections or subsections omitted from the full prescribing information are not listed.

FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

1.1 Treatment of Asthma

ASMANEX® HFA is indicated for the maintenance treatment of asthma as prophylactic therapy in patients 5 years of age and older.

Important Limitations of Use

- ASMANEX HFA is NOT indicated for the relief of acute bronchospasm.

2 DOSAGE AND ADMINISTRATION

2.1 Administration Information

Administer ASMANEX HFA only by the orally inhaled route *[see Instructions for Use in the Patient Information leaflet]*. After each dose, advise patients to rinse their mouth with water and, without swallowing, spit out the contents to help reduce the risk of oropharyngeal candidiasis.

Remove the cap from the mouthpiece of the actuator before using ASMANEX HFA.

Prime ASMANEX HFA before using for the first time by releasing 4 test sprays into the air, away from the face, shaking well before each spray. In cases where the inhaler has not been used for more than 5 days, prime the inhaler again by releasing 4 test sprays into the air, away from the face, shaking well before each spray.

Only use the ASMANEX HFA canister with the ASMANEX HFA actuator. Do not use the ASMANEX HFA actuator with any other inhalation drug product. Do not use actuators

from other products with the ASMANEX HFA canister.

2.2 Recommended Dosage

Administer ASMANEX HFA as two inhalations twice daily every day (morning and evening) by the orally inhaled route. Shake well prior to each inhalation. If symptoms arise between doses, use an inhaled short-acting beta$_2$-agonist for immediate relief. The maximum benefit may not be achieved for 1 week or longer after beginning treatment. Individual patients may experience a variable time to onset and degree of symptom relief.

Adult and Adolescent Patients Aged 12 Years and Older

For patients 12 years of age and older, the dosage is either 2 inhalations twice daily of ASMANEX HFA 100 mcg or 200 mcg. The starting dosage is based on previous asthma therapy and disease severity, including considerations of the patients' current control of asthma symptoms and risk of future exacerbations. The recommended starting dosage for patients 12 years of age and older who are not on an inhaled corticosteroid is ASMANEX HFA 100 mcg, 2 inhalations twice daily. It is recommended that patients currently receiving chronic oral corticosteroid therapy (e.g., prednisone) begin with ASMANEX HFA 200 mcg (2 inhalations twice daily). For patients who do not respond adequately to the initial dosage after 2 weeks of therapy, increasing the dosage may provide additional asthma control. The maximum daily recommended dose is two inhalations of ASMANEX HFA 200 mcg twice daily (maximum of 800 mcg a day).

After asthma stability has been achieved, it may be desirable to titrate to the lowest effective dosage to reduce the possibility of side effects.

If a dosage regimen of ASMANEX HFA fails to provide adequate control of asthma, re-evaluate the therapeutic regimen and consider additional therapeutic options, e.g., replacing the current strength of ASMANEX HFA with a higher strength, initiating an inhaled corticosteroid and long-acting beta$_2$-agonist combination product, or initiating oral corticosteroids.

Pediatric Patients Aged 5 to Less Than 12 Years

For patients aged 5 to less than 12 years, the dosage is 2 inhalations of ASMANEX HFA 50 mcg twice daily. The maximum daily dosage is 200 mcg.

3 DOSAGE FORMS AND STRENGTHS

ASMANEX HFA is a pressurized metered dose inhaler (MDI) that is available in 2 strengths (100 mcg and 200 mcg) for adult and adolescent patients aged 12 years and older; and 1 strength (50 mcg) for pediatric patients aged 5 to less than 12 years.

ASMANEX HFA 50 mcg delivers 50 mcg of mometasone furoate per actuation.

ASMANEX HFA 100 mcg delivers 100 mcg of mometasone furoate per actuation.

ASMANEX HFA 200 mcg delivers 200 mcg of mometasone furoate per actuation.

Each strength of ASMANEX HFA is supplied with a blue colored actuator and pink dust cap *[see How Supplied/Storage and Handling (16.1)]*.

4 CONTRAINDICATIONS

4.1 Status Asthmaticus

ASMANEX HFA is contraindicated in the primary treatment of status asthmaticus or other acute episodes of asthma where intensive measures are required.

4.2 Hypersensitivity

ASMANEX HFA is contraindicated in patients with known hypersensitivity to mometasone furoate or any of the ingredients in ASMANEX HFA *[see Warnings and Precautions (5.8)]*.

5 WARNINGS AND PRECAUTIONS

5.1 Deterioration of Asthma and Acute Episodes

ASMANEX HFA is not indicated for the relief of acute symptoms, i.e., as rescue therapy for the treatment of acute episodes of bronchospasm. An inhaled, short-acting beta$_2$-agonist, not ASMANEX HFA, should be used to relieve acute symptoms such as shortness of breath. When prescribing ASMANEX HFA, the physician must also provide the patient with an inhaled, short-acting beta$_2$-agonist (e.g., albuterol) for treatment of acute symptoms, despite regular twice-daily (morning and evening) use of ASMANEX HFA. Instruct patients to contact their physician immediately if episodes of asthma that are not responsive to bronchodilators occur during the course of treatment with ASMANEX HFA. During such episodes, patients may require therapy with oral corticosteroids.

5.2 Local Effects

In clinical trials, the development of localized infections of the mouth and pharynx with *Candida albicans* have occurred in patients treated with ASMANEX HFA. If oropharyngeal candidiasis develops, treat with appropriate local or systemic (i.e., oral) antifungal therapy while remaining on treatment with ASMANEX HFA therapy, but at times therapy with ASMANEX HFA may need to be interrupted. To reduce the risk of oropharyngeal candidiasis, after dosing with ASMANEX HFA, advise patients to rinse their mouth with water and spit out the contents without swallowing.

5.3 Immunosuppression

Persons who are using drugs that 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 susceptible children or adults using corticosteroids. In such children or adults who have not had these diseases or who are not properly immunized, 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) or pooled intravenous immunoglobulin (IVIG) may be indicated. If exposed to measles, prophylaxis with pooled intramuscular immunoglobulin (IG) may be indicated. (See the respective package inserts for complete VZIG and IG prescribing

information.) If chickenpox develops, treatment with antiviral agents may be considered.

Inhaled corticosteroids should be used with caution, if at all, in patients with active or quiescent tuberculosis infection of the respiratory tract, untreated systemic fungal, bacterial, viral, or parasitic infections; or ocular herpes simplex.

5.4 Transferring Patients from Systemic Corticosteroid Therapy

Particular care is needed for patients who are transferred from systemically active corticosteroids to ASMANEX HFA 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) function.

Patients who have been previously maintained on 20 mg or more per day of prednisone (or its equivalent) may be most susceptible, particularly when their systemic corticosteroids have been almost completely withdrawn. During this period of HPA suppression, patients may exhibit signs and symptoms of adrenal insufficiency when exposed to trauma, surgery, or infection (particularly gastroenteritis) or other conditions associated with severe electrolyte loss. Although ASMANEX HFA may improve control of asthma symptoms during these episodes, in recommended doses it supplies less than normal physiological amounts of corticosteroid systemically and does NOT provide the mineralocorticoid activity necessary for coping with these emergencies.

During periods of stress or severe asthma attack, patients who have been withdrawn from systemic corticosteroids should be instructed to resume oral corticosteroids (in large doses) immediately and to contact their physicians for further instruction. These patients should also be instructed to carry a medical identification card indicating that they may need supplementary systemic corticosteroids during periods of stress or severe asthma attack.

Patients requiring oral or other systemic corticosteroids should be weaned slowly from oral or other systemic corticosteroid use after transferring to ASMANEX HFA. Lung function (FEV_1 or PEF), beta-agonist use, and asthma symptoms should be carefully monitored during withdrawal of oral or other systemic corticosteroids. In addition to monitoring asthma signs and symptoms, patients should be observed for signs and symptoms of adrenal insufficiency such as fatigue, lassitude, weakness, nausea and vomiting, and hypotension.

Transfer of patients from systemic corticosteroid therapy to ASMANEX HFA may unmask allergic conditions previously suppressed by the systemic corticosteroid therapy, e.g., rhinitis, conjunctivitis, eczema, arthritis, and eosinophilic conditions.

During withdrawal from oral corticosteroids, some patients may experience symptoms of systemically active corticosteroid withdrawal, e.g., joint and/or muscular pain, lassitude, and depression, despite maintenance or even improvement of respiratory function.

5.5 Hypercorticism and Adrenal Suppression

ASMANEX HFA will often help control asthma symptoms with less suppression of HPA function than therapeutically equivalent oral doses of prednisone. Since mometasone furoate is absorbed into the circulation and can be systemically active at higher doses,

the beneficial effects of ASMANEX HFA in minimizing HPA dysfunction may be expected only when recommended dosages are not exceeded and individual patients are titrated to the lowest effective dose.

Because of the possibility of systemic absorption of inhaled corticosteroids, patients treated with ASMANEX HFA should be observed carefully for any evidence of systemic corticosteroid effects. Particular care should be taken in observing patients postoperatively or during periods of stress for evidence of inadequate adrenal response.

It is possible that systemic corticosteroid effects such as hypercorticism and adrenal suppression (including adrenal crisis) may appear in a small number of patients, particularly when mometasone furoate is administered at higher than recommended doses over prolonged periods of time. If such effects occur, the dosage of ASMANEX HFA should be reduced slowly, consistent with accepted procedures for reducing systemic corticosteroids and for management of asthma symptoms.

