Antitussive Power

- The only 12-hour liquid hydrocodone
- No middle-of-the-night or mid-day dosing
- Contains no iodinated glycerol
- One of the most economical prescription antitussives
- The most frequently prescribed liquid hydrocodone

Please see following page for Full Prescribing Information, including complete precautionary information.

TUSSIONEX is contraindicated in the presence of known allergy to hydrocodone or chlorpheniramine. The most common adverse reactions are sedation, drowsiness, and mental clouding, which may impair the mental and/or physical abilities required for potentially hazardous tasks, such as driving a car or operating machinery.

TUSSIONEX® (hydrocodone polisiloxane or chlorpheniramine polisiloxane)

Extended-Release Suspension

Each teaspoonful (5 mL) provides the equivalent of 10 mg hydrocodone bitartrate and 8 mg chlorpheniramine maleate.
**Tussionex®**

**Pennkinetic®**

(hydrocodone polisiloxane)

**[Warning] May be habit forming and chlorpheniramine polisiloxane**

**Extended-Release Suspension**

**DESCRIPTION:** Each teaspoonful (5 mL) of Tussionex® Pennkinetic® Extended-Release Suspension contains hydrocodone polisiloxane equivalent to 10 mg of hydrocodone bitartrate. (Warning: May be habit forming) and chlorpheniramine polisiloxane equivalent to 8 mg of chlorpheniramine maleate. Tussionex® Pennkinetic® Extended-Release Suspension may exhibit an additive CNS depression when combined therapy is contemplated. Dose reduction is recommended if concurrent use with hydrocodone preparations is required.

Hydrocodone is centrally acting narcotic antitussive. Chlorpheniramine is a phenothiazine derivative. Tussionex® Pennkinetic® Extended-Release Suspension is for oral use only.

**INDICATIONS**

As with all narcotics, Tussionex® Pennkinetic® Extended-Release Suspension may produce marked drowsiness and impair the mental and physical abilities required for the performance of potentially hazardous tasks such as driving a car or operating machinery. Therefore, Tussionex® Pennkinetic® Extended-Release Suspension must not be diluted with fluids or mixed with other drugs as this may alter the level of absorption and change the therapeutic action, possibly increasing the toxicity. Keep out of the reach of children.

**CONTRAINDICATIONS:**

Cough Reflex: Hydrocode suppresses the cough reflex, as with all narcotics, caution should be exercised when Tussionex® Pennkinetic® Extended-Release Suspension is used postoperatively, and in patients with a history of productive asthma.

**Drug Interactions:** Patients receiving narcotics, antihistamines, antipsychotics, antianxiety agents or CNS depressants, including alcohol, concomitantly with Tussionex® Pennkinetic® Extended-Release Suspension may exhibit excessive CNS depression. When combined therapy is contemplated, the dose of one or both agents should be reduced.

**NURSING AND PREGNANCY:** Nursing Mothers: It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk and because of the potential for serious adverse reactions in nursing infants from Tussionex® Pennkinetic® Extended-Release Suspension, a decision should be made before prescribing a drug, taking into account the importance of the drug to the mother.

**ADVERSE REACTIONS:** CNS: Sedation, drowsiness, mental clouding, forgetfulness, impaired mental and physical performance, dizziness, headache, hallucinations, nervousness, changes in behavior.

**Gastrointestinal System:** Nausea, vomiting, diarrhea.

**Respiratory System:** Dryness of the pharynx, occasional tightness of the chest, and increased respiratory rate.

**Skin:** Urticaria, rash, pruritus.

**Laboratory Tests:** Hyperglycemia may be increased.

**Breastfeeding: Use Tussionex® Pennkinetic® Extended-Release Suspension in breastfeeding women with caution, as studies have not been conducted.

**DOSE AND ADMINISTRATION:**

Adults: 300 mg daily. The dose may be increased to 600 mg daily if necessary.

Children: 300 mg daily. The dose may be increased to 600 mg daily if necessary.

**PRECAUTIONS:** General. Caution is advised when prescribing this drug to patients with a history of restrictive asthma or chronic obstructive pulmonary disease. Caution should be exercised when administering Tussionex® Pennkinetic® Extended-Release Suspension to children with other CNS depressants such as antihistamines, sedatives, hypnotics, or narcotics. Caution is also advised when administering Tussionex® Pennkinetic® Extended-Release Suspension to patients with concomitant use of anxiolytics, antipsychotics, or other CNS depressants.

**Special Risk Patients:** As with any narcotic agent, Tussionex® Pennkinetic® Extended-Release Suspension should be used with caution in elderly or debilitated patients and those with severe or unstable renal or hepatic disease. In addition, patients with prostatic hypertrophy, edema, or bladder neck obstruction should be monitored carefully. The usual precautions should be observed and the possibility of respiratory depression should be kept in mind.
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In Reply
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In Reply
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All articles published, including editorials, letters, and book reviews, represent the opinions of the authors and do not reflect the policy of the American Medical Association, the Editorial Board, or the institution with which the author is affiliated, unless this is clearly specified.
Give allergic noses relief for itchy eyes due to seasonal allergic conjunctivitis.

When seasonal allergies strike, it's not just the nose they ambush. The eyes are fair game, too. In fact, 8 out of 10 patients with allergic noses also suffer from itchy eyes due to seasonal allergic conjunctivitis. Stop the itch with ACULAR® Solution.

