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

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(ketorolac tromethamine) 0.5%

Sterile Ophthalmic Solution

**STOPS THE ITCH**
ACULAR®
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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 exhibited sensitivity to any of the ingredients in the formulation.

WARNINGS
There is the potential for cross-sensitivity to acetylsalicylic acid, phenylacetate 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 hyphemas) 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 1590 mg/kg (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: Category C. Reproduction studies have been performed in rabbits, using daily oral doses of 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 benefits justify 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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She feared a physician’s intrusion—lung cancer terror voiced with still eyes.
I chose to assist her surgeon
with the neck-node biopsy;
was drafted to assist
her fate’s savage bite.
Her sweat-spent face sagged
toward purpling right hand
as the gaping trench we dug
finally let loose her lump,
then fired back its red missiles.
Panic sparked through our guts
fueled by routine’s dry tinder.
“Unfair!” my clenched teeth screamed
when I saw her dusky fist
seize our sterile barrier.
Then, “Flat line—stand back!”
from chest’s spongy twitch
and sickening heavy bounce.
Pus-filled lungs and clammy groin
were quickly invaded by blades,
needles and tubes—
while my mind grew thicker,
“We gotta stick her . . .”
She did not say goodbye
or where she wanted to go.
Death spills the suffering life contains.
This afternoon her pain passed on;
trenchant hours measured to me,
lifelong pangs for her children.
With quiet whispers the others
filed out beside me.
My heart wanted comfort of wailing—
tropical gusts to blow the chill
out of the now-dimmed surgical suite—but I found no loved ones,
no beating of breasts.
Believing I might shake off
sodden heaviness like a drenched cat
I headed home to watch the sunset,
the Discovery Channel
(black bears grinning, trout stuck to paws)
and MTV videos
(RadioHead singing, “I am a creep, a weirdo”).
Still numb, I could only wonder:
had Christ felt the blade placed
between his ribs with love?
I prayed that she ask Him,
and then for her children—who had no chance to say goodbye.

Tim Van Ert
Selah, Wash
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Please consult Brief Summary of Prescribing Information on adjacent page.
Flonase™ (fluticasone propionate) Nasal Spray, 0.05%

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 there is a natural increase in glucocorticoid production during pregnancy, most women will require a lower exogenous glucocorticoid dose and many will not need glucocorticoid treatment during pregnancy.

Nursing Mothers: It is not known whether fluticasone propionate is excreted in human breast milk. Subcutaneous administration of trialed drug to lactating rats (10 mg/kg, 50 mg/kg) resulted in measurable radioactivity in both plasma and milk. Because other glucocorticoids are excreted in human milk, caution should be exercised when Flonase Nasal Spray is administered to a nursing woman.

Pediatric Use: The safety and effectiveness of Flonase Nasal Spray in children below 12 years of age have not been established. Oral glucocorticoids have been shown to cause growth suppression in children and teenagers with extended use. If a child or teenager on any glucocorticoids appears to have growth suppression, the possibility that they are particularly sensitive to this effect of glucocorticoids should be considered (see PRECAUTIONS).

Serum Use: A limited number of patients above 60 years of age (3512) have been treated with Flonase Nasal Spray in US and non-US clinical trials. While the number of patients is too small to permit separate analysis of efficacy and safety, the adverse reactions reported in this population were similar to those reported by younger patients.

ADVERSE REACTIONS: In controlled US studies, 2.477 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., Cushings's syndrome, could occur.

The following incidence of common adverse reactions is based upon seven controlled clinical trials in which 136 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 for 6 months. Incidence Greater than 1% (Causal Relationship Possible): Respiratory: Epistaxis, nasal burning (incidence 3% to 6%); blood in nasal mucus, pharyngitis, nasal irritation (incidence 1% to 3%);

Neurological: Headache.

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Special Senses: Eye disorder, unpleasant taste.

Digestive: Nausea and vomiting, xerostomia.

