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SEREVENT® DISKUS®
(salmeterol xinafoate inhalation powder)

BRIEF SUMMARY

For Oral Inhalation Only
The following is a brief summary only; see full prescribing information for complete product information.

CONTRAINDICATIONS: SEREVENT DISKUS is contraindicated in patients with a history of hypersensitivity to salmeterol or any of its components.

WARNINGS:
IMPORTANT INFORMATION: SEREVENT DISKUS SHOULD NOT BE INITIATED IN PATIENTS WITH SIGNIFICANTLY WORSENING OR ACUTELY DETERIORATING ASTHMA, WHICH MAY BE A LIFE-THREATENING CONDITION. Serious acute respiratory events, including fatalities, have been reported, both in the United States and worldwide, when SEREVENT has been initiated in this situation.

Although it is not possible from these reports to determine whether SEREVENT contributed to these adverse events or simply failed to relieve the deteriorating asthma, the use of SEREVENT DISKUS in this setting is inappropriate.

SEREVENT DISKUS SHOULD NOT BE USED TO TREAT ACUTE SYMPTOMS. It is crucial to inform patients of this and prescribe an inhaled, short-acting $beta_2$-agonist for this purpose as well as warn them that increasing inhaled $beta_2$-agonist use is a signal of deteriorating asthma.

SEREVENT DISKUS IS NOT A SUBSTITUTE FOR INHALED OR ORAL CORTICOSTEROIDS. Corticosteroids should not be stopped or reduced when SEREVENT DISKUS is initiated.

(See PRECAUTIONS: Information for Patients and the PATIENT'S INSTRUCTIONS FOR USE leaflet.)

1. Do Not Introduce SEREVENT DISKUS as a Treatment for Acutely Deteriorating Asthma: SEREVENT DISKUS is intended for the maintenance treatment of asthma (see INDICATIONS AND USAGE section of full prescribing information) and should not be introduced in acutely deteriorating asthma, which is a potentially life-threatening condition. There are no data demonstrating that SEREVENT DISKUS provides greater efficacy than or additional efficacy to inhaled, short-acting $beta_2$-agonists in patients with worsening asthma. Serious acute respiratory events, including fatalities, have been reported, both in the United States and worldwide, in patients receiving SEREVENT. In most cases, these have occurred in patients with severe asthma (e.g., patients with a history of corticosteroid dependence, low pulmonary function, intubation, mechanical ventilation, frequent hospitalizations, or previous life-threatening acute asthma exacerbations) and/or in some patients in whom asthma has been acutely deteriorating (e.g., unresponsive to usual medications; increasing need for inhaled, short-acting $beta_2$-agonists; increasing need for systemic corticosteroids; significant increase in symptoms; recent emergency room visits; sudden or progressive deterioration in pulmonary function). However, they have occurred in a few patients with less severe asthma as well. It was not possible from these reports to determine whether SEREVENT contributed to these events or simply failed to relieve the deteriorating asthma.
2. Do Not Use SEREVENT DISKUS to Treat Acute Symptoms: An inhaled, short-acting $beta_2$-agonist, not SEREVENT DISKUS, should be used to relieve acute asthma symptoms. When prescribing SEREVENT DISKUS, the physician must also provide the patient with an inhaled, short-acting $beta_2$-agonist (e.g., albuterol) for treatment of symptoms that occur acutely, despite regular twice-daily (morning and evening) use of SEREVENT DISKUS.