In a recent survey (n=272), the vast majority of responding patients confirmed that ACULAR® stopped their ocular itching quickly and effectively. Plus, ACULAR® has a favorable safety profile. There are no steroid-like side effects that can alter intraocular pressure, and no decongestant-like side effects, i.e., no risk to patients with narrow chamber angles.

So help rescue eyes from itching with ACULAR®, the #1 prescribed ophthalmic preparation for the #1 patient complaint of seasonal allergic conjunctivitis — ocular itch. Because annoying antigens prey on more than just the nose.

The most frequently reported adverse events have been transient stinging and burning on instillation (approximately 40%). Not for use while wearing soft contact lenses.

ACULAR®
(ketorolac tromethamine) 0.5%
Sterile Ophthalmic Solution

Please see adjacent page for prescribing information.
ACULAR®
(ketorolac tromethamine) 0.5%
Sterile Ophthalmic Solution

INDICATIONS AND USAGE
ACULAR® ophthalmic solution is indicated for the relief of ocular itching due to seasonal allergic conjunctivitis.

CONTRAINDICATIONS
ACULAR® ophthalmic solution is contraindicated in patients while wearing soft contact lenses and in patients with previously demonstrated hypersensitivity to any of the ingredients in the formulation.

WARNINGS
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetic acid derivatives, and other nonsteroidal anti-inflammatory agents. Therefore, caution should be used when treating individuals who have previously exhibited sensitivities to these drugs.

With some nonsteroidal anti-inflammatory drugs, there exists the potential for increased bleeding time due to interference with thrombocyte aggregation. There have been reports that ocularly applied nonsteroidal anti-inflammatory drugs may cause increased bleeding of ocular tissues (including hemorhasa) in conjunction with ocular surgery.

PRECAUTIONS
General: It is recommended that ACULAR® ophthalmic solution be used with caution in patients with known bleeding tendencies or who are receiving other medications which may prolong bleeding time.

Carcinogenesis, Mutagenesis, and Impairment of Fertility: An 18-month study in mice at oral doses of ketorolac tromethamine equal to the parenteral MRHD (Maximum Recommended Human Dose) and a 24-month study in rats at oral doses 2.5 times the parenteral MRHD, showed no evidence of tumorigenicity. Ketorolac tromethamine was not mutagenic in Ames test, unscheduled DNA synthesis and repair, and in forward mutation assays. Ketorolac did not cause chromosome breakage in the in vivo mouse micronucleus assay. At 1500 μg/mL (approximately 1000 times the average human plasma levels) and at higher concentrations ketorolac tromethamine increased the incidence of chromosomal aberrations in Chinese hamster ovarian cells. Impairment of fertility did not occur in male or female rats at oral doses of 9 mg/kg (53.1 mg/m²) and 16 mg/kg (94.4 mg/m²) respectively.

Pregnancy: Pregnancy Category C. Reproduction studies have been performed in rabbits, using daily oral doses at 3.6 mg/kg (42.35 mg/m²) and in rats at 10 mg/kg (59 mg/m²) during organogenesis. Results of these studies did not reveal evidence of teratogenicity to the fetus. Oral doses of ketorolac tromethamine at 1.5 mg/kg (8.8 mg/m²), which was half of the human oral exposure, administered after gestation day 17 caused dystocia and higher pup mortality in rats. There are no adequate and well-controlled studies in pregnant women. Ketorolac tromethamine should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers: Caution should be exercised when ACULAR® is administered to a nursing woman.

Pediatric Use: Safety and efficacy in children have not been established.

ADVERSE REACTIONS
In patients with allergic conjunctivitis, the most frequent adverse events reported with the use of ACULAR® ophthalmic solution have been transient stinging and burning on instillation. These events were reported by approximately 40% of patients treated with ACULAR® ophthalmic solution. In all development studies conducted, other adverse events reported during treatment with ACULAR® include ocular irritation (3%), allergic reactions (3%), superficial ocular infections (0.5%) and superficial keratitis (1%).

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Teenagers die hard. Their youth and power and beauty hang so—though they will never lead the pack nor graduate. Their feet will still beat to rap songs and rock songs as they flail at life, flash then dim like stars—their idols; and their cavities fill and their blood counts jump and their muscles fail and their culverts stop forever. Then most fall silent, have lost the voice to scream: Why me, why me? into the waiting air. But puberty and death don’t lie like lovers together. And there are some who hang there, some rebels, mutinous, hot, and high on ramparts: See this one: grunting her last gasp behind her lipstick gash behind her O2 mask, her painted fingerpoints entwining flares of light within her boyfriend’s fingers. And this one, who won’t die, won’t die: bleeding, decaying, defying, demanding one more of our experiments in renewing vital things.

John Graham-Pole, MD, MRCP
University of Florida
College of Medicine
Gainesville
AQ Comfort and QD Convenience...

Just One Nasal Steroid Has Both:

NEW FLONASE™
(fluticasone propionate)

- A first-line therapy for management of seasonal and perennial allergic rhinitis in patients 12 years and older – not indicated for nonallergic rhinitis.

- Relief of nasal symptoms may begin within 12 hours.

- Maximum benefit may take several days. Onset of action and degree of relief may vary in individual patients.

- Effectiveness depends on regular use.

- Side effects occurring at >1% (causal relationship possible) included epistaxis and nasal burning (3% to 6%) and nasal irritation, headache, and pharyngitis (1% to 3%).

Please consult Brief Summary of Prescribing Information on adjacent page.

Focused Relief for Allergic Rhinitis...