OVERDOSE: There are no data available on the effects of acute or chronic overdosage with Flonase Nasal Spray. Intranasal administration of 2 mg (10 times the recommended dose) of fluticasone propionate twice daily for 7 days in 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 or moderate severity, and incidences were similar in active and placebo treatment groups. Acute overdosage with this dosage form is unlikely since one bottle of Flonase Nasal Spray contains approximately 8 mg of fluticasone propionate. Chronic overdosage may result in signs/symptoms of hypercorticism (see PRECAUTIONS).
In studies up to 5 years, cumulative GI side effects included diarrhea (14%), dyspepsia (13%), and abdominal pain (12%). In patients treated chronically with NSAID therapy, serious GI toxicity such as perforation, ulceration, and bleeding can occur. Contraindicated in patients who have shown hypersensitivity to aspirin, Relafen, or other NSAIDs. Should not be given to patients in whom aspirin or other NSAIDs induce asthma, urticaria, or other allergic-type reactions.

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Barbara A. Morris, MD
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Editor's Note:

I keep learning new things about decision making at the end of life, often through the school of hard knocks. I recently had a wonderful patient with end-stage chronic obstructive pulmonary disease who died after a decision was reached not to reintubate yet again. However, in spite of several discussions of his wishes over several years and his intermittent episodes of lucidity near the end, he could never make the decision to sign a living will or an advance directive. He also did not want to put his wife in the position of having to make the decision, believing it would be emotionally too difficult for her. He would not choose among his three children. Instead, he wanted me, his doctor, to make the decision. In the end, his ongoing misery was clear, as was the unlikelihood of anything but small, temporary success. His children, with his wife in agreement, made the decision, with the support of myself and the intensive care unit attending physicians, that reintubation no longer met his standard criterion: “If I won’t get off the respirator, don’t put me on.” In many ways, that simple statement was as clear as many sheets of paper of an advance directive.

Marjorie A. Bowman, MD, MPA
Editor

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**CARIDZEM CD**
(diltiazem HCl)
120-, 180-, 240-, 300-mg Capsules

**FOR HYPERTENSION OR ANGINA**

**CONTRAINDICATIONS**
CARIDZEM CD 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, (3) patients with hypotension (less than 50 mm Hg systolic), (4) patients who have demonstrated hypertrophy to the drug, and (5) patients with acute 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 recovery intervals except in patients with sick sinus syndrome. The effect may be greater in patients with heart disease, particularly those with abnormal left ventricular function, slow heart rates (particularly in patients with sick sinus syndrome) or second- or third-degree AV block (13 of 3292 patients or 0.4%). Concomitant use of diltiazem with beta-blockers or digitalis may result in additive effects on cardiac conduction. A patient with third-degree AV block developed periods of asystole (2 to 5.6 seconds) after a single dose of 60 mg of diltiazem.

2. **Conversive Angina**
   Diltiazem has a negative inotropic effect in isolated animal tissue preparations; hemodynamic studies in humans with normal ventricular function have not shown a reduction in cardiac index nor consistent negative effects on contractility (dp/dt). An acute study of oral diltiazem in patients with impaired ventricular function revealed 24% to 41% decreases in contractility in the rate of wavefront velocity function without significant decrease in contractile function (dp/dt). Worsening of congestive heart failure has been reported in 1/2400 patients, with worsening in angina pectoris in ventricular function. Experience with the use of CARIDZEM (diltiazem hydrochloride) in combination with beta-blockers in patients with impaired ventricular function is limited. Caution should be exercised when using this combination.

3. **Hypotension**
   Blood pressure reduction with CARIDZEM therapy may occasionally result in symptomatic hypotension.

4. **Acute Hepatic Injury**
   Mild elevations of transaminases with or without concomitant elevation in alkaline phosphatase and bilirubin have been observed in clinical studies. Such elevations were usually transient and frequently resolved even with continued treatment with diltiazem. In rare instances, significant elevations in the transaminases and bilirubin have been reported. In patients with liver disease, these changes were reversible with the drug discontinued. In dogs, doses of 1 mg/kg or more were also associated with hepatic changes; however, these changes were reversible with continued dosing.

**PRECAUTIONS**

**General**
CARIDZEM (diltiazem hydrochloride) is extensively metabolized by the liver and excreted by the kidneys and bile. As with the use of drugs affecting the coronary circulation and in patients with unstable 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. In subacute and chronic dog and rat studies designed to produce toxicity, high doses of diltiazem were associated with hepatic damage. In canine subacute toxicologic studies, oral doses of 125 mg/kg and higher or in rats were associated with histological changes in the liver which were reversible when the drug was discontinued. In dogs, doses of 1 mg/kg or more were also associated with hepatic changes; however, these changes were reversible with continued dosing.