When beginning treatment with SEREVENT DISKUS, patients who have been taking inhaled, short-acting $beta_2$-agonists on a regular basis (e.g., four times a day) should be instructed to discontinue the regular use of these drugs and use them only for symptomatic relief of acute asthma symptoms (see PRECAUTIONS: Information for Patients).
3. Watch for Increasing Use of Inhaled, Short-Acting $Beta_2$-Agonists, Which Is a Marker of Deteriorating Asthma: Asthma may deteriorate acutely over a period of hours or chronically over several days or longer. If the patient's inhaled, short-acting $beta_2$-agonist becomes less effective or the patient needs more inhalations than usual, this may be a marker of destabilization of asthma. In this setting, the patient requires immediate reevaluation with reassessment of the treatment regimen, giving special consideration to the possible need for corticosteroids. If the patient uses four or more inhalations per day of an inhaled, short-acting $beta_2$-agonist for 2 or more consecutive days, or if more than one canister (200 inhalations per canister) of inhaled, short-acting $beta_2$-agonist is used in an 8-week period in conjunction with SEREVENT DISKUS, then the patient should consult the physician for reevaluation. **Increasing the daily dosage of SEREVENT DISKUS in this situation is not appropriate. SEREVENT DISKUS should not be used more frequently than twice daily (morning and evening) at the recommended dose of one inhalation.**
4. Do Not Use SEREVENT DISKUS as a Substitute for Oral or Inhaled Corticosteroids: The use of beta-adrenergic agonist bronchodilators alone may not be adequate to control asthma in many patients. Early consideration should be given to adding anti-inflammatory agents, e.g., corticosteroids. There are no data demonstrating that SEREVENT DISKUS has a clinical anti-inflammatory effect and could be expected to take the place of, or reduce the dose of, corticosteroids. Patients who already require oral or inhaled corticosteroids for treatment of asthma should be continued on a suitable dose to maintain clinical stability even if they feel better as a result of initiating SEREVENT DISKUS. Any change in corticosteroid dosage should be made ONLY after clinical evaluation (see PRECAUTIONS: Information for Patients).
5. Do Not Exceed Recommended Dosage: As with other inhaled $beta_2$-adrenergic drugs, SEREVENT DISKUS should not be used more often or at higher doses than recommended. Fatalities have been reported in association with excessive use of inhaled sympathomimetic drugs. Large doses of inhaled or oral salmeterol (12 to 20 times the recommended dose) have been associated with clinically significant prolongation of the QT_c interval, which has the potential for producing ventricular arrhythmias.
6. Paradoxical Bronchospasm: Inhalation of salmeterol xinafoate can produce paradoxical bronchospasm, which may be life threatening. If paradoxical bronchospasm occurs, SEREVENT DISKUS should be discontinued immediately and alternative therapy instituted.
7. Immediate Hypersensitivity Reactions: Immediate hypersensitivity reactions may occur after administration of SEREVENT DISKUS, as demonstrated by cases of urticaria, angioedema, rash, and bronchospasm.
8. Upper Airway Symptoms: Symptoms of laryngeal spasm, irritation, or swelling, such as stridor and choking, have been reported in patients receiving SEREVENT DISKUS.

SEREVENT DISKUS, like all other beta-adrenergic agonists, can produce a clinically significant cardiovascular effect in some patients as measured by pulse rate, blood pressure, and/or symptoms. Although such effects are uncommon after administration of SEREVENT DISKUS at recommended doses, if they occur, the drug may need to be discontinued. In addition, beta-agonists have been reported to produce electrocardiogram (ECG) changes, such as flattening of the T wave, prolongation of the QT_c interval, and ST segment depression. The clinical significance of these findings is unknown. Therefore, SEREVENT DISKUS, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension.

PRECAUTIONS:
General: 1. Cardiovascular and Other Effects: No effect on the cardiovascular system is usually seen after the administration of inhaled salmeterol at recommended doses, but the cardiovascular and central nervous system effects seen with all sympathomimetic drugs (e.g., increased blood pressure, heart rate, excitement) can occur after use of salmeterol and may require discontinuation of the drug. Salmeterol, like all sympathomimetic amines, should be used with caution in patients with cardiovascular disorders, especially coronary insufficiency, cardiac arrhythmias, and hypertension; in patients with convulsive disorders or thyrotoxicosis; and in patients who are unusually responsive to sympathomimetic amines.

As has been described with other beta-adrenergic agonist bronchodilators, clinically significant changes in systolic and/or diastolic blood pressure, pulse rate, and electrocardiograms have been seen infrequently in individual patients in controlled clinical studies with salmeterol.

2. Metabolic Effects: Doses of the related $beta_2$-adrenoceptor agonist albuterol, when administered intravenously, have been reported to aggravate preexisting diabetes mellitus and ketoacidosis. No effects on glucose have been seen with SEREVENT DISKUS at recommended doses. Beta-adrenergic agonist medications may produce significant hypokalemia in some patients, possibly through intracellular shunting, which has the potential to produce adverse cardiovascular effects. The decrease in serum potassium is usually transient, not requiring supplementation.

Clinically significant changes in blood glucose and/or serum potassium were seen rarely during clinical studies with long-term administration of SEREVENT DISKUS at recommended doses.