NEW FLONASE™
(fluticasone propionate)

The Aqueous/Once-a-Day ANTI-RHINITIC™

NASAL SPRAY, 0.05% QD AQ
**Flonase™** (Fluticasone Propionate) Nasal Spray, 0.05%

**INDICATIONS:** Flonase Nasal Spray is contraindicated in patients with a hypersensitivity to any of its components.

**WARNINGS:** The replacement of a systemic glucocorticoid with a topical glucocorticoid can be accompanied by signs of adrenal insufficiency, and in addition some patients may experience symptoms of withdrawal, e.g., fluid and/or muscular pain, lassitude, and depression. Patients previously treated for prolonged periods with systemic glucocorticoids and transferred to topical glucocorticoids should be cautions for the potential for adrenal insufficiency in response to stress. In these patients who have asthma or other clinical conditions requiring long-term systemic glucocorticoid treatment, too rapid a decrease in systemic glucocorticoid use may cause a severe exacerbation of their symptoms.

The use of Flonase™ Nasal Spray with alternate-day systemic prednisone could increase the likelihood of hypothalamic-pituitary-adrenal (HPA) axis suppression compared with a therapeutic dose of either alone. Therefore, Flonase Nasal Spray should be used with caution in patients already receiving alternate-day prednisone treatment for any disease. In addition, the concomitant use of Flonase Nasal Spray with other inhaled glucocorticoids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA axis.

**PRECAUTIONS:**

**General:** Inhaled immediate hypersensitivity reactions or contact dermatitis may occur after the intranasal administration of fluticasone propionate. Rare instances of wheezing, nasal septum perforation, catarracts, glaucoma, and increased intracocular pressure have been reported following the intranasal application of glucocorticoids.

Use of excessive doses of glucocorticoids may lead to signs or symptoms of hypercorticism, suppression of HPA function, and/or suppression of growth in children and teenagers. Kneemistry studies in asthmatic children on long-term inhaled glucocorticoids showed statistically significant decreases in the rates of growth improvement in children with asthma. The relationship between short-term changes in lower leg growth and long-term effects on growth is unclear at this time. Physicians should closely follow the growth of adolescents taking glucocorticoids, by any route, and weigh the benefits of glucocorticoid therapy against the possibility of growth suppression if an adolescent's growth appears slowed.

Although systemic effects have been minimal with recommended doses of Flonase™ Nasal Spray, potential risk increases with larger doses. Therefore, larger than recommended doses of Flonase Nasal Spray should be avoided.

When used at larger doses, systemic glucocorticoid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, the dosage of Flonase Nasal Spray should be discontinued slowly and simultaneously with accepted procedures for discontinuing oral glucocorticoids.

In clinical studies with fluticasone propionate administered intranasally, the development of localized infections of the nose and pharynx with Candida albicans has occurred rarely. When such an infection develops, it may require treatment with appropriate local therapy and discontinuation of treatment with Flonase Nasal Spray. Patients using Flonase Nasal Spray over several months or longer should be examined periodically for evidence of Candida infection or other signs of adverse effects on the nasal mucosa.

**OVERDOSAGE:** Flonase Nasal Spray should be used with caution if at all, in patients with active or quiescent herpetic infections; untreated fungal, bacterial, or systemic viral infections; or ulcerative herpes simplex.

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

**Information for Patients:**
- **Patients being treated with Flonase Nasal Spray should receive the following information:**
  - This information is intended to aid them in the safe and effective use of this medication.
  - It is not a disclosure of all possible adverse or intended effects.

**Contraindications:** Flonase Nasal Spray is contraindicated in patients with a hypersensitivity to any of its components. Flonase Nasal Spray should be avoided in patients with nasal septal ulcers, nasal surgery, or nasal trauma.

**Dosage and Administration:** Flonase Nasal Spray is designed to be used as a single dose twice daily, one spray per nostril, in the morning and evening.

**Dosage Forms:** Flonase Nasal Spray is available as a 200 mcg per spray, 0.05% solution per spray, in a 200-mcg/ml solution, in a 1-mL pump bottle.

**Storage:** Flonase Nasal Spray should be stored at room temperature, 25°C (77°F), protected from freezing and from direct sunlight.

**Injection:** Flonase Nasal Spray is not intended for intranasal injection or intrathecal use.

**Advantages:** Flonase Nasal Spray is a metered-dose, aqueous solution, and it provides a convenient and accurate delivery of medication to the nasal cavity.

**References:**
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- A first-line therapy for management of seasonal and perennial allergic rhinitis in patients 12 years and older – not indicated for nonallergic rhinitis.

- Relief of nasal symptoms may begin within 12 hours.

- Maximum benefit may take several days. Onset of action and degree of relief may vary in individual patients.

- Effectiveness depends on regular use.

- Side effects occurring at >1% (causal relationship possible) included epistaxis and nasal burning (3% to 6%) and nasal irritation, headache, and pharyngitis (1% to 3%).

Please consult Brief Summary of Prescribing Information on adjacent page.

Focused Relief for Allergic Rhinitis...

NEW FLONASE™
(fluticasone propionate)

NASAL SPRAY, 0.05%

QD AQ

The Aqueous/Once-a-Day ANTI-RHINITIC™
CONTRAINDICATIONS: Flonase Nasal Spray is contraindicated in patients with a hypersensitivity to any of its ingredients.