Dermatologic events (see **ADVERSE REACTIONS** section) may be transient and may disappear despite continued use of CARIDZEM. Increased liver enzymes, pruritus, and edema have been reported with the use of diltiazem. In addition, patients treated with multiple medications. CARIDZEM undergoes biotransformation by cytochrome P-450 mixed function oxidase. Coadministration of CARIDZEM with other agents which follow the same route of biotransformation may result in the competitive inhibition of metabolism. Especially in patients with renal or hepatic impairment: dosages of similarly metabolized drugs, particularly those of low therapeutic ratio, may require adjustment when starting or stopping concomitantly administered dilitazem to maintain optimum therapeutic blood levels.

**Beta-Blockers.**
Controlled and uncontrolled domestic studies suggest that concomitant use of CARIDZEM and beta-blockers is usually well tolerated, but available data are not sufficient to predict the effects of concomitant treatment in patients with ventricular dysfunction or cardiac conduction abnormalities.

**Drug Interactions**
Due to the potential for additive effects, caution and careful titration are warranted in patients receiving CARIDZEM concomitantly with other agents known to affect cardiac conduction and/or contractility. (See WARNINGS.) Pharmacologic studies indicate that there may be additive effects in prolonging AV conduction when beta-blockers or digitalis concomitantly with CARIDZEM. (See WARNINGS.)

As with all drugs, CARIDZEM may interfere with the response (includingdocumentation) to certain operative procedures, including endotracheal intubation and some cardiac procedures. The use of other agents which follow the same route of biotransformation may result in the competitive inhibition of metabolism. Especially in patients with renal or hepatic impairment: dosages of similarly metabolized drugs, particularly those of low therapeutic ratio, may require adjustment when starting or stopping concomitantly administered dilitazem to maintain optimum therapeutic blood levels.

**Beta-Blockers.**
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**NURSING MOTHERS**
Diltiazem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels in women. 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 angina and hypertension trials in patients receiving CARIDZEM CD up to 300 mg with rates in placebo patients shown for comparison.

<table>
<thead>
<tr>
<th>CARIDZEM CD Capsule Placebo-Controlled</th>
<th>Angina and Hypertension Trials Combined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Adverse Reactions</td>
<td>Caridzem CD (n=607)</td>
</tr>
<tr>
<td>Headache</td>
<td>5.4%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>3.0%</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>2.3%</td>
</tr>
<tr>
<td>AV Block First Degree</td>
<td>3.3%</td>
</tr>
<tr>
<td>Edema</td>
<td>2.6%</td>
</tr>
<tr>
<td>ECG Abnormality</td>
<td>1.6%</td>
</tr>
<tr>
<td>Asthma</td>
<td>1.8%</td>
</tr>
</tbody>
</table>

In clinical trials of CARIDZEM CD capsules, CARIDZEM tablets, and CARIDZEM SR capsules involving over 3000 patients, the most common events (w, greater than 1%) were edema (4.8%), headache (4.8%), 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 angina 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

**Nervous System**
- Abnormal dreams, amnesia, depression, gait ataxia, hallucinations, insomnia, nervousness, parasthesia, personality change, somnolence, tension

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

**Dermatologic**
- Petechiae, photosensitivity, pruritus

**Other**
- Amblyopia, CPM increase, dyspnea, epistaxis, eye irritation, hyperglycemia, hyperuricemia, impotence, muscle cramps, muscle weakness, myalgia, nocturia, oedema, pain, paresthesia, sexual difficulties

The following postmarketing events have been reported infrequently in patients receiving CARIDZEM:
- Alopecia, ataxia, choreoathetosis, cutaneous四个and/or bullous rash, dysphonia, episodes of severe chest pain, dysphagia, exfoliative dermatitis, fever, forearm pain, gynecomastia, gynecomastia and/or hyperthyroidism, hirsutism, hirsutism and/or hypothyroidism, increased thirst, leukopenia, malaise, myalgia, myopathy, muscle cramps, myositis, myopathy, nausea, nocturia, paresthesia, phlebitis, photophobia, pruritus, psychomotor retardation, rash, rash and/or temperature, reactivation of hepatitis, retinopathy, reversible inflammatory, rhinitis, stomatitis, syncope, tachycardia, toxic psychosis, urticaria, ventricular extrasystoles

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(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

- A side-effect discontinuation rate comparable to placebo in both hypertension and angina trials
- 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%)

Please see brief summary of prescribing information on adjacent page.