In the management of depression...

sertraline HCl

ZOLOFT®

CONSIDER SAFETY.

CONSIDER EFFECTIVENESS.

CHOOSE ZOLOFT FOR FIRST-LINE THERAPY.

The most common side effects include nausea, diarrhea or loose stools, tremor, insomnia, somnolence, and dry mouth.

ONCE-A-DAY, AM or PM

Zoloft®

(servtraline HCl)

Please see brief summary of prescribing information on adjacent page.

ZOLOFT SAFETY...ZOLOFT EFFECTIVENESS...ZOLOFT FOR FIRST-LINE THERAPY

© 1994, Pfizer Inc


ZOLFO® (sertraline HCl)

INDICATIONS AND USAGE: ZOLFO® (sertraline hydrochloride) is indicated for the treatment of depression.

ZOLFO® (sertraline hydrochloride) is metabolized by hepatic drug inactivating enzymes such as cytochrome P450 2D6 and 2C19. As a consequence, co-administration with drugs that inhibit cytochrome P450 2D6 or 2C19, or induce these enzymes, may alter the metabolism of ZOLFO® (sertraline hydrochloride) and consequently its pharmacodynamic effects.

In addition, ZOLFO® (sertraline hydrochloride) is primarily excreted through the kidneys. Therefore, caution should be used in administering ZOLFO® (sertraline hydrochloride) to patients with renal impairments.

BRIEF SUMMARY

ZOLFO® (sertraline hydrochloride) is indicated for the treatment of depression. ZOLFO® (sertraline hydrochloride) is metabolized by hepatic drug inactivating enzymes such as cytochrome P450 2D6 and 2C19. As a consequence, co-administration with drugs that inhibit cytochrome P450 2D6 or 2C19, or induce these enzymes, may alter the metabolism of ZOLFO® (sertraline hydrochloride) and consequently its pharmacodynamic effects.

In addition, ZOLFO® (sertraline hydrochloride) is primarily excreted through the kidneys. Therefore, caution should be used in administering ZOLFO® (sertraline hydrochloride) to patients with renal impairments.

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J. Roerig & Co.:

Pharmaceuticals

Roerig

Pharmaceuticals

RTD1/4/4
DDAVP Nasal Spray
(deamino vasopressin acetate) 5mL

Dry Nights For Good Mornings

Brief Summary

DESCRIPTION: Known hypotensive is due to DDAVP Nasal Spray

WARNINGS:

1. Do not use on a regular basis.
2. In young children or elderly patients in particular fluid intake should be adjusted in order to decrease the potential occurrence of water intoxication and hyponatremia. Particular attention should be paid to the possibility of the rare occurrence of an extreme decrease in plasma osmolality and resulting seizures.

PRECAUTIONS:

General: DDAVP Nasal Spray of high dosage has been shown to produce a slight elevation of blood pressure, which disappeared with a reduction in dosage. The drug should be used with caution in patients with coronary artery insufficiency and/or for therapeutic arteriosclerotic disorders because of possible rise in blood pressure.

DDAVP Nasal Spray should be used with caution in patients associated with fluid and electrolyte imbalances, such as cir- culating fluids, because these patients are prone to hyponatremia.

Central CNS Depression: Several studies of DDAVP Nasal Spray of high dosage have been shown to cause a decrease in plasma osmolality such as occur in the normal child and in the adult, with associated changes in plasma volume. Even in cases of hyponatremia, DDAVP Nasal Spray administration has been shown to be safe and well tolerated in children aged 1 year or older with dehydrated children.

Adverse Reactions: Adverse reactions include headache, flushing, and nausea.

DDAVP Nasal Spray administration in the presence of normal electrolyte balance has been shown to be safe and well tolerated in children aged 1 year or older with dehydrated children.

ADVERSE REACTIONS: Adverse reactions include headache, flushing, and nausea.

DDAVP Nasal Spray administration in the presence of normal electrolyte balance has been shown to be safe and well tolerated in children aged 1 year or older with dehydrated children.

ADVERSE REACTIONS: Adverse reactions include headache, flushing, and nausea.

DDAVP Nasal Spray administration in the presence of normal electrolyte balance has been shown to be safe and well tolerated in children aged 1 year or older with dehydrated children.

REFERENCES:

TAKE EFFECTIVE CONTROL OF BED-WETTING

- Rapid response—substantial effect seen in as little as 1 to 3 nights of therapy
- A combined 15-year record of successful and safe use in the U.S. and Europe
- May be used hand in hand with behavior modification

Nighttime fluid intake should be restricted to decrease the potential occurrence of fluid overload; serum electrolytes should be checked at least once when therapy is continued beyond 7 days.

DDAVP® Nasal Spray
(desmopressin acetate) 5mL
DRY NIGHTS FOR GOOD MORNINGS

Please see brief summary of prescribing information on adjacent page.
Living in Medicine

My Drug Problem
Tim Wolter, MD

Letters to the Editor

About Intending Death:
The Family and Quality of Care
Michael D. Fetters, MD

In Reply
John M. Freeman, MD,
Edmund D. Pellegrino, MD

Incorporation of Genetics in
Primary Care Practice
Stephanie Revels, MD

In Reply
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Does What We Do Make a Difference?
Susan E. Skochelak, MD, MPH

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Joseph C. Koen, MD, MSPH

The Role of Family Physicians
in Immunization
Richard K. Zimmerman, MD, MPH,
L. Jeannine Petry, MD

Chaotic Family Dynamics
Blake W. H. Smith, PhD

Health System Reform:
A Provider or a Patient Perspective?
David N. Mirvis, MD

American Medical Association
Physicians dedicated to the health of America.

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Ask your SmithKline Beecham Pharmaceuticals representative about new information.
PEARLS OF WISDOM

For many years, Calan SR has been one of the most trusted and effective drugs for the treatment of hypertension. Its sustained-release formulation allows for a once-daily dosing regimen, which simplifies patient management and improves compliance. The use of a long-acting antihypertensive agent like Calan SR can lead to better blood pressure control over the long term, reducing the risk of cardiovascular events. This makes Calan SR an ideal choice for patients with hypertension who are looking for a reliable and convenient treatment option.
Working Continuously
24 Hours a Day...
Once a Day

SUPRAX maintains inhibitory concentrations above MIC₉₀
for virtually 24 hours

Proven Clinical Efficacy

*Although a useful guide, in vitro activity does not necessarily correlate with clinical response.
†Due to indicated susceptible organisms.

For your pediatric patients
### SUPRAX* cefazime

**WARNINGS:**

**BEFORE THERAPY WITH SUPRAX IS INSTITUTED