WARNINGS: The replacement of a systemic glucocorticoid with a topical glucocorticoid can be accompanied by signs of adrenal insufficiency, and in addition some patients may experience symptoms of withdrawal, e.g., joint or muscular pain, lassitude, and depression. Patients previously treated for prolonged periods with systemic glucocorticoids and transferred to topical glucocorticoids should be monitored for complications related to their systemic therapy. Since some patients who have asthma or other clinical conditions requiring long-term systemic glucocorticoid treatment, too rapid a decrease in systemic glucocorticoids may cause a severe exacerbation of their symptoms.

The use of Flonase Nasal Spray with alternate-day systemic prednisone could increase the likelihood of hypothalamic-pituitary-adrenal (HPA) axis suppression compared with a therapeutic dose of either drug alone. Therefore, Flonase Nasal Spray should be used with caution in patients already receiving alternate-day prednisone treatment for any disease. In addition, the concomitant use of Flonase Nasal Spray with other inhaled glucocorticoids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA axis.

Patients who are on immunosuppressant drugs are more susceptible to infections than healthy individuals. Chickenpox and measles, for example, can be more serious or even fatal in patients on immunosuppressant doses of corticosteroids. In such patients who have not had these diseases, particular care should be taken to avoid exposure. How the dose, route, and duration of corticosteroid administration affects the risk and magnitude of this suppression 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, patients with cortico-steroids zoster immune globulin (VZIG) may be indicated. If exposed to measles, prophylaxis with pooled immune globulin is recommended (see prescribing information).

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

PRECAUTIONS: General: Nasal: Immediate hypersensitivity reactions or contact dermatitis may occur after the intranasal administration of fluticasone propionate. Rare instances of wheezing, nasal septum perforation, catarracts, glaucoma, and increased intracranial pressure have been reported following the intranasal application of other glucocorticosteroids.

Use of excessive doses of glucocorticoids may lead to signs or symptoms of hypercorticism, suppression of HPA function, and/or suppression of growth in children or teenagers. Apremometry studies in asthmatic children on long-term inhaled glucocorticoids showed inhibitory effects on short-term growth rate. The relationship between short-term changes in lower leg growth and long-term effects on growth is unclear at this time. Physicians should consider the growth of adolescents taking glucocorticoids, by any route, and weigh the benefits of glucocorticoid therapy against the possibility of growth suppression if an adolescent's growth appears slowed.

Although systemic effects have been minimal with recommended doses of Flonase Nasal Spray, potential risks increase with larger doses. Therefore, larger than recommended doses of Flonase Nasal Spray should be avoided.

When used at larger doses, systemic glucocorticoid effects such as hypercorticism and adrenal suppression may appear. If such changes occur, the dosage of Flonase Nasal Spray should be discontinued slowly consistent with accepted procedures for discontinuing oral glucocorticoid therapy.

In clinical studies with fluticasone propionate administered intranasally, the development of localized infections of the nose and pharynx with Candida albicans has occurred rarely. When such an infection develops, it may require treatment with appropriate local therapy and suspension of use of Flonase Nasal Spray Patients using Flonase Nasal Spray over several months or longer should be examined periodically for evidence of Candida infection or other signs of adverse effects on the nasal mucosa.

Flonase Nasal Spray should be used with caution. If at all, in patients with active or quiescent tuberculosis infections; untreated fungal, bacterial, or systemic viral infections; or ocular herpes simplex.

Because of the inhibitory effect of glucocorticoids on wound healing, patients who have experienced recent nasal septal ulcers, nasal sepsis, or nasal trauma should not use a glucocorticoid until healing has occurred.

Information for Patients: Patients being treated with Flonase Nasal Spray should be given the following information and instructions. This information is intended to aid them in the safe and effective use of this medication. It is not a disclosure of all possible adverse or intended effects. Patients should be warned to avoid exposure to chickenpox or measles and, if exposed, to consult their physician without delay.

Patients should use Flonase Nasal Spray at regular intervals as directed since its effectiveness depends on its regular administration. A decrease in nasal symptoms may occur as soon as 12 hours after starting therapy with Flonase Nasal Spray. Results in several clinical trials indicate statistically significant improvement within the first day or two of treatment; however, the full benefit of Flonase Nasal Spray may not be achieved until treatment has been administered for several days. The patient should not increase the prescribed dosage but should consult the physician if symptoms do not improve or if the condition worsens. For the proper use of the nasal spray and to attain maximum improvement, the patient should read and follow carefully the patient's instructions accompanying the product.

Carcinogenesis, Mutagenesis, Impairment of Fertility: Fluticasone propionate demonstrated no tumorigenic potential in studies of oral doses up to 1.0 mg/kg (3 mg/g) as calculated on a surface area basis) for 78 weeks in the mouse or inhaled or oral doses of up to 57 mcg/kg (5.3 mg/kg) for 104 weeks in the rat.

Fluticasone propionate did not induce gene mutation in prokaryotic or eukaryotic cells in vivo. No significant clastogenic effect was seen in cultured human peripheral lymphocytes in vitro or in vivo in the mouse micronucleus test when administered at high doses by the oral or subcutaneous routes. Furthermore, the compound did not delay erythroblast division in bone marrow.

No evidence of impairment of fertility was observed in reproductive studies conducted in rats dosed subcutaneously with doses up to 50 mcg/kg (250 mcg/kg) in males and females. However, prostatic weight was significantly reduced in rats.