Information for Patients: See illustrated PATIENT'S INSTRUCTIONS FOR USE.

It is important that patients understand how to use the DISKUS inhalation device appropriately and how it should be used in relation to other asthma medications they are taking. Patients should be given the following information:
1. The action of SEREVENT DISKUS may last up to 12 hours or longer. The recommended dosage (one inhalation twice daily, morning and evening) should not be exceeded.
2. SEREVENT DISKUS is not meant to relieve acute asthma symptoms and extra doses should not be used for that purpose. Acute symptoms should be treated with an inhaled, short-acting $beta_2$-agonist such as albuterol (the physician should provide the patient with such medication and instruct the patient in how it should be used).
3. • When used for the treatment of exercise-induced bronchospasm (EIB), one inhalation of SEREVENT DISKUS inhalation powder should be taken 30 minutes before exercise.
• Additional doses of SEREVENT should not be used for 12 hours.
• Patients who are receiving SEREVENT DISKUS inhalation powder twice daily should not use additional SEREVENT for prevention of EIB.
4. The physician should be notified immediately if any of the following situations occur, which may be a sign of seriously worsening asthma:
• Decreasing effectiveness of inhaled, short-acting $beta_2$-agonists
• Need for more inhalations than usual of inhaled, short-acting $beta_2$-agonists
• Use of four or more inhalations per day of a short-acting $beta_2$-agonist for 2 or more days consecutively
• Use of more than one canister of an inhaled, short-acting $beta_2$-agonist in an 8-week period (i.e., canister with 200 inhalations)
5. SEREVENT DISKUS should not be used as a substitute for oral or inhaled corticosteroids. The dosage of these medications should not be changed and they should not be stopped without consulting the physician, even if the patient feels better after initiating treatment with SEREVENT DISKUS.
6. Patients should be cautioned regarding common adverse cardiovascular effects, such as palpitations, chest pain, rapid heart rate, tremor, or nervousness.
7. In patients receiving SEREVENT DISKUS, other inhaled medications should be used only as directed by the physician.
8. SEREVENT DISKUS should not be used with a spacer.
9. If you are pregnant or nursing, contact your physician about use of SEREVENT DISKUS.
10. Effective and safe use of the DISKUS device includes an understanding of the way that it should be used:
• Never exhale into the DISKUS device.
• Always activate and use the DISKUS device in a level, horizontal position.
• Never wash the mouthpiece or any part of the DISKUS device. KEEP IT DRY.

Drug Interactions: ***Short-Acting Beta-Agonists:*** In the two 12-week, repetitive-dose adolescent and adult clinical trials (n = 149), the mean daily need for additional $beta_2$-agonist use in patients using salmeterol inhalation powder was approximately 1½ inhalations per day. Twenty-six percent of the patients in these trials used between 8 and 24 inhalations of short-acting beta-agonist per day on one or more occasions. Nine percent of the patients in these trials averaged over 4 inhalations per day over the course of the 12-week trials. No observed increase in frequency of cardiovascular events was noted among the 3 patients who used an average of 8 to 11 inhalations per day; however, the safety of concomitant use of more than 8 inhalations per day of short-acting $beta_2$-agonist with salmeterol inhalation powder has not been established. In 29 patients who experienced worsening of asthma while receiving salmeterol inhalation powder during these trials, albuterol therapy administered via either nebulizer or inhalation aerosol (one dose in most cases) led to improvement in FEV_1 and no increase in occurrence of cardiovascular adverse events.

Monoamine Oxidase Inhibitors and Tricyclic Antidepressants: Salmeterol should be administered with extreme caution to patients being treated with monoamine oxidase inhibitors or tricyclic antidepressants, or within 2 weeks of discontinuation of such agents, because the action of salmeterol on the vascular system may be potentiated by these agents.

Corticosteroids and Cromoglycate: In clinical trials, inhaled corticosteroids and/or inhaled cromolyn sodium did not alter the safety profile of SEREVENT when administered concurrently.

Methylxanthines: The concurrent use of intravenously or orally administered methylxanthines (e.g., aminophylline, theophylline) by patients receiving SEREVENT has not been completely evaluated. In one clinical asthma trial, 87 patients receiving SEREVENT Inhalation Aerosol 42 mcg twice daily concurrently with a theophylline product had adverse event rates similar to those in 71 patients receiving SEREVENT Inhalation Aerosol without theophylline. Resting heart rates were slightly higher in the patients on theophylline but were little affected by therapy with SEREVENT Inhalation Aerosol.