5.6 Drug Interactions with Strong Cytochrome P450 3A4 Inhibitors

Caution should be exercised when considering the coadministration of ASMANEX HFA with ketoconazole, and other known strong cytochrome P450 (CYP) isoenzyme 3A4 (CYP3A4) inhibitors (e.g., ritonavir, cobicistat-containing products, atazanavir, clarithromycin, indinavir, itraconazole, nefazodone, nelfinavir, saquinavir, telithromycin) because adverse effects related to increased systemic exposure to mometasone furoate may occur *[see Drug Interactions (7.1) and Clinical Pharmacology (12.3)].*

5.7 Paradoxical Bronchospasm and Upper Airway Symptoms

ASMANEX HFA may produce inhalation induced bronchospasm with an immediate increase in wheezing after dosing that may be life-threatening. If inhalation induced bronchospasm occurs, it should be treated immediately with an inhaled, short-acting bronchodilator. ASMANEX HFA should be discontinued immediately and alternative therapy instituted.

5.8 Hypersensitivity Reactions Including Anaphylaxis

Hypersensitivity reactions such as urticaria, flushing, allergic dermatitis, and bronchospasm, may occur after administration of ASMANEX HFA. Discontinue ASMANEX HFA if such reactions occur *[see Contraindications (4.2)].*

The following additional hypersensitivity reactions, such as rash, pruritus, angioedema, and anaphylactic reaction, have been reported after administration of mometasone furoate dry powder inhaler (DPI) *[see Adverse Reactions (6.2)].*

5.9 Reduction in Bone Mineral Density

Decreases in bone mineral density (BMD) have been observed with long-term administration of products containing inhaled corticosteroids, including mometasone furoate. The clinical significance of small changes in BMD with regard to long-term outcomes, such as fracture, is unknown. Patients with major risk factors for decreased bone mineral content, such as prolonged immobilization, family history of osteoporosis, or chronic use of drugs that can reduce bone mass (e.g., anticonvulsants and corticosteroids) should be monitored and treated with established standards of care.

In a 2-year double-blind study in 103 male and female asthma patients 18 to 50 years of

age previously maintained on bronchodilator therapy (Baseline FEV_1 85%-88% predicted), treatment with mometasone furoate dry powder inhaler 200 mcg twice daily resulted in significant reductions in lumbar spine (LS) BMD at the end of the treatment period compared to placebo. The mean change from Baseline to Endpoint in the lumbar spine BMD was -0.015 (-1.43%) for the mometasone furoate dry powder inhaler group compared to 0.002 (0.25%) for the placebo group. In another 2-year double-blind study in 87 male and female asthma patients 18 to 50 years of age previously maintained on bronchodilator therapy (Baseline FEV_1 82%-83% predicted), treatment with mometasone furoate dry powder inhaler 400 mcg twice daily demonstrated no statistically significant changes in lumbar spine BMD at the end of the treatment period compared to placebo. The mean change from Baseline to Endpoint in the lumbar spine BMD was -0.018 (-1.57%) for the mometasone furoate group compared to -0.006 (-0.43%) for the placebo group.

5.10 Effect on Growth

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

5.11 Glaucoma and Cataracts

Glaucoma, increased intraocular pressure, and cataracts have been reported following the use of long-term administration of inhaled corticosteroids, including mometasone furoate. Consider referral to an ophthalmologist in patients who develop ocular symptoms or use ASMANEX HFA long term *[see Adverse Reactions (6)]*.

6 ADVERSE REACTIONS

Systemic and local corticosteroid use may result in the following:

- *Candida albicans* infection *[see Warnings and Precautions (5.2)]*
- Immunosuppression *[see Warnings and Precautions (5.3)]*
- Hypercorticism and adrenal suppression *[see Warnings and Precautions (5.5)]*
- Growth effects in pediatrics *[see Warnings and Precautions (5.10)]*
- Glaucoma and cataracts *[see Warnings and Precautions (5.11)]*

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.

6.1 Clinical Trials Experience

Adult and Adolescent Patients Aged 12 Years and Older

The safety of ASMANEX HFA was evaluated in 2 randomized placebo and active-controlled trials of 12 and 26 weeks' duration, conducted as part of a mometasone furoate/formoterol fumarate combination product asthma program, which enrolled 1509 patients with persistent asthma. Patient ages ranged from 12 to 84 years of age, 41%

were male and 59% female, 73% were Caucasian and 27% non-Caucasian. Of the total population enrolled in the 2 trials, 432 patients received two inhalations twice daily of either ASMANEX HFA, 100 mcg or 200 mcg/actuation. In the 26-week trial (Trial 1) 192 patients received two inhalations twice daily of ASMANEX HFA 100 mcg/actuation and 196 patients received placebo. In the 12 week trial (Trial 2) 240 patients received two inhalations twice daily of ASMANEX HFA 200 mcg/actuation and 233 and 255 patients received mometasone furoate and formoterol fumarate 100 mcg/5 mcg and 200 mcg/5 mcg/actuation combination products, respectively, as comparators.

In these trials, the proportion of patients who discontinued study treatment early due to adverse reactions was 3% and 2% for ASMANEX HFA 100 and 200 mcg treated patients, respectively, and 4% for placebo-treated patients. Serious adverse reactions, whether considered drug-related or not by the investigators, which occurred more frequently in ASMANEX HFA-treated patients included colitis ulcerative, colonic polyp, chest pain, gastroenteritis, endometriosis, asthma, and hemoptysis; all events occurred at rates less than 1%.

The incidence of treatment emergent adverse events associated with ASMANEX HFA are shown in Tables 1 and 2. These are based upon data from each of the 2 clinical trials of 12 or 26 weeks in duration in patients 12 years and older treated with two inhalations twice daily of ASMANEX HFA (100 mcg or 200 mcg), mometasone furoate/formoterol fumarate (100 mcg/5 mcg or 200 mcg/5 mcg), or placebo.

TABLE 1: Trial 1: Treatment-Emergent Adverse Events Occurring at an Incidence of ≥3% and More Commonly than Placebo Over 26 Weeks

	ASMANEX HFA 100 mcg N=192 n (%)	**Placebo N=196 n (%)**
Nasopharyngitis	15 (8)	7 (4)
Headache	10 (5)	7 (4)
Influenza	7 (4)	5 (3)
Sinusitis	6 (3)	2 (1)

TABLE 2: Trial 2: Treatment-Emergent Adverse Events Occurring at an Incidence of ≥3% Over 12 Weeks

	ASMANEX HFA 200 mcg N=240 n (%)	**MF/F* 100/5 mcg N=233 n (%)**	**MF/F* 200/5 mcg N=255 n (%)**
Nasopharyngitis	13 (5)	8 (3)	12 (5)
Headache	8 (3)	10 (4)	5 (2)
Bronchitis	6 (3)	2 (1)	7 (3)

* MF/F = mometasone furoate/formoterol fumarate.

Oral candidiasis has been reported in clinical trials at an incidence of 0.5% in patients using ASMANEX HFA 100 mcg, 0.8% in patients using ASMANEX HFA 200 mcg and 0.5%

in the placebo group.

Pediatric Patients Aged 5 to Less Than 12 Years

The safety profile for ASMANEX HFA 50 mcg, 2 inhalations twice daily, is based on two clinical trials consisting of a total of 759 patients aged 5 to less than 12 years with persistent asthma. The first trial was a placebo-controlled trial comparing ASMANEX HFA 50 mcg (administered as 2 inhalations, twice daily) to 2 other dosage strengths of mometasone furoate MDI (25 mcg or 100 mcg, each administered as two inhalations, twice daily) as well as mometasone furoate DPI 100 mcg, administered as one evening inhalation. The second trial compared ASMANEX HFA 50 mcg to the combination of mometasone furoate and formoterol fumarate 50 mcg/5 mcg, each administered by MDI as two inhalations, twice daily.

Overall, the safety profile for pediatric patients is similar to that observed in patients aged 12 years and older.

6.2 Postmarketing Experience

There are no postmarketing adverse experiences reported to date with ASMANEX HFA. However, the postmarketing safety experience with mometasone furoate dry powder inhaler is relevant to ASMANEX HFA since they contain the same active ingredient. The following adverse reactions have been reported during post-approval use of mometasone furoate dry powder inhaler. 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.

Eye Disorders: Vision blurred *[see Warnings and Precautions (5.11)]*.

Immune System Disorders: Immediate and delayed hypersensitivity reactions including rash, pruritus, angioedema and anaphylactic reaction *[see Contraindications (4.2) and Warnings and Precautions (5.8)]*.

Respiratory, Thoracic and Mediastinal Disorders: Asthma aggravation, which may include cough, dyspnea, wheezing and bronchospasm.

7 DRUG INTERACTIONS

In clinical trials, concurrent administration of ASMANEX HFA and other drugs, such as short-acting beta$_2$-agonist and intranasal corticosteroids have not resulted in an increased frequency of adverse drug reactions. No formal drug interaction studies have been performed with ASMANEX HFA.