Pregnancy: Teratogenic Effects: Pregnancy Category: Subcutaneous injections in the mouse and rat at 45 and 100 mcg/kg, respectively (135 and 500 mcg/kg, respectively, as calculated on a surface area basis), resulted in fetal toxicity characterized by partial glucocorticoid compounds, including embryonic growth retardation, cleft palate, and retardation of ossification.

In the rabbit, fetal weight reduction and cleft palate were observed following subcutaneous doses of 4 mcg/kg (140 mcg/kg). However, following oral administration of up to 300 mcg/kg (36 mg/kg) of fluticasone propionate to the rabbit, there were no maternal effects or increased incidences of external, visceral, or skeletal fetal defects. No teratogenic effects were exhibited in the rat in this study. Consistent with the established low bioavailability following oral administration (see CLINICAL PHARMACOLOGY section of the full prescribing information).

There are no adequate and well-controlled studies in pregnant women. Fluticasone propionate should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. Experience with oral glucocorticoids since their introduction in pharmacologic, as opposed to physiologic, doses suggests that rodents are more prone to teratogenic effects from glucocorticoids than humans. In addition, because Flonase Nasal Spray is contraindicated in patients with asthma or other clinical conditions requiring long-term systemic glucocorticoid treatment, too rapid a decrease in systemic glucocorticoids may cause a severe exacerbation of their symptoms.

The use of Flonase Nasal Spray with alternate-day systemic prednisone could increase the likelihood of hypothalamic-pituitary-adrenal (HPA) axis suppression compared with a therapeutic dose of either drug alone. Therefore, Flonase Nasal Spray should be used with caution in patients already receiving alternate-day prednisone treatment for any disease. In addition, the concomitant use of Flonase Nasal Spray with other inhaled glucocorticoids could increase the risk of signs or symptoms of hypercorticism and/or suppression of the HPA axis.

ADVERSE REACTIONS: In controlled US studies, 2,427 patients received treatment with intranasal fluticasone propionate. In general, adverse reactions in clinical studies have been primarily associated with irritation of the nasal mucous membranes, and the adverse reactions were reported with approximately the same frequency by patients treated with the vehicle itself. The complaints did not usually interfere with treatment. Less than 2% of patients in clinical trials discontinued because of adverse events; this rate was similar for vehicle and active comparators.

Systemic glucocorticoid side effects were not reported during controlled clinical studies up to 6 months duration with Flonase Nasal Spray. If recommended doses are exceeded, however, or if individuals are particularly sensitive or if in conjunction with systemically administered glucocorticoids, symptoms of hypercorticism, e.g., Cushing's syndrome, could occur.

The following incidence of common adverse reactions is based upon seven controlled clinical trials in which 536 patients (57 girls and 108 boys aged 4 to 11 years, 137 female and 234 male adolescents and adults) were treated with Flonase Nasal Spray 200 mcg once daily over 2 to 4 weeks and two controlled clinical trials in which 246 patients (119 female and 127 male adolescents and adults) were treated with Flonase Nasal Spray 200 mcg once daily over 6 months.

Incidence Greater than 1% (Causal Relationship Possible): Respiratory: Epistaxis, nasal burning (incidence 3% to 5%); blood in nasal mucus, pharyngitis, nasal irritation (incidence 1% to 3%).

Incidence Less than 1% (Causal Relationship Possible): Respiratory: Sneezing, runny nose, nasal dryness, sneezing, nasal congestion, bronchitis, nasal ulcer, nasal septum exudation.

Neurological: Dizziness.

Special Senses: Eye disorder, unpleasant taste.

Digestive: Nausea and vomit, anorexia.

Skin and Appendages: Eczema.

OVERDOSAGE: There are no data available on the effects of acute or chronic overdose with Flonase Nasal Spray. Intranasal administration of 2 mg (10 times the recommended dose) of fluticasone propionate twice daily for 7 days to healthy human volunteers was well tolerated. Single oral doses up to 16 mg have been studied in human volunteers with no acute toxic effects reported. Repeat oral doses up to 80 mg daily for 10 days in volunteers and repeat oral doses up to 10 mg daily for 14 days in patients were well tolerated. Adverse reactions were of mild to moderate severity, and incidences were similar in active and placebo treatment groups. Acute overdose with this drug is unlikely since one bottle of Flonase Nasal Spray contains approximately 8 mg of fluticasone propionate. Chronic overdose may result in signs/symptoms of hypercorticism (see PRECAUTIONS).
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Imagine walking into a practice where your services are truly needed. You will thrive in this financially lucrative practice while maintaining an excellent quality of life sharing call on a 1 in 4 basis. Dallas, Texas offers a combination of southwestern friendliness, abundant cultural activities, excellent shopping, and beautiful homes. A low cost of living, a major international airport, and excellent weather have made this city a top choice among physicians. Reference #2805

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5) The Sioux City area is outperforming the rest of Iowa and the nation economically!
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7) Abundance of recreational opportunities – close to the Iowa Great Lakes!
8) Home to a major medical provider with tertiary services and measurable high-quality care!
9) Homespun feel while only hours away from several large metropolitan cities!
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Phone (970) 350-2416

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Plus optional day of psychiatry just before and optional day of obstetrics just after

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<tr>
<th>OBJECTIVES</th>
<th>METHODS</th>
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<tr>
<td>Improve basic and clinical knowledge in family practice</td>
<td>SELF-DIRECTED STUDY questions, answers, and assignments</td>
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<tr>
<td>Prepare candidates to take Family Practice board exams</td>
<td>SEMINAR with projection slides and lecture-note syllabus</td>
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<tr>
<td>Provide family practitioners with a review and update</td>
<td>PRACTICE EXAMS with written questions and answers</td>
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### OPTIONAL DAY BEFORE CORE