Beta-adrenergic receptor blocking agents not only block the pulmonary effect of beta-agonists, such as SEREVENT DISKUS, but may produce severe bronchospasm in asthmatic patients. Therefore, patients with asthma should not normally be treated with beta-blockers. However, under certain circumstances, e.g., as prophylaxis after myocardial infarction, there may be no acceptable alternatives to the use of beta-adrenergic blocking agents in patients with asthma. In this setting, cardioselective beta-blockers could be considered, although they should be administered with caution.

The ECG changes and/or hypokalemia that may result from the administration of nonpotassium-sparing diuretics (such as loop or thiazide diuretics) can be acutely worsened by beta-agonists, especially when the recommended dose of the beta-agonist is exceeded. Although the clinical significance of these effects is not known, caution is advised in the coadministration of beta-agonists with nonpotassium-sparing diuretics.

Carcinogenesis, Mutagenesis, Impairment of Fertility: In an 18-month carcinogenicity study in CD-mice, salmeterol xinafoate at oral doses of 1.4 mg/kg and above (approximately 20 times the maximum recommended daily inhalation dose in adults and children based on comparison of the area under the plasma concentration versus time curves [AUCs]) caused a dose-related increase in the incidence of smooth muscle hyperplasia, cystic glandular hyperplasia, leiomyomas of the uterus, and cysts in the ovaries. The incidence of leiomyosarcomas was not statistically significant. No tumors were seen at 0.2 mg/kg (approximately 3 times the maximum recommended daily inhalation doses in adults and children based on comparison of the AUCs).

In a 24-month oral and inhalation carcinogenicity study in Sprague Dawley rats, salmeterol caused a dose-related increase in the incidence of mesovarian leiomyomas and ovarian cysts at doses of 0.68 mg/kg and above (approximately 60 times the maximum recommended daily inhalation dose in adults and approximately 30 times the maximum recommended daily inhalation dose in children on a mg/m^2 basis). No tumors were seen at 0.21 mg/kg (approximately 20 times the maximum recommended daily inhalation dose in adults and approximately 9 times the maximum recommended daily inhalation dose in children on a mg/m^2 basis). These findings in rodents are similar to those reported previously for other beta-adrenergic agonist drugs. The relevance of these findings to human use is unknown.

Salmeterol produced no detectable or reproducible increases in microbial and mammalian gene mutation in vitro. No clastogenic activity occurred in vitro in human lymphocytes or in vivo in a rat micronucleus test. No effects on fertility were identified in male and female rats treated with salmeterol at oral doses up to 2 mg/kg (approximately 170 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis).

Pregnancy: ***Teratogenic Effects:*** Pregnancy Category C. No teratogenic effects occurred in rats at oral doses up to 2 mg/kg (approximately 170 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis). In pregnant Dutch rabbits administered oral doses of 1 mg/kg and above (approximately 50 times the maximum recommended daily inhalation dose in adults based on comparison of the AUCs), salmeterol exhibited fetal toxic effects characteristically resulting from beta-adrenoceptor stimulation. These included precocious eyelid openings, cleft palate, sternebral fusion, limb and paw flexures, and delayed ossification of the frontal cranial bones. No significant effects occurred at an oral dose of 0.6 mg/kg(approximately 20 times the maximum recommended daily inhalation dose in adults based on comparison of the AUCs).

New Zealand White rabbits were less sensitive since only delayed ossification of the frontal bones was seen at an oral dose of 10 mg/kg (approximately 1700 times the maximum recommended daily inhalation dose in adults on a mg/m^2 basis). Extensive use of other beta-agonists has provided no evidence that these class effects in animals are relevant to their use in humans. There are no adequate and well controlled studies with SEREVENT DISKUS in pregnant women. SEREVENT DISKUS should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Use in Labor and Delivery: There are no well controlled human studies that have investigated effects of salmeterol on preterm labor or labor at term. Because of the potential for beta-agonist interference with uterine contractility, use of SEREVENT DISKUS for relief of bronchospasm during labor should be restricted to those patients in whom the benefits clearly outweigh the risks.