7.1 Inhibitors of Cytochrome P450 3A4

The main route of metabolism of corticosteroids, including mometasone furoate, is via CYP3A4. After oral administration of ketoconazole, a strong inhibitor of CYP3A4, the mean plasma concentration of orally inhaled mometasone furoate increased. 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 ASMANEX HFA 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 Warnings and Precautions (5.6) and 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 randomized clinical studies of ASMANEX HFA in pregnant women. There are clinical considerations with the use of ASMANEX HFA in pregnant women *[see Clinical Considerations]*. 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/m^2 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. 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.

Clinical Considerations

Disease-associated maternal and/or embryo/fetal risk

In women with poorly or moderately controlled asthma, there is an increased risk of several perinatal adverse outcomes such as preeclampsia in the mother and prematurity, low birth weight, and small for gestational age in the neonate. Pregnant women with asthma should be closely monitored and medication adjusted as necessary to maintain optimal asthma control.

Data

Animal Data

In an embryofetal development study with pregnant mice dosed throughout the period of organogenesis, mometasone furoate produced cleft palate at an exposure approximately one-third of the MRHD (on a mcg/m^2 basis with maternal subcutaneous doses of 60 mcg/kg and above) and decreased fetal survival at an exposure approximately equivalent to the MRHD (on a mcg/m^2 basis with a maternal subcutaneous dose of 180 mcg/kg). No toxicity was observed with a dose that produced an exposure approximately one-tenth of the MRHD (on a mcg/m^2 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 6 times the MRHD (on a mcg/m^2 basis with maternal topical dermal doses of 600 mcg/kg and above) and delays in fetal ossification at exposures approximately 3 times the MRHD (on a mcg/m^2 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 an exposure that was approximately 8 times the MRHD (on an area under the curve (AUC) basis with a maternal subcutaneous dose of 15 mcg/kg). There were no findings with an exposure approximately 4 times the MRHD (on an AUC 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 an exposure approximately 3 times the MRHD (on a mcg/m^2 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 an exposure approximately 1/2 of the MRHD (on AUC basis with a maternal oral dose of 700 mcg/kg). At an exposure approximately 2 times the MRHD (on an AUC basis with a maternal oral dose of 2800 mcg/kg), most litters were aborted or resorbed. No effects were observed at an exposure approximately 1/10 of the MRHD (on an AUC basis with a maternal oral dose of 140 mcg/kg).

8.2 Lactation

Risk Summary

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

8.4 Pediatric Use

The safety and effectiveness of ASMANEX HFA have been established in patients 12 years of age and older in 2 clinical trials of 12 and 26 weeks in duration. In the 2 clinical trials, 32 patients 12 to 17 years of age were treated with ASMANEX HFA. No overall differences in effectiveness were observed between patients in this age group compared to those observed in patients 18 years of age and older. There were no obvious differences in the type or frequency of adverse reactions reported in this age group compared to patients 18 years of age and older.

The safety and effectiveness of ASMANEX HFA 50 mcg, two inhalations twice daily, have been established in patients with asthma aged 5 to less than 12 years in clinical trials up to 24 weeks of treatment duration. The safety profile and overall effectiveness in this age group were consistent with that observed in patients aged 12 years and older who also received ASMANEX HFA *[see Adverse Reactions (6.1) and Clinical Studies (14.1)].*

The safety and effectiveness of ASMANEX HFA have not been established in children younger than 5 years of age.

Controlled clinical studies have shown that inhaled corticosteroids may cause a reduction in growth velocity in pediatric patients. In these studies, the mean reduction in growth velocity was approximately 1 cm per year (range 0.3 to 1.8 per year) and appears to depend upon dose and duration of exposure. This effect was observed in the absence of laboratory evidence of 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 orally inhaled corticosteroids, including the impact on final adult height, are unknown. The potential for "catch-up" growth following discontinuation of treatment with orally inhaled corticosteroids has not been adequately studied.

The growth of children and adolescents receiving orally inhaled corticosteroids, including ASMANEX HFA, should be monitored routinely (e.g., via stadiometry). If a child or adolescent on any corticosteroid appears to have growth suppression, the possibility that he/she is particularly sensitive to this effect should be considered. The potential growth effects of prolonged treatment should be weighed against clinical benefits obtained and the risks associated with alternative therapies. To minimize the systemic effects of orally inhaled corticosteroids, including ASMANEX HFA, each patient should be titrated to his/her lowest effective dose *[see Dosage and Administration (2.2)]*.

8.5 Geriatric Use

A total of 38 patients 65 years of age and older (3 of whom were 75 years and older) have been treated with ASMANEX HFA in 2 clinical trials of 12 and 26 weeks in duration. No overall differences in safety or effectiveness were observed between these patients and younger patients, but greater sensitivity of some older individuals cannot be ruled out. Based on available data for ASMANEX HFA, no adjustment of dosage in geriatric patients is warranted.

8.6 Hepatic Impairment

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

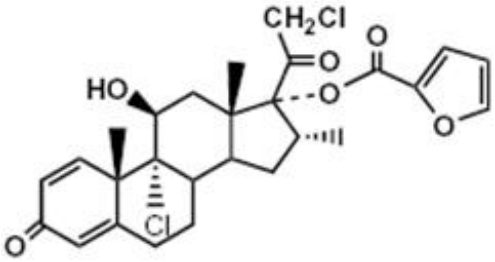
10 OVERDOSAGE

Chronic overdosage may result in signs/symptoms of hypercorticism *[see Warnings and Precautions (5.5)]*. Single oral doses up to 8000 mcg of mometasone furoate have been studied on adult subjects with no adverse reactions reported.

11 DESCRIPTION

ASMANEX HFA is a metered dose inhaler for oral inhalation only, consisting of 50 mcg, 100 mcg, or 200 mcg of mometasone furoate per actuation.

Mometasone furoate, the active component of ASMANEX HFA, is a corticosteroid having the chemical name 9,21-dichloro-11(Beta),17-dihydroxy-16 (alpha)-methylpregna-1,4-diene-3,20-dione 17-(2-furoate) with the following chemical structure:



Mometasone furoate is a white powder with an empirical formula of $C_{27}H_{30}Cl_2O_6$, and molecular weight 521.44. It is practically insoluble in water; slightly soluble in methanol, ethanol, and isopropanol; soluble in acetone.

ASMANEX HFA 50 mcg, 100 mcg, and 200 mcg are each formulated as a hydrofluoroalkane (HFA-227: 1,1,1,2,3,3,3-heptafluoropropane) propelled pressurized metered dose inhaler containing sufficient amount of drug for 120 actuations *[see How Supplied/Storage and Handling (16)]*. After priming, each actuation of the inhaler delivers 60, 115, or 225 mcg of mometasone furoate in 69.6 mg of suspension from the valve and delivers 50, 100, or 200 mcg of mometasone furoate from the actuator. The actual amount of drug delivered to the lung may depend on patient factors, such as the coordination between actuation of the device and inspiration through the delivery system. ASMANEX HFA also contains ethanol as a cosolvent and oleic acid as a surfactant.

ASMANEX HFA should be primed before using for the first time by releasing 4 test sprays into the air, away from the face, shaking well before each spray. In cases where the inhaler has not been used for more than 5 days, prime the inhaler again by releasing 4 test sprays into the air, away from the face, shaking well before each spray.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Mometasone furoate is a corticosteroid demonstrating potent anti-inflammatory activity. The precise mechanism of corticosteroid action on asthma is not known. Inflammation is an important component in the pathogenesis of asthma. Corticosteroids have been shown to have a wide range of inhibitory 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 and in the asthmatic response. These anti-inflammatory actions of corticosteroids may contribute to their efficacy in asthma.

Mometasone furoate has been shown *in vitro* to exhibit a binding affinity for the human glucocorticoid receptor, which is approximately 12 times that of dexamethasone, 7 times that of triamcinolone acetonide, 5 times that of budesonide, and 1.5 times that of fluticasone. The clinical significance of these findings is unknown.

12.2 Pharmacodynamics

Systemic effects of inhaled corticosteroids are related to systemic exposure. Pharmacokinetic data have demonstrated that, in adults, systemic exposure to mometasone furoate administered by MDI is the same or lower than that of equivalent

doses of inhaled mometasone furoate administered via DPI *[see Clinical Pharmacology (12.3)]*. Based upon the pharmacokinetic data, the systemic effects (e.g., HPA-axis suppression and growth retardation) of mometasone furoate delivered by MDI in adult and pediatric patients would be expected to be no greater than what is reported for inhaled mometasone furoate when administered at comparable doses via DPI *[see Use in Specific Populations (8.4)]*.

HPA Axis Effects (Adults)

The effects of inhaled mometasone furoate administered via ASMANEX HFA on adrenal function have not been directly evaluated. However, the effects of inhaled mometasone furoate, administered as part of a mometasone furoate/formoterol fumarate inhalation aerosol combination product, on adrenal function were evaluated in two clinical trials in patients with asthma. As no evidence of a pharmacokinetic drug interaction between mometasone furoate and formoterol was observed when the two drugs were administered in combination, the HPA axis effects from the combination product are applicable to ASMANEX HFA. For the mometasone furoate/formoterol fumarate combination product clinical program, HPA-axis function was assessed by 24-hour plasma cortisol AUC. Although both these trials have open-label design and contain a small number of subjects per treatment arm, results from these trials taken together demonstrated suppression of 24-hour plasma cortisol AUC for the combination mometasone furoate/formoterol fumarate 200 mcg/5 mcg compared to placebo consistent with the known systemic effects of inhaled corticosteroid.