**Psychiatry**
- Depression and Mania
- Schizophrenia
- Anxiety and Neurosis
- Personality Disorders
- Psych. Emergencies
- Alcohol & Drug Abuse
- Obesity/Eating Disorders
- Sleep Disorders
- Geriatric Psychiatry
- Psychotherapeutic Drugs

**Gastroenterology**
- Abdominal Pain
- Common Infections
- Ulcers
- Other Gastroesophageal Problems

**Endocrinology**
- Diabetes Mellitus
- Thyroid Diseases
- Parathyroid & Adrenal Osteoporosis

**Heme. & Oncology**
- Anemia
- Abnormal White Counts
- Bleeding Disorders
- Cancer Detection
- Cancer Prevention
- Primary Care Oncology

**Respiratory**
- Pulmonary Hypertension
- Asthma & COPD
- Diffuse Lung Diseases
- Pulmonary Emboli

**Cardiology**
- EKG's & Arrhythmias
- Preventive Cardiology
- Hypertension
- Myocardial Infarction
- Valvular Disease
- Congestive Failure

**Surgery**
- Breast Diseases
- Trauma Assessment
- Vascular Problems
- Common Eye Problems
- Hand Injuries
- Office Orthopedics
- Otitis and Sinusitis
- Head and Neck Masses
- Prostate Problems
- Urinary Incontinence

**Gynaecology**
- Gynecologic Infections
- Menstrual Disorders
- Pelvic Pain Evaluation
- Contraception
- Inertility Options
- Sexual Assault
- Abnormal Pap Smears
- Cancer in Women
- Menopause Management

**Community Med.**
- Preventive Health Care
- Occupational Medicine
- Environmental Medicine
- Ethical & Legal Issues

**Pediatrics**
- Care of the Newborn
- Growth & Development
- Vaccinations
- Behavior Problems
- Learning Disorders
- Fever and Infections
- Vomiting and Diarrhea
- Seizures and Epilepsy
- Allergy & Immunology
- Common Exanthems
- Child Abuse
- Adolescent Medicine

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**SEVEN DAY COURSE**

**Medicine and Gerontology**
- Pulmonology
- Asthma and COPD
- Pneumonia & Bronchitis
- Diffuse Lung Diseases
- Pulmonary Emboli

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<th>Limited Enrollment: Family Practice Review Registration</th>
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<tr>
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<td>Address ____________________________</td>
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<td>City/State/Zip ____________________________</td>
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<td>Phone ____________________________</td>
</tr>
<tr>
<td>Mail Today to: 1094 East Dawn Drive, Dept. 504</td>
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<tr>
<td>P.O. Box 2218</td>
</tr>
<tr>
<td>Terre Haute, IN 47802-0218</td>
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### OPTIONS AFTER CORE

**Obstetrics**
- Prenatal Care
- Fetal Testing
- Diabetes in Pregnancy
- Hypertension
- Spontaneous Abortion
- Preterm and Post Dates
- Induction of Labor
- Labor Complications
- Obstetric Analgesia
- Perinatal Infections
- Medical Genetics

Robert Balk, M.D.
Rush Medical College
B. Banahan, M.D.
University of Mississippi
R. Baumann, M.D.
University of Kentucky
P. K. Chaudhuri, M.D.
Medical College of Ohio
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VA Outpatient Clinic
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Cleveland Clinic Foundation
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University of Cincinnati
Ana Eng, M.D.
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Larry Johnson, M.D.
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Penn State University
John Pottage, M.D.
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Bernard Silver, M.D.
Case Western Reserve Univ.
Terry Taylor, M.D.
Georgetown University
John Wyrick, M.D.
University of Cincinnati

Course Description
Course enrollment is limited to 120 to give personal attention to your questions. Self-directed study questions will be sent before the courses – which will include case reviews and lectures with slides and syllabus and question sessions each evening.

"Accommodations were comfortable..."**

Locations and Travel
Crowne Sterling Suites San Francisco Airport; Regal Hotel Cincinnati; Radisson Plaza, Manhattan Beach, near Los Angeles Airport; Baltimore Washington Airport (BWI) Marriott; and Radisson Lisle/Naperville – 20 miles southwest of Chicago’s O’Hare Airport. For personal service with travel reservations, please call 800-356-7537 ext. 218.

"...the most education for the money."**

### Fees and Course Hours

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<tr>
<td>7 Day Core Course</td>
<td>$870 $580</td>
<td>70</td>
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<tr>
<td>Optional Day Before</td>
<td>$150 $100</td>
<td>10</td>
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<tr>
<td>Optional Day After</td>
<td>$150 $100</td>
<td>10</td>
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<tr>
<td>9 Day Board Review</td>
<td>$1080 $720</td>
<td>90</td>
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<tr>
<td>Repeating within 2 yrs.</td>
<td>$540 $540</td>
<td>90</td>
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<tr>
<td>Add 10% within 10 days of the course.</td>
<td>$500</td>
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<tr>
<td>Not in course hotel package add $30 per day.</td>
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<td>A $100 deposit will reserve your position.</td>
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<tr>
<td>Subject to $100 fee, refunds will be made until the seminar begins.</td>
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"...home study...was extremely helpful.**

### AAFP Prescribed Credit

This program has been reviewed and is acceptable up to 88 Prescribed hours by the AAFP. AAFP Prescribed credit is accepted by the AMA as equivalent to AMA PRA Category 1 for the AMA Physicians Recognition Award. When applying for the AMA PRA, Prescribed hours earned must be reported as Prescribed hours, not as Category 1.