Nursing Mothers: Plasma levels of salmeterol after inhaled therapeutic doses are very low. In rats, salmeterol xinafoate is excreted in the milk. However, since there are no data from controlled trials on the use of SEREVENT by nursing mothers, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother. Caution should be exercised when salmeterol xinafoate is administered to a nursing woman.

Pediatric Use: The safety and efficacy of salmeterol inhalation powder has been evaluated in over 2500 patients aged 4 to 11 years with asthma, 346 of whom were administered salmeterol inhalation powder for 1 year. Based on available data, no adjustment of salmeterol dosage in pediatric patients is warranted for either asthma or EIB (see DOSAGE AND ADMINISTRATION section of full prescribing information).

In two randomized, double-blind, controlled clinical trials of 12 weeks' duration, salmeterol 50-mcg powder was administered to 211 pediatric asthma patients who did and who did not receive concurrent inhaled corticosteroids. The efficacy of salmeterol inhalation powder was demonstrated over the 12-week treatment period with respect to peak expiratory flow and FEV_1. Salmeterol inhalation powder was effective in demographic subgroups (gender and age) of the population. Salmeterol was effective when coadministered with other inhaled asthma medications, such as short-acting bronchodilators and inhaled corticosteroids. Salmeterol inhalation powder was well tolerated in the pediatric population, and there were no safety issues identified specific to the administration of salmeterol inhalation powder to pediatric patients.

In two randomized studies in children 4 to 11 years old with asthma and EIB, a single 50-mcg dose of salmeterol inhalation powder prevented EIB when dosed 30 minutes prior to exercise, with protection lasting up to 11.5 hours in repeat testing following this single dose in many patients.

Geriatric Use: Of the total number of patients who received salmeterol inhalation powder in adolescent and adult chronic dosing clinical trials, 209 were 65 years of age and older. No apparent differences in the efficacy and safety of SEREVENT inhalation powder were observed when geriatric patients were compared with younger patients in clinical trials. As with other $beta_2$-agonists, however, special caution should be observed when using SEREVENT inhalation powder in geriatric patients who have concomitant cardiovascular disease that could be adversely affected by this class of drug. Based on available data, no adjustment of salmeterol dosage in geriatric patients is warranted.

ADVERSE REACTIONS: Adverse reactions to salmeterol are similar in nature to reactions to other selective $beta_2$-adrenoceptor agonists, i.e., tachycardia; palpitations; immediate hypersensitivity reactions, including urticaria, angioedema, rash, bronchospasm (see WARNINGS); headache; tremor; nervousness; and paradoxical bronchospasm (see WARNINGS).

Two multicenter, 12-week, controlled studies have evaluated twice-daily doses of SEREVENT inhalation powder in patients 12 years of age and older with asthma. The following table reports the incidence of adverse events in these two studies.

Adverse Experience Incidence in Two Large 12-Week Adolescent and Adult Clinical Trials

	Percent of Patients		
Adverse Event Type	Placebo n = 152	SEREVENT Inhalation Powder 50 mcg twice daily n = 149	Albuterol Inhalation Aerosol 180 mcg four times daily n = 150
Ear, nose, and throat			
Nasal/sinus congestion, pallor	6	9	8
Rhinitis	4	5	4
Neurological			
Headache	9	13	12
Respiratory			
Asthma	1	3	<1
Tracheitis/bronchitis	4	7	3
Influenza	2	5	5

The table above includes all events (whether considered drug-related or nondrug-related by the investigator) that occurred at a rate of ≥3% in the SEREVENT inhalation powder treatment group and were more common in the SEREVENT inhalation powder group than in the placebo group.

Pharyngitis, sinusitis, upper respiratory tract infection, and cough occurred at ≥3% but were more common in the placebo group. However, throat irritation has been described at rates exceeding that of placebo in other controlled clinical trials. Other events occurring in the SEREVENT inhalation powder group at a frequency of 1% to 3% and at a greater rate than in placebo were as follows:

Ear, Nose, and Throat: Sinus headache.
Gastrointestinal: Nausea.
Mouth and Teeth: Oral mucosal abnormality.
Musculoskeletal: Pain in joint.
Neurological: Sleep disturbance, paresthesia.
Skin: Contact dermatitis, eczema.
Miscellaneous: Localized aches and pains, pyrexia of unknown origin.