In a 42-day, open-label, placebo- and active-controlled study, the mean change from baseline plasma cortisol $AUC_{(0\text{-}24\ hr)}$ was 8%, 22% and 34% lower compared to placebo for the mometasone furoate/formoterol fumarate 100 mcg/5 mcg (n=13), mometasone furoate/formoterol fumarate 200 mcg/5 mcg (n=15) and fluticasone propionate/salmeterol xinafoate 230 mcg/21 mcg (n=16) treatment groups, respectively.

In a 52-week, open-label safety study, the mean plasma cortisol $AUC_{(0\text{-}24\ hr)}$ was 2.2%, 29.6%, 16.7%, and 32.2% lower from baseline for the mometasone furoate/formoterol fumarate 100 mcg/5 mcg (n=18), mometasone furoate/formoterol fumarate 200 mcg/5 mcg (n=20), fluticasone propionate/salmeterol xinafoate 125/25 mcg (n=8), and fluticasone propionate/salmeterol xinafoate 250/25 mcg (n=11) treatment groups, respectively.

The potential effect of mometasone furoate via a dry powder inhaler (DPI) on the HPA axis was also assessed in a 29-day study. A total of 64 adult patients with mild to moderate asthma were randomized to one of 4 treatment groups: mometasone furoate DPI 440 mcg twice daily, mometasone furoate DPI 880 mcg twice daily, oral prednisone 10 mg once daily, or placebo. The 30-minute post-Cosyntropin stimulation serum cortisol concentration on Day 29 was 23.2 mcg/dL for the mometasone furoate DPI 440 mcg twice daily group and 20.8 mcg/dL for the mometasone furoate DPI 880 mcg twice daily group, compared to 14.5 mcg/dL for the oral prednisone 10 mg group and 25 mcg/dL for the placebo group. The difference between mometasone furoate DPI 880 mcg twice daily (twice the maximum recommended dose) and placebo was statistically significant.

HPA Axis Effects (Pediatrics)

The potential effect of mometasone furoate via a DPI on the HPA axis was assessed in

50 children aged 6 to 11 years in a 29-day, randomized, double-blind, placebo-controlled, parallel-group clinical trial. In this study, the mean difference from placebo in plasma cortisol $AUC_{(0\text{-}12hr)}$ for DPI 110 mcg twice daily was 3.4 mcg•hr/dL (95% CI: -14.0, 20.7) and for 220 mcg twice daily was -16.0 mcg•hr/dL (95% CI: -33.9, 1.9). The mean difference from placebo in plasma cortisol $AUC_{(0\text{-}12hr)}$ for the 440 mcg twice daily group (eight times the currently recommended mometasone furoate dose via a DPI in children ages 4-11) was -17.9 mcg•hr/dL (95% CI: -35.8, 0.0). The mean differences in urinary-free cortisol changes from baseline compared to placebo were 3.1 mcg/day (95% CI: -3.3, 9.6), 3.3 mcg/day (95% CI: -3.0, 9.7), and -2.0 mcg/day (95% CI: -8.6, 4.6) for the groups treated with 110 mcg twice daily, 220 mcg twice daily, and 440 mcg twice daily, respectively.

12.3 Pharmacokinetics

As no evidence of a pharmacokinetic drug interaction between mometasone furoate and formoterol was observed when the two drugs were administered from a mometasone furoate/formoterol fumarate combination product, the pharmacokinetics information from the combination product is applicable to ASMANEX HFA.

Absorption

Adult Healthy Subjects: Following oral inhalation of single doses of ASMANEX HFA, mometasone furoate was absorbed in healthy subjects with median T_{max} values ranging from 0.50 to 2 hours. Following single-dose administration of higher than recommended dose of ASMANEX HFA (4 inhalations of ASMANEX HFA 200 mcg) in healthy subjects, the arithmetic mean (CV%) C_{max} and $AUC_{(0\text{-}tf)}$ values for mometasone furoate were 53 (102) pg/mL and 992 (80) pg•hr/mL, respectively. Studies using oral dosing of labeled and unlabeled drug have demonstrated that the oral systemic bioavailability of mometasone furoate is negligible (<1%).

Following single-dose administration of a higher than recommended dose of mometasone furoate (4 inhalations of mometasone furoate/formoterol fumarate 200 mcg/5 mcg) in healthy subjects, the arithmetic mean (CV%) C_{max} and $AUC_{(0\text{-}12\ hr)}$ values for mometasone furoate were 67.8 (49) pg/mL and 650 (51) pg•hr/mL, respectively, while the corresponding estimates following 5 days of BID dosing with mometasone furoate 800 mcg/20 mcg were 241 (36) pg/mL and 2200 (35) pg•hr/mL. The systemic exposure to mometasone furoate (based on AUC) was approximately 52% and 25% lower on Day 1 and Day 5, respectively, following mometasone furoate administration compared to mometasone furoate via a DPI.

Adult Asthma Patients: Following oral inhalation of single and multiple doses of the mometasone furoate/formoterol fumarate combination product, mometasone furoate was absorbed in asthma patients with median T_{max} values ranging from 1 to 2 hours. Following single-dose administration of mometasone furoate/formoterol fumarate 400 mcg/10 mcg, the arithmetic mean (CV%) C_{max} and $AUC_{(0\text{-}12\ hr)}$ values for mometasone furoate were 20 (88) pg/mL and 170 (94) pg•hr/mL, respectively, while the corresponding estimates following twice daily dosing of mometasone furoate/formoterol fumarate 400 mcg/10 mcg at steady-state were 60 (36) pg/mL and 577 (40) pg•hr/mL.

Distribution

Based on the study employing a 1000 mcg inhaled dose of tritiated mometasone furoate inhalation powder in humans, no appreciable accumulation of mometasone furoate in

the red blood cells was found. Following an intravenous 400 mcg dose of mometasone furoate, the plasma concentrations showed a biphasic decline, with a mean steady-state volume of distribution of 152 liters. The *in vitro* protein binding for mometasone furoate was reported to be 98% to 99% (in a concentration range of 5 to 500 ng/mL).

Metabolism

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 human liver CYP3A4 in the metabolism of this compound; however, no major metabolites were identified. Human liver CYP3A4 metabolizes mometasone furoate to 6-beta hydroxy mometasone furoate.

Excretion

Following an intravenous dosing, the terminal half-life was reported to be about 5 hours. Following the inhaled dose of tritiated 1000 mcg mometasone furoate, the radioactivity is excreted mainly in the feces (a mean of 74%), and to a small extent in the urine (a mean of 8%) up to 7 days. No radioactivity was associated with unchanged mometasone furoate in the urine. Absorbed mometasone furoate is cleared from plasma at a rate of approximately 12.5 mL/min/kg, independent of dose. The effective $t_{½}$ for mometasone furoate following inhalation was 25 hours in adult healthy subjects and in adult patients with asthma.

Special Populations

Hepatic/Renal Impairment: There are no data regarding the specific use of ASMANEX HFA in patients with hepatic or renal impairment.

A study evaluating the administration of a single inhaled dose of 400 mcg mometasone furoate by a dry powder inhaler to adult 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 50-105 pg/mL). The observed peak plasma concentrations appear to increase with severity of hepatic impairment; however, the numbers of detectable levels were few.

Gender and Race: Specific studies to examine the effects of gender and race on the pharmacokinetics of ASMANEX HFA have not been specifically studied.

Geriatrics: The pharmacokinetics of ASMANEX HFA have not been specifically studied in the elderly population.

Drug-Drug Interactions

A single-dose crossover study was conducted to compare the pharmacokinetics of 4 inhalations of the following: mometasone furoate MDI, formoterol MDI, mometasone furoate/formoterol fumarate MDI combination product, and mometasone furoate MDI plus formoterol fumarate MDI administered concurrently. The results of the study indicated that there was no evidence of a pharmacokinetic interaction between mometasone furoate and formoterol.

Inhibitors of Cytochrome P450 Enzymes: Ketoconazole: In a drug interaction study, an inhaled dose of mometasone furoate 400 mcg delivered by a dry powder inhaler was given to 24 adult 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 pg/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 pg/mL on Day 9 (211-324 pg/mL). Mometasone furoate plasma levels appeared to increase and plasma cortisol levels appeared to decrease upon concomitant administration of ketoconazole.

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 14 times the MRHD on an AUC 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 9 times the MRHD on an AUC basis).

Mometasone furoate increased chromosomal aberrations in an *in vitro* Chinese hamster ovary cell assay, but did not have this effect 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, 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 (approximately 8 times the MRHD on an AUC basis).

14 CLINICAL STUDIES

14.1 Asthma

Adult and Adolescent Patients Aged 12 Years of Age and Older

The safety and efficacy of ASMANEX HFA was demonstrated in two randomized, double-blind, placebo- or active-controlled multi-center clinical trials of 12 and 26 weeks' duration, conducted as part of a mometasone furoate/formoterol fumarate 100/5 mcg or 200/5 mcg combination product development program. A total of 1509 patients 12 years of age and older with persistent asthma (mean baseline FEV_1 of 66% to 73% predicted) were evaluated.