"I feel [the course] helped me pass..."**

### Information

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*Comments by Osler participants*
FOR HYPERTENSION OR ANGINA

CARIDZEM® CD
(diltiazem HCl)

100-, 180-, 240-, 300-mg Capsules

Brief Summary of
Prescribing Information as of April 1993

CARIDZEM® CD (diltiazem HCl)
Capsules

CONTAINING
CARIDZEM® is contraindicated in (1) patients with sick sinus syndrome except in the presence of a functioning ventricular pacemaker; (2) patients with second- or third-degree AV block except in the presence of a functioning ventricular pacemaker; and (3) patients with symptomatic heart failure. It is not recommended for patients who demonstrate hypersensitivity to the drug, and (5) patients with acyanotic myocardial infarction and pulmonary congestion documented by x-ray on admission.

WARNINGS

1. Cardiac Conduction. CARIDZEM® prolongs AV node refractory periods without significantly prolonging sinus node refractory periods. This effect may result in abnormally slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (13 of 3292 patients; 0.4%). Concomitant use of CARIDZEM® with beta-blockers or digoxin may result in additive effects on cardiac conduction. A patient with Prinzmetal's angina developed asystole (2 to 5 seconds) after a single dose of 60 mg of diltiazem.

2. Complications in Heart Failure. Diltiazem has a negative inotropic effect in isolated animal tissue preparations; however, human studies in patients with normal ventricular function have not shown a reduction in cardiac index or non-competitive negative effects on contractility (opist). An acute study of oral diltiazem in patients with impaired ventricular function (fraction injection 24% to 6%) showed improvement in indices of ventricular function without significant decrease in contractile function (opist). Worsening of congestive heart failure has been reported in patients with pre-existing impaired ventricular function. Experience with the use of CARIDZEM® (diltiazem hydrochloride) in combination with beta-blockers in patients with impaired ventricular function has not shown an additive negative effect on ventricular function.

3. Hypotension. Decreases in blood pressure associated with CARIDZEM® therapy may occasionally result in symptomatic hypotension.

4. Acute Hepatic Injury. Mild elevations of transaminases with and without concomitant elevation in alkaline phosphatase and bilirubin have been observed in clinical studies. Such elevations were usually transient and frequently were noted even with concomitant treatment with other drugs. In some cases, increased elevations in enzymes such as alkaline phosphatase, LDH, SGOT, SGPT, and other phenomena consistent with acute hepatic injury have been noted. These reactions have been reported to occur early after therapy initiation (1 to 8 weeks) and have been reversible upon discontinuation of drug therapy. The relationship to CARIDZEM® is uncertain in some cases; probable in some. (See PRECAUTIONS.)

PRECAUTIONS

General

CARIDZEM® (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and bile. As with any drug given over prolonged periods, laboratory parameters of renal and hepatic function should be monitored at regular intervals. The drug should be used with caution in patients with impaired renal or hepatic function. No dosage adjustment is necessary for either diltiazem or its active metabolite in patients with chronic renal or hepatic failure. In patients with renal and/or hepatic impairment, dosages of similarly metabolized drugs, particularly those of low therapeutic ratio, may require adjustment when starting or stopping concomitantly administered diltiazem to maintain optimum therapeutic blood levels.

Beta-blockers. Controlled and uncontrolled clinical studies suggest that concomitant use of CARIDZEM® and beta-blockers is usually well tolerated, but still to date are not sufficient to predict the effects of concomitant treatment in patients with left ventricular dysfunction or cardiac conduction abnormalities.

Administration of CARIDZEM® (diltiazem hydrochloride) concomitantly with propranolol in five normal volunteers resulted in increased propranolol levels in all subjects and bioavailability of propranolol was increased approximately 50%. In vitro, propranolol appeared to be displaced from its binding sites by diltiazem. If combination therapy is used, dosages should be reduced at least 50% in conjunction with propranolol, its use adjustment in the propranolol dosage may not be warranted. (See WARNINGS.)

Climidem. In a study of six healthy volunteers has shown a significant increase in peak diltiazem plasma levels (58%) and area-under-the-curve (53%) after a 1-week course of climidem at 1200 mg per day and single dose of diltiazem 60 mg. Ramitidine produced smaller, nonsignificant increases. The effect may be mediated by competitive binding with the metabolite form of diltiazem. This may result in an increase in the free or unbound portion of diltiazem. The plasma levels of diltiazem should be monitored when initiating and discontinuing therapy with climidem. An adjustment in the climidem dosage might be warranted.

Digitalis. Administration of CARIDZEM® with digoxin is 24 healthy male subjects increased plasma digoxin concentrations approximately 37%. Another investigator found no increase in digoxin levels in 15 patients with coronary artery disease. Since there have been conflicting results regarding the effect of digoxin levels, it is recommended that digoxin be monitored when initiating and adjusting, and discontinuing CARIDZEM therapy to avoid possible over- or under-digitalization. (See WARNINGS.)

Anesthetics. The depression of cardiac contractility, conductivity, and automatically as well as the vascular dilation associated with anesthetics may be potentiated by calcium channel blockers. When used concomitantly, anesthetics and calcium blockers should be titrated carefully.