Two multicenter, 12-week, controlled studies have evaluated twice-daily doses of salmeterol inhalation powder in patients aged 4 to 11 years with asthma. The following table includes all events (whether considered drug-related or nondrug-related by the investigator) that occurred at a rate of ≥3% in the SEREVENT inhalation powder treatment group and were more common in the SEREVENT inhalation powder group than in the placebo group.

Adverse Experience Incidence in Two Large 12-Week Pediatric Clinical Trials

	Percent of Patients		
Adverse Event Type	Placebo n = 215	SEREVENT Inhalation Powder 50 mcg twice daily n = 211	Albuterol Powder 200 mcg four times daily n = 115
Ear, nose, and throat			
Ear signs and symptoms	3	4	9
Pharyngitis	3	6	3
Neurological			
Headache	14	17	20
Respiratory			
Asthma	2	4	<1
Skin			
Skin rashes	3	4	2
Urticaria	0	3	2

The following events were reported at an incidence of 1% to 2% (3 to 4 patients) in the salmeterol group and with a higher incidence than in the albuterol and placebo groups: gastrointestinal signs and symptoms, lower respiratory signs and symptoms, photodermatitis, and arthralgia and articular rheumatism.

Observed During Clinical Practice: In extensive United States and worldwide postmarketing experience with SEREVENT, serious exacerbations of asthma, including some that have been fatal, have been reported. In most cases, these have occurred in patients with severe asthma and/or in some patients in whom asthma has been acutely deteriorating (see WARNINGS no. 1), but they have also occurred in a few patients with less severe asthma as well. It was not possible from these reports to determine whether SEREVENT contributed to these events or simply failed to relieve the deteriorating asthma.

The following events have also been identified during postapproval use of SEREVENT in clinical practice. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made. These events have been chosen for inclusion due to a combination of their seriousness, frequency of reporting, or potential causal connection to SEREVENT.

Respiratory: Reports of upper airway symptoms of laryngeal spasm, irritation, or swelling such as stridor or choking.
Cardiovascular: Cases of hypertension, arrhythmias (including atrial fibrillation, supraventricular tachycardia, extrasystoles), and anaphylaxis.

OVERDOSAGE: The expected signs and symptoms with overdosage of SEREVENT DISKUS are those of excessive beta-adrenergic stimulation and/or occurrence or exaggeration of any of the signs and symptoms listed under ADVERSE REACTIONS, e.g., seizures, angina, hypertension or hypotension, tachycardia with rates up to 200 beats/min, arrhythmias, nervousness, headache, tremor, muscle cramps, dry mouth, palpitation, nausea, dizziness, fatigue, malaise, and insomnia. Overdosage with salmeterol may be expected to result in exaggeration of the pharmacologic adverse effects associated with beta-adrenoceptor agonists, including tachycardia and/or arrhythmia, tremor, headache, and muscle cramps. Overdosage with salmeterol can lead to clinically significant prolongation of the QT_c interval, which can produce ventricular arrhythmias. Other signs of overdosage may include hypokalemia and hyperglycemia.

As with all sympathomimetic medications, cardiac arrest and even death may be associated with abuse of SEREVENT DISKUS.

Treatment consists of discontinuation of SEREVENT DISKUS together with appropriate symptomatic therapy. The judicious use of a cardioselective beta-receptor blocker may be considered, bearing in mind that such medication can produce bronchospasm. There is insufficient evidence to determine if dialysis is beneficial for overdosage of SEREVENT DISKUS. Cardiac monitoring is recommended in cases of overdosage.

No deaths were seen in rats at an inhalation dose of 2.9 mg/kg (approximately 250 times the maximum recommended daily inhalation dose in adults and approximately 120 times the maximum recommended daily inhalation dose in children on a mg/m^2 basis) and in dogs at an inhalation dose of 0.7 mg/kg (approximately 200 times the maximum recommended daily inhalation dose in adults and approximately 95 times the maximum recommended daily inhalation dose in children on a mg/m^2 basis). By the oral route, no deaths occurred in mice at 150 mg/kg (approximately 6500 times the maximum recommended daily inhalation dose in adults and approximately 3100 times the maximum recommended daily inhalation dose in children on a mg/m^2 basis) and in rats at 1000 mg/kg (approximately 86,000 times the maximum recommended daily inhalation dose in adults and approximately 41,000 times the maximum recommended daily inhalation dose in children on a mg/m^2 basis).

Rx only

GlaxoWellcome

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