Trial 1: Clinical Trial with ASMANEX HFA 100 mcg

This 26-week, placebo-controlled trial (NCT00383240) conducted as part of a mometasone furoate/formoterol fumarate combination product asthma program evaluated 781 patients 12 years of age and older. Of these patients, 192 patients received ASMANEX HFA 100 mcg and 196 patients received placebo, each administered as 2 inhalations twice daily by metered dose inhalation aerosols. All other maintenance therapies were discontinued. The study included a 2- to 3-week run-in period with ASMANEX HFA 100 mcg, 2 inhalations twice daily. Patients ranged from 12 to 76 years

of age, 41% were male and 59% female, and 72% were Caucasian and 28% non-Caucasian. Patients had persistent asthma and were not well controlled on medium dose of inhaled corticosteroids prior to randomization. Mean FEV_1 and mean percent predicted FEV_1 were similar among all treatment groups (2.33 L, 73%). Thirteen (7%) patients receiving ASMANEX HFA 100 mcg and 46 (23%) patients receiving placebo discontinued the study early due to treatment failure.

The change in mean trough FEV_1 from baseline to Week 12 compared to placebo was assessed to evaluate the efficacy of ASMANEX HFA 100 mcg. The change from baseline to week 12 in the mean trough FEV_1 was greater among patients receiving ASMANEX HFA 100 mcg 2 inhalations twice daily than among those receiving placebo (treatment difference from placebo 0.12 L and 95% confidence interval [0.05, 0.20]).

Clinically judged deteriorations in asthma or reductions in lung function were also assessed to evaluate the efficacy of ASMANEX HFA 100 mcg. Deteriorations in asthma were defined as any of the following: a 20% decrease in FEV_1; a 30% decrease in PEF on two or more consecutive days; emergency treatment, hospitalization, or treatment with systemic corticosteroids or other asthma medications not allowed per protocol. Sixty-five (34%) patients who received ASMANEX HFA 100 mcg reported an event compared to 109 (56%) patients who received placebo.

Treatment of asthma patients with ASMANEX HFA 100 mcg, two inhalations twice daily also resulted in fewer nocturnal awakenings and improved morning peak flow compared to those who received placebo.

Trial 2: Clinical Trial with ASMANEX HFA 200 mcg

This 12-week randomized, double-blind, active-controlled trial (NCT00381485) also conducted as part of a mometasone furoate/formoterol fumarate combination product asthma program evaluated a total of 728 patients 12 years of age and older comparing ASMANEX HFA 200 mcg (n=240 patients), mometasone furoate/formoterol fumarate 200 mcg/5 mcg (n=255 patients), and mometasone furoate/formoterol fumarate 100 mcg/5 mcg (n=233 patients), each administered as 2 inhalations twice daily by metered dose inhalation aerosols. All other maintenance therapies were discontinued. This trial included a 2- to 3-week run-in period with ASMANEX HFA 200 mcg, 2 inhalations twice daily. Patients had persistent asthma and were uncontrolled on high-dose inhaled corticosteroids prior to study entry. Patients ranged from 12 to 84 years of age, 44% were male and 56% female, and 89% were Caucasian and 11% non-Caucasian. Mean FEV_1 and mean percent predicted FEV_1 values were similar among all treatment groups (2.05 L, 66%). The number of patients who discontinued the trial early due to treatment failure were 11 (5%) in the mometasone furoate/formoterol fumarate 100 mcg/5 mcg group, 8 (3%) in the mometasone furoate/formoterol fumarate 200 mcg/5 mcg group, and 13 (5%) in the ASMANEX HFA 200 mcg group.

In order to assess the added benefit of a higher dose of mometasone in the 200 mcg/actuation mometasone furoate product compared to the lower dose 100 mcg/actuation product, trough FEV_1 at 12 weeks was compared between the combination mometasone furoate/formoterol fumarate 200 mcg/5 mcg and 100 mcg/5 mcg treatment groups as a secondary endpoint. Improvement in trough FEV_1 from baseline to week 12 in patients who received mometasone furoate 200 mcg in combination with formoterol fumarate 5 mcg was numerically greater than among patients who received mometasone furoate 100 mcg in combination with formoterol fumarate 5 mcg (treatment difference of 0.05 L and 95% confidence interval [-0.02,

0.10]).

Other Studies in Adult and Adolescent Patients

In addition to Trial 1 and Trial 2, the safety and efficacy of mometasone furoate MDI 100 mcg and 200 mcg (each administered as 2 inhalations, twice daily), in comparison to placebo were demonstrated in two other 12-week, placebo-controlled trials which evaluated the mean change in FEV_1 from baseline as a primary endpoint. A 26-week trial (NCT00383552) also evaluated the same endpoint with a lower dose of mometasone furoate MDI.

Pediatric Patients Aged 5 to Less Than 12 Years

The safety and efficacy of ASMANEX HFA were demonstrated in a 12-week, randomized, double-blind, placebo-controlled, multicenter clinical trial in a total of 583 patients aged 5 to less than 12 years with persistent asthma (mean baseline FEV_1 of 79%-predicted) who had been using a low-to-medium dose of ICS with or without LABA for at least 12 weeks prior to study entry. After an approximate 2-week run-in period, subjects were randomized to ASMANEX HFA 50 mcg dose (administered as two inhalations, twice daily), two other doses of ASMANEX HFA, ASMANEX dry-powder inhaler (DPI) or placebo. Patients were 60% male, 71% were Caucasian, and 13% were aged 5 to 6 years old. Primary endpoint results show that after 12 weeks of treatment, ASMANEX HFA 50 mcg (administered as two inhalations, twice daily) was statistically superior to placebo with respect to the improvement from baseline in AM pre-dose percent predicted FEV_1 at the end of the dosing interval (6.29%, 95% CI: 3.05, 9.53).

16 HOW SUPPLIED/STORAGE AND HANDLING

16.1 How Supplied

ASMANEX HFA is available in three strengths and supplied in the following package size (TABLE 3):

TABLE 3

Package	NDC	Strength Identifier (Color Band)*
ASMANEX HFA 50 mcg 120 metered actuations	78206-111-01	Orange
ASMANEX HFA 100 mcg 120 metered actuations	78206-112-01	Green
ASMANEX HFA 200 mcg 120 metered actuations	78206-113-01	Blue

* Included on the outer carton, actuator, and canister labels.

Each strength is supplied as a pressurized aluminum canister that has a blue plastic actuator integrated with a dose counter and a pink dust cap. Each canister has a net fill weight of 13 grams. Each inhaler is placed into a carton. Each carton contains 1 inhaler.

Initially the dose counter will display "124" actuations. After the initial priming with 4

actuations, the dose counter will read "120" and the inhaler is now ready for use.

16.2 Storage and Handling

Only use the ASMANEX HFA canister with the ASMANEX HFA actuator. Do not use the ASMANEX HFA actuator with any other inhalation drug product. Do not use actuators from other products with the ASMANEX HFA canister.

Do not remove the canister from the actuator because the correct amount of medication may not be discharged; the dose counter may not function properly; reinsertion may cause the dose counter to count down by 1 and discharge a puff.

The correct amount of medication in each inhalation cannot be ensured after the labeled number of actuations from the canister has been used, even though the inhaler may not feel completely empty and may continue to operate. Discard the inhaler when the labeled number of actuations has been used (the dose counter will read "0").

Store at controlled room temperature 20°C-25°C (68°F-77°F); excursions permitted to 15°C-30°C (59°F-86°F) [see USP Controlled Room Temperature].

After priming, store the inhaler with the mouthpiece down or in a horizontal position.

For best results, keep the canister at room temperature before use. Shake well and remove the cap from the mouthpiece of the actuator before using. Keep out of reach of children. Avoid spraying in eyes.

Contents Under Pressure: Do not puncture. Do not use or store near heat or open flame. Exposure to temperatures above 120°F may cause bursting. Never throw container into fire or incinerator.

17 PATIENT COUNSELING INFORMATION

Advise the patient to read the FDA-approved patient labeling (Patient Information and Instructions for Use).

Not for Acute Symptoms

Advise patients that ASMANEX HFA is not indicated to relieve acute asthma symptoms, and extra doses should not be used for that purpose. ASMANEX HFA is not a bronchodilator and should not be used to treat status asthmaticus or to relieve acute asthma symptoms. Treat acute asthma symptoms with an inhaled, short-acting $beta_2$-agonist such as albuterol. Prescribe the patient with such medication and instruct the patient on how to use it *[see Warnings and Precautions (5.1)].*

Instruct patients to seek medical attention immediately if they experience any of the following:

- If their symptoms worsen
- Significant decrease in lung function as outlined by the physician
- If they need more inhalations of a short-acting $beta_2$-agonist than usual

Advise patients not to increase the dose or frequency of ASMANEX HFA. Do not exceed the daily dosage of ASMANEX HFA two inhalations twice daily. If they miss a dose, instruct patients to take their next dose at the same time they normally do.

Advise patients not to stop or reduce ASMANEX HFA therapy without physician/provider

guidance since symptoms may recur after discontinuation.