Cyclosporine. A pharmacokinetic interaction between diltiazem and cyclosporine has been observed during studies involving renal and cardiac transplant patients. In renal and cardiac transplant recipients, a reduction of cyclosporine exposure ranging from 15% to 48% was necessary to maintain cyclosporine trough concentrations to those seen prior to the addition of diltiazem. If these agents are to be administered concurrently, cyclosporine concentrations should be monitored. especially when diltiazem therapy is initiated, adjusted, or discontinued. The effect of cyclosporine on diltiazem plasma concentrations has not been evaluated.

Catecholamine. Concomitant administration of diltiazem and catecholamines has been reported to result in elevations serum levels of carbacholamine (40% to 22% increase), resulting in toxicity in some cases. Patients receiving these drugs concurrently should be monitored for a potential drug interaction.

Cardiovascular. Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of CARIDZEM® is deemed essential, an alternative method of infant feeding should be instituted.

Pediatric Use

Safety and effectiveness in children have not been established.

ADVERSE REACTIONS

Serious adverse reactions have been rare in studies carried out to date, but it should be recognized that patients with impaired ventricular function and cardiac conduction abnormalities have usually been excluded from these studies.

The following table presents the most common adverse reactions reported in placebo-controlled angiographic and hypertension trials in patients receiving CARIDZEM® CD to 569 mg with rates in placebo patients shown for comparison.

CARIDZEM® CD Capsule Placebo-Controlled

Anxiety and Hypertension Trials Combined

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>CARIDZEM® CD</th>
<th>Placebo</th>
<th>p-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>5.4%</td>
<td>5.0%</td>
<td></td>
</tr>
<tr>
<td>Dizziness</td>
<td>3.0%</td>
<td>3.9%</td>
<td></td>
</tr>
<tr>
<td>Bradycardia</td>
<td>3.3%</td>
<td>1.3%</td>
<td></td>
</tr>
<tr>
<td>AV Block First Degree</td>
<td>0.0%</td>
<td>0.0%</td>
<td></td>
</tr>
<tr>
<td>Edema</td>
<td>2.6%</td>
<td>1.3%</td>
<td></td>
</tr>
<tr>
<td>ECG Abnormality</td>
<td>1.6%</td>
<td>2.3%</td>
<td></td>
</tr>
<tr>
<td>Asthenia</td>
<td>1.8%</td>
<td>1.7%</td>
<td></td>
</tr>
</tbody>
</table>

In clinical trials of CARIDZEM® CD capsules, CARIDZEM® tablets, and CARIDZEM® SR capsules involving over 3200 patients, the most common events (ie, greater than 1%) were edema (4.6%), headache (4.6%), dizziness (3.5%), asthenia (2.6%), first-degree AV block (2.4%), bradycardia (1.7%), flushing (1.4%), nausea (1.4%), and rash (1.2%).

In addition, the following events were reported infrequently (less than 1%) in angora or hypertension trials:

Cardiovascular: Angina, arrhythmia, AV block (second- or third-degree), bundle branch block, congestive heart failure, ECG abnormalities, hypotension, palpitations, syncope, tachycardia, ventricular extrasystoles.

Neurological: Abnormal dreams, anxiety, depression, gall bladder, hallucinations, insomnia, nervousness, paresthesia, personality change, somnolence, tremor, tinnitus.

Gastrointestinal: Anorexia, constipation, diarrhea, dry mouth, dysgeusia, dyspepsia, mild elevations of SGOT, SGPT, LDH, and alkaline phosphatase (see hepatic warnings), thirst, vomiting, weight increase.

Dermatological: Pustules, photosensitivity, pruritus, urticaria.

Other: Arthralgia, CPK increase, dyspnea, epistaxis, eye irritation, hyperglycemia, hypomagnesemia, impotence, muscle cramps, nasal congestion, nocturia, phlebitis, pain, polyuria, sexual difficulties.

The following postmarketing events have been reported infrequently in patients receiving CARIDZEM®: alopecia, retinopathy, subacute bacterial endocarditis, extrapulmonary symptoms, gingival hyperplasia, hemolytic anemia, increased bleeding time, leukopenia, purpura, retinopathy, and thrombocytopenia. In addition, events such as myocardial infarction have been observed which are not readily distinguishable from the natural history of the disease in these patients. A number of well-documented cases of generalized rash, characterized as liquorcoelastic vesciculosis, have been reported. However, a definitive cause and effect relationship between these events and CARIDZEM therapy is yet to be established.

Prescribing Information as of April 1993
Marion Merrell Dow Inc.
Kansas City, MO 64114

References:
1. Cardizem CD prescribing information. 2. Data on file, Marion Merrell Dow Inc.

CVM#4013001

RX
Cardizem CD
Start with one 180-mg capsule daily
IN HYPERTENSION OR ANGINA

CARDIZEM® CD
(diltiazem HCl) 120-, 180-, 240-, 300-mg Capsules

FOR EFFECTIVE
24-HOUR CONTROL

ONCE A DAY

A unique hemodynamic and safety profile for hypertension or angina\(^1\,^2\)

- A side-effect discontinuation rate comparable to placebo in both hypertension and angina trials\(^2\)
- Most commonly reported side effects are headache (5.4%), bradycardia (3.3%), first-degree AV block (3.3%), dizziness (3.0%), edema (2.6%), ECG abnormality (1.6%), and asthenia (1.8%)\(^1\)

Please see brief summary of prescribing information on adjacent page.