Local Effects

Advise patients that localized infections with *Candida albicans* occurred in the mouth and pharynx in some patients. If oropharyngeal candidiasis develops, treat with appropriate local or systemic (i.e., oral) antifungal therapy while still continuing with ASMANEX HFA therapy, but at times therapy with ASMANEX HFA may need to be temporarily interrupted under close medical supervision. After dosing, advise patients to rinse their mouth with water and spit out contents without swallowing *[see Warnings and Precautions (5.2)].*

Immunosuppression

Warn patients who are on immunosuppressant doses of corticosteroids to avoid exposure to chickenpox or measles and, if exposed, to consult their physician without delay. Inform patients of potential worsening of existing tuberculosis, fungal, bacterial, viral, or parasitic infections, or ocular herpes simplex *[see Warnings and Precautions (5.3)].*

Hypercorticism and Adrenal Suppression

Advise patients that ASMANEX HFA may cause systemic corticosteroid effects of hypercorticism and adrenal suppression. Additionally, instruct patients that deaths due to adrenal insufficiency have occurred during and after transfer from systemic corticosteroids. Instruct patients to slowly taper from systemic corticosteroids if transferring to ASMANEX HFA *[see Warnings and Precautions (5.4 and 5.5)].*

Reduction in Bone Mineral Density

Advise patients who are at an increased risk for decreased BMD that the use of corticosteroids may pose an additional risk and should be monitored and, where appropriate, be treated for this condition *[see Warnings and Precautions (5.9)].*

Reduced Growth Velocity

Inform patients that orally inhaled corticosteroids, including ASMANEX HFA, may cause a reduction in growth velocity when administered to pediatric patients. Physicians should closely follow the growth of pediatric patients taking corticosteroids by any route *[see Warnings and Precautions (5.10)].*

Glaucoma and Cataracts

Advise patients that long-term use of inhaled corticosteroids may increase the risk of some eye problems (glaucoma or cataracts); consider regular eye examinations *[see Warnings and Precautions (5.11)].*

Hypersensitivity Reactions Including Anaphylaxis

Advise patients that hypersensitivity reactions, such as urticaria, flushing, allergic dermatitis, bronchospasm, rash, pruritus, angioedema, and anaphylactic reaction, may occur after administration of ASMANEX HFA. Instruct patients to discontinue ASMANEX HFA if such reactions occur *[see Warnings and Precautions (5.8)].*

Use Daily for Best Effect

Advise patients to use ASMANEX HFA at regular intervals, since its effectiveness depends on regular use. Maximum benefit may not be achieved for 1 week or longer

after starting treatment. If symptoms do not improve after 2 weeks of therapy or if the condition worsens, instruct patients to contact their physician.

Instructions for Use

Instruct patients regarding the following:

- Read the Patient Information before use and follow the Instructions for Use carefully.
- Remind patients to:
  - Remove the cap from the mouthpiece of the actuator before use.
  - After dosing, rinse their mouth with water and spit out contents without swallowing. This will help reduce the risk of oropharyngeal candidiasis.
  - Not remove the canister from the actuator.
  - Not wash inhaler in water. The mouthpiece should be cleaned using a dry wipe after every 7 days of use.

Manufactured for: Organon LLC, a subsidiary of
ORGANON & Co.,
Jersey City, NJ 07302, USA

Manufactured by: Kindeva Drug Delivery Limited, Loughborough, United Kingdom.

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

uspi-og0887-ao-2506r001

Patient Information
ASMANEX® HFA (AZ-ma-neks) 50 mcg
ASMANEX® HFA 100 mcg
ASMANEX® HFA 200 mcg
(mometasone furoate)
Inhalation Aerosol

What is ASMANEX HFA?

ASMANEX HFA is an inhaled corticosteroid (ICS) prescription medicine used as maintenance treatment for the prevention and control of asthma symptoms in people 5 years of age and older.

- ASMANEX HFA is not used to treat sudden severe symptoms of asthma.
- ASMANEX HFA should not be used as a rescue inhaler.
- It is not known if ASMANEX HFA is safe and effective in children less than 5 years of age.

Who should not use ASMANEX HFA?

Do not use ASMANEX HFA:

- to treat sudden severe symptoms of asthma.
- if you are allergic to mometasone furoate or any of the ingredients in ASMANEX HFA. See the end of this Patient Information leaflet for a complete list of ingredients in ASMANEX HFA.

What should I tell my doctor before and during treatment with ASMANEX HFA?

Before you use ASMANEX HFA, tell your healthcare provider if you:

- have liver problems.
- have osteoporosis.
- have an immune system problem.
- have eye problems such as increased pressure in the eye, glaucoma, cataracts, blurred vision, or other changes in your vision.
- are allergic to any medicines.
- are exposed to chickenpox or measles.
- have or had tuberculosis (TB).
- have any other medical problems.
- are pregnant or planning to become pregnant. It is not known if ASMANEX HFA may harm your unborn baby.
- are breastfeeding. It is not known if ASMANEX HFA passes into your breast milk and if it can harm your baby. You and your healthcare provider should decide if you will either take ASMANEX HFA or breastfeed.

Tell your healthcare provider about all the medicines you take, including prescription and over-the-counter medicines, vitamins, and herbal supplements. ASMANEX HFA may affect the way other medicines work, and other medicines may affect how ASMANEX HFA works.

Especially, tell your healthcare provider if you take antifungal medicines, antibiotic medicines, or anti-HIV medicines such as:

- ritonavir
- atazanavir
- cobicistat-containing products
- ketoconazole
- clarithromycin
- nefazodone
- saquinavir
- nelfinavir
- telithromycin
- indinavir
- itraconazole

Ask your healthcare provider if you are not sure if any of your medicines are the kinds listed above.

For some medicines (including medicines for HIV such as ritonavir, cobicistat-containing products, and certain antifungals and antibiotics) your doctor may wish to monitor you carefully.

Know the medicines you take. Keep a list and show it to your healthcare provider and pharmacist each time you get a new medicine.

How should I use ASMANEX HFA?

Read the step-by-step instructions for using ASMANEX HFA in the Instructions for Use.

- Use ASMANEX HFA exactly as prescribed. **Do not** use ASMANEX HFA more often than prescribed.
- You must use ASMANEX HFA regularly. It may take 1 week or longer after you start using ASMANEX HFA for your asthma symptoms to get better. Do not stop using ASMANEX HFA even if you are feeling better, unless your healthcare provider tells you to.
- **Do not** change or stop using ASMANEX HFA or other asthma medicines used to control or treat your breathing problems unless told to do so by your healthcare provider. Your healthcare provider will change your medicines as needed.
- ASMANEX HFA comes in 3 strengths. Your healthcare provider has prescribed the strength that is best for you. Pay attention to the differences between ASMANEX HFA and your other inhaled medicines, including their prescribed use and the way

they look.
- For children aged 5 to less than 12 years, use ASMANEX HFA 50 mcg.
- For adults and adolescents 12 years of age and older, use ASMANEX HFA 100 mcg or 200 mcg.
- Take ASMANEX HFA every day, with 2 puffs in the morning and 2 puffs in the evening.
- If you miss a dose of ASMANEX HFA, skip your missed dose and take your next dose at your regular time. Do not take ASMANEX HFA more often or use more puffs than you have been prescribed.
- If you take more ASMANEX HFA than your healthcare provider has prescribed, call your healthcare provider right away.
- ASMANEX HFA does not relieve sudden asthma symptoms. Always have a rescue inhaler with you to treat sudden symptoms. Use your rescue inhaler if you have breathing problems between doses of ASMANEX HFA. If you do not have a rescue inhaler, call your healthcare provider to have a rescue inhaler prescribed for you.
- Do not use the ASMANEX HFA canister or actuator with any other medicines. Do not use any other medicine canister or actuator with ASMANEX HFA.
- Rinse your mouth with water after each dose (2 puffs) of ASMANEX HFA. Spit out the water. Do not swallow it. This will help to lessen the chance of getting a yeast infection (thrush) in your mouth and throat.
- Do not spray ASMANEX HFA in your eyes. If you accidentally get ASMANEX HFA in your eyes, rinse your eyes with water and if redness or irritation continues, call your healthcare provider.
- **Call your healthcare provider or get medical care right away if:**
  - your breathing problems worsen with ASMANEX HFA
  - you need to use your rescue inhaler more often than usual
  - your rescue inhaler does not work as well for you at relieving symptoms
  - you need to use 4 or more inhalations of your rescue inhaler for 2 or more days in a row
  - you use 1 whole canister of your rescue inhaler within 8 weeks
  - your peak flow meter results decrease. Your healthcare provider will tell you the numbers that are right for you
  - you have asthma and your symptoms do not improve after using ASMANEX HFA regularly for 1 to 2 weeks

What are the possible side effects of ASMANEX HFA?
ASMANEX HFA can cause serious side effects, including

- **Thrush in your mouth and throat.** You may develop thrush, a yeast infection (Candida albicans), in your mouth or throat. After each dose (2 puffs) of ASMANEX HFA, rinse your mouth with water. Spit out the water. Do not swallow it. This will help to prevent thrush in your mouth or throat.
- **Immune system effects and a higher chance for infections.** Tell your healthcare provider about any signs of infection such as:

  - fever
  - feeling tired
  - body aches
  - vomiting
  - pain
  - nausea
  - chills

- **Adrenal insufficiency that can lead to death** can happen when you stop taking oral corticosteroid medicines and start using inhaled corticosteroid medicines. Adrenal insufficiency can also happen in people who take higher doses of ASMANEX

HFA than recommended over a long period of time. When your body is under stress such as from fever, trauma (such as a car accident), infection, or surgery, adrenal insufficiency can get worse. Symptoms of adrenal insufficiency include:

- feeling tired or exhausted (fatigue)
- weakness
- lack of energy
- nausea and vomiting
- low blood pressure (hypotension)
- dizziness or feeling faint

- **Increased wheezing right after taking ASMANEX HFA.** Always have a rescue inhaler with you to treat sudden wheezing.
- **Serious allergic reactions.** Stop taking ASMANEX HFA and call your healthcare provider or get emergency medical care right away if you get any of the following symptoms of a serious allergic reaction:

- rash
- hives
- swelling, including swelling of the face, mouth, and tongue
- breathing problems

- **Lower bone mineral density.** This may be a problem for people who already have a higher chance for low bone density (osteoporosis).
- **Slowed growth in children.** A child's growth should be checked often.
- **Eye problems including glaucoma, cataracts, and blurred vision.** You should have regular eye exams while using ASMANEX HFA.

The most common side effects reported while using ASMANEX HFA include:

- inflammation of the nose and throat (nasopharyngitis)
- inflammation of the sinuses (sinusitis)
- headache
- bronchitis
- flu infection (influenza)

Other side effects: Worsening asthma or sudden asthma attacks have been reported with the use of inhaled mometasone furoate.
Tell your healthcare provider about any side effect that bothers you or that does not go away.
These are not all the side effects with ASMANEX HFA. Ask your healthcare provider or pharmacist for more information.
Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.

How should I store ASMANEX HFA?

- Store ASMANEX HFA at room temperature between 68°F to 77°F (20°C to 25°C).
- After priming, store the inhaler with the mouthpiece down or sideways.
- The contents of your ASMANEX HFA are under pressure. **Do not** puncture. **Do not** use or store near heat or open flame. Storage above 120°F may cause the canister to burst.
- **Do not** throw container into fire or incinerator.
- **Keep ASMANEX HFA and all medicines out of the reach of children.**

General Information about the safe and effective use of ASMANEX HFA.
Medicines are sometimes prescribed for purposes other than those listed in a Patient Information leaflet. Do not use ASMANEX HFA for a condition for which it was not

prescribed. Do not give your ASMANEX HFA to other people, even if they have the same condition that you have. It may harm them.
This Patient Information leaflet summarizes the most important information about ASMANEX HFA. If you would like more information, talk with your healthcare provider. You can ask your healthcare provider or pharmacist for information about ASMANEX HFA that was written for healthcare professionals.
For more information about ASMANEX HFA go to www.ASMANEX.com, or to report side effects call 1-844-674-3200.

What are the ingredients in ASMANEX HFA?
Active ingredient: mometasone furoate
Inactive ingredients: hydrofluoroalkane (HFA-227: 1,1,1,2,3,3,3-heptafluoropropane), ethanol and oleic acid

This Patient Information has been approved by the U.S. Food and Drug Administration. Revised Date: 6/2025

Instructions for Use

ASMANEX® HFA (AZ-ma-neks) 50 mcg
ASMANEX® HFA 100 mcg
ASMANEX® HFA 200 mcg
(mometasone furoate)
Inhalation Aerosol

Read these Instructions for Use before you start using ASMANEX HFA and each time you get a refill. There may be new information. This leaflet does not take the place of talking to your healthcare provider about your medical condition or your treatment.

The parts of your ASMANEX HFA:

There are 2 main parts to your ASMANEX HFA inhaler: the metal canister that holds the medicine and the blue plastic actuator that sprays the medicine from the canister.

- The inhaler also has a pink cap that covers the mouthpiece of the actuator **(see Figure 1)**. The cap from the mouthpiece must be removed before use. The inhaler contains **"120"** actuations (puffs).

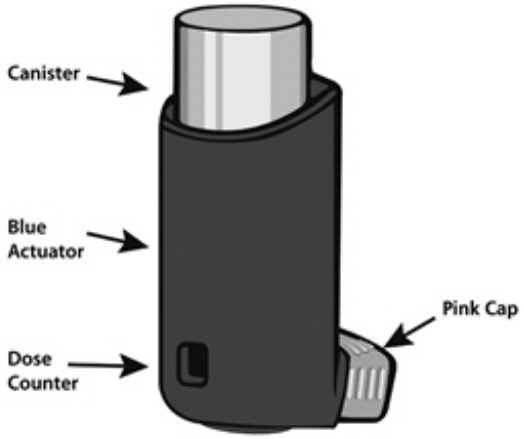


Figure 1

- The inhaler comes with a dose counter located on the plastic actuator **(see Figure 1).** The counter display will show the number of actuations (puffs) of medicine

remaining. The first time you use ASMANEX HFA the dose counter will show **"124"** actuations remaining. Each time you press the canister, a puff of medicine is released and the counter will count down by **1**. The counter will stop counting at **0**.

Important Information:

- Use ASMANEX HFA exactly as your healthcare provider tells you to. Adults may assist children with using ASMANEX HFA as prescribed. Children may use ASMANEX HFA with or without a spacer device.
- **Remove the cap from the mouthpiece of the actuator before using ASMANEX HFA.**
- **Do not remove the canister from the actuator** because:
  - you may not receive the correct amount of medication.
  - the dose counter may not function properly.
  - if you try to insert the canister back into the actuator this may cause the dose counter to count down by 1 and may discharge a puff.
- Use the ASMANEX HFA canister only with the actuator supplied with the product. **Do not** use parts of the ASMANEX HFA inhaler with parts from any other inhalation medicine.

Before using your ASMANEX HFA:

Remove the cap from the mouthpiece of the actuator before using ASMANEX HFA (see Figure 2). Check the mouthpiece for objects before use. Make sure the canister is fully inserted into the actuator.

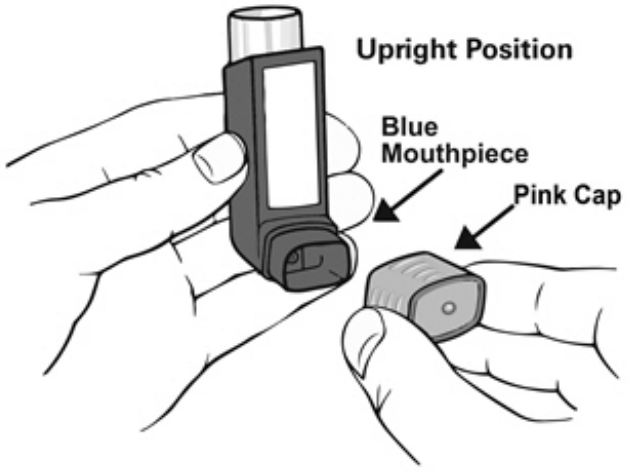


Figure 2

Priming your ASMANEX HFA Inhaler:

Before you use ASMANEX HFA for the first time, you must prime the inhaler.

1. To prime the inhaler, hold it in the upright position away from your face, and press down firmly and fully on the top of the canister until it stops moving in the actuator. Do this **4** times to release a total of **4** actuations (puffs) into the air.
2. Shake the inhaler well before each of the priming actuations. After priming **4** times, the dose counter should read **"120"**.
3. **If you do not use your ASMANEX HFA for more than 5 days, you will need to prime it again before use.**

Using your ASMANEX HFA:

4. Confirm that the strength indicated on the actuator and canister labels matches the prescribed dosage.
5. **Remove the cap from the mouthpiece of the actuator (see Figure 3)**. Check the mouthpiece for objects before use. Make sure the canister is fully inserted into the actuator.
6. Shake the inhaler well before each use.
7. Breathe out as fully as you comfortably can through your mouth. Push out as much air from your lungs as possible. Hold the inhaler in the upright position and place the mouthpiece into your mouth **(see Figure 4)**. Close your lips around the mouthpiece.

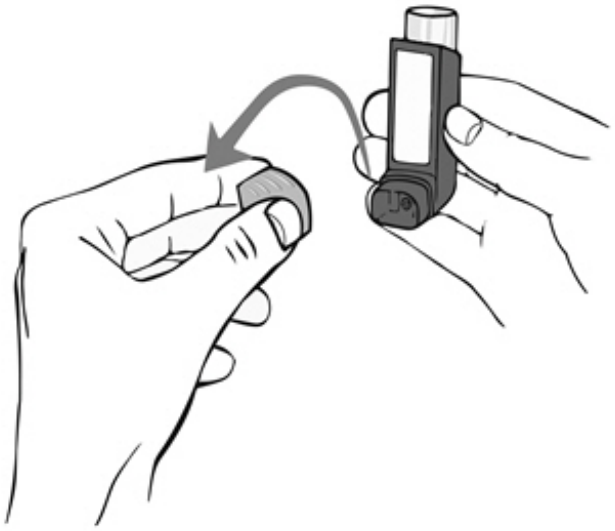


Figure 3

Figure 4

8. Take a deep breath (inhale) in slowly through your mouth. While doing this, press down firmly and fully on the top of the canister until it stops moving in the actuator. Take your finger off the canister.
9. When you have finished breathing in, hold your breath as long as you comfortably can, up to **10 seconds**. Then remove the inhaler from your mouth and breathe out through your nose, while keeping your lips closed.
10. Wait at least **30 seconds** to take your second puff of ASMANEX HFA.
11. Shake the inhaler well again and repeat steps 6 through 8 to take your second puff of ASMANEX HFA.

After using your ASMANEX HFA inhaler:

12. Replace the cap over the mouthpiece right away after use **(see Figure 5)**.

Figure 5

13.After you finish taking ASMANEX HFA (**2** puffs), rinse your mouth with water.

Reading the counter:

- The dose counter identifies the number of inhalations (puffs) left in your inhaler **(see Figure 6)**.
- The counter will count down each time you release a puff of medicine (either when preparing your ASMANEX HFA inhaler for use or when using the medicine).

Figure 6

When to replace your ASMANEX HFA:

- It is important that you pay attention to the number of inhalations (puffs) left in your ASMANEX HFA inhaler by reading the counter.
- When the counter reads **"20"**, you should refill your prescription or ask your healthcare provider if you need a new prescription for ASMANEX HFA.
- Throw away ASMANEX HFA after the counter reaches **"0"**, indicating that you have used the number of actuations on the product label and box. Your inhaler may not feel empty and it may continue to operate, but you will not get the right amount of

medicine if you keep using it.
- Never try to change the numbers on the counter or remove the counter from the actuator.
- Do not use the inhaler after the expiration date.

How to clean your ASMANEX HFA:

The mouthpiece should be cleaned using a dry wipe after every 7 days of use.

Routine cleaning instructions:
- Remove the cap off the mouthpiece. Wipe the inside and outside surfaces of the actuator mouthpiece with a clean, dry, lint-free tissue or cloth. **Do not wash or put any parts of your inhaler in water.** Put the cap back on the mouthpiece after cleaning.
- Do not remove the canister from the actuator.
- Do not attempt to unblock the actuator with a sharp object, such as a pin.

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Manufactured for: Organon LLC, a subsidiary of
ORGANON & Co.,
Jersey City, NJ 07302, USA

Manufactured by: Kindeva Drug Delivery Limited, Loughborough, United Kingdom.
For patent information: www.organon.com/our-solutions/patent/

Revised: 6/2025
usppi-og0887-ao-2506r001

PRINCIPAL DISPLAY PANEL - 100 mcg Canister Carton

NDC 78206-112-01

Asmanex® HFA
(mometasone furoate)
Inhalation Aerosol

100 mcg *per actuation*

For oral inhalation only

Asmanex HFA canister to be used
with Asmanex HFA actuator only.

SHAKE WELL BEFORE USING.

Rx only

120 Metered Actuations
Net Wt. 13g

PRINCIPAL DISPLAY PANEL - 200 mcg Canister Carton

NDC 78206-113-01

Asmanex® HFA
(mometasone furoate)
Inhalation Aerosol

200 mcg *per actuation*

For oral inhalation only

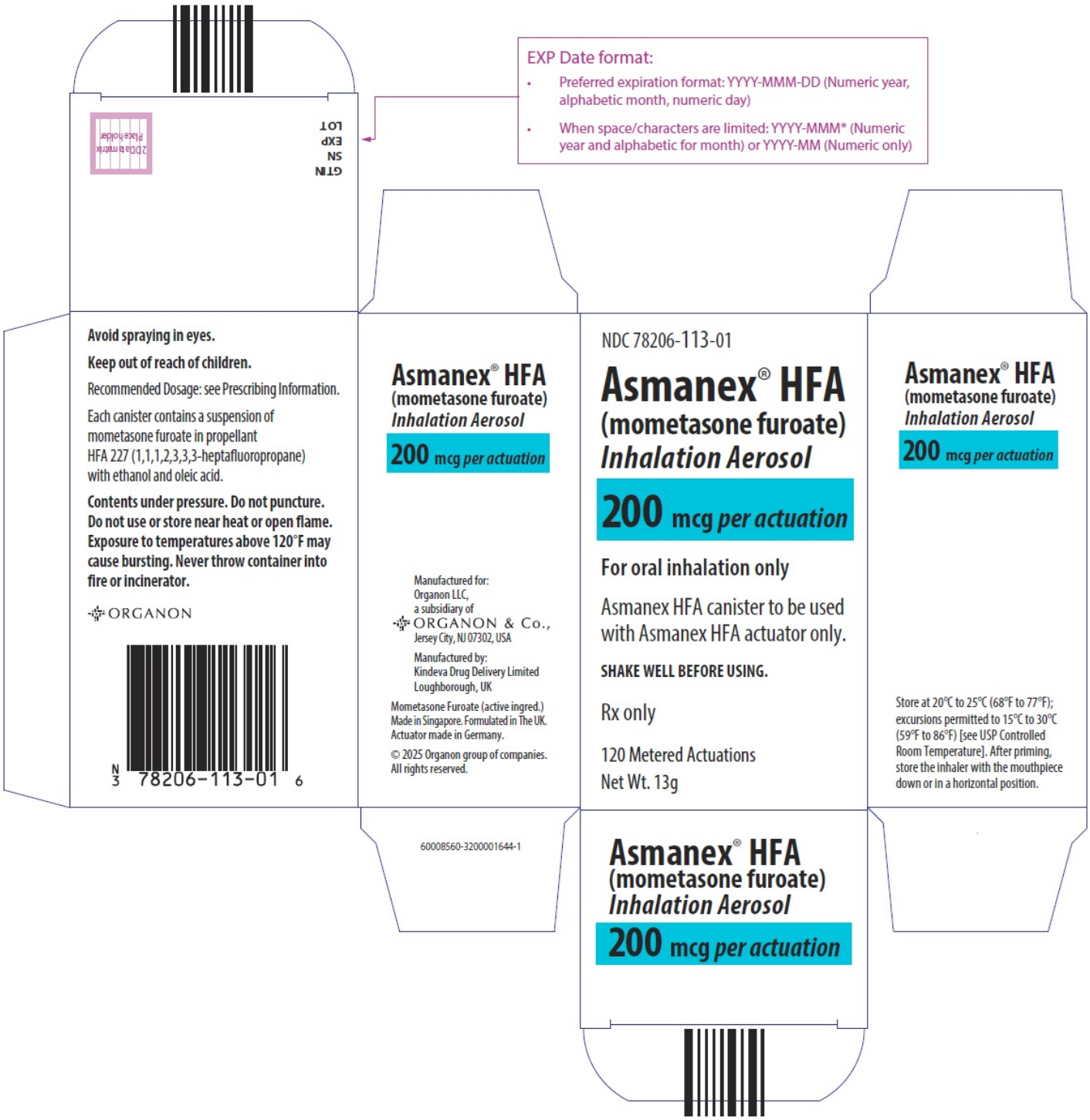
Asmanex HFA canister to be used

with Asmanex HFA actuator only.

SHAKE WELL BEFORE USING.

Rx only

120 Metered Actuations
Net Wt. 13g



PRINCIPAL DISPLAY PANEL - 50 mcg Canister Carton

NDC 78206-111-01

Asmanex® HFA
(mometasone furoate)
Inhalation Aerosol

50 mcg *per actuation*

For oral inhalation only

Asmanex HFA canister to be used with Asmanex HFA actuator only.

SHAKE WELL BEFORE USING.

Rx only

120 Metered Actuations
Net Wt. 13g

ASMANEX HFA

mometasone furoate aerosol

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:78206-112
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
MOMETASONE FUROATE (UNII: 04201GDN4R) (MOMETASONE - UNII:8HR4QJ6DW8)	MOMETASONE FUROATE	100 ug

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
OLEIC ACID (UNII: 2UMI9U37CP)	
APAFLURANE (UNII: R40P36GDK6)	

Product Characteristics

Color	WHITE (White to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78206-112-01	1 in 1 CARTON	06/01/2021	
1		120 in 1 CANISTER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:78206-112-59	1 in 1 CARTON	06/01/2021	
2		120 in 1 CANISTER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205641	06/01/2021	

ASMANEX HFA

mometasone furoate aerosol

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:78206-113
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength

MOMETASONE FUROATE (UNII: 04201GDN4R) (MOMETASONE - UNII:8HR4QJ6DW8)	MOMETASONE FUROATE	200 ug

Inactive Ingredients	
Ingredient Name	**Strength**
ALCOHOL (UNII: 3K9958V90M)	
OLEIC ACID (UNII: 2UMI9U37CP)	
APAFLURANE (UNII: R40P36GDK6)	

Product Characteristics			
Color	WHITE (White to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78206-113-01	1 in 1 CARTON	06/01/2021	
1		120 in 1 CANISTER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:78206-113-59	1 in 1 CARTON	06/01/2021	
2		120 in 1 CANISTER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205641	06/01/2021	

ASMANEX HFA

mometasone furoate aerosol

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:78206-111
Route of Administration	RESPIRATORY (INHALATION)		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
MOMETASONE FUROATE (UNII: 04201GDN4R) (MOMETASONE - UNII:8HR4QJ6DW8)	MOMETASONE FUROATE	50 ug

Inactive Ingredients

Ingredient Name	Strength
ALCOHOL (UNII: 3K9958V90M)	
OLEIC ACID (UNII: 2UMI9U37CP)	
APAFLURANE (UNII: R40P36GDK6)	

Product Characteristics

Color	WHITE (White to off-white)	**Score**	
Shape		**Size**	
Flavor		**Imprint Code**	
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:78206-111-01	1 in 1 CARTON	06/01/2021	
1		120 in 1 CANISTER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		
2	NDC:78206-111-59	1 in 1 CARTON	06/01/2021	
2		120 in 1 CANISTER; Type 2: Prefilled Drug Delivery Device/System (syringe, patch, etc.)		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA205641	06/01/2021	

Labeler - Organon LLC (117494753)

Revised: 1/2026 Organon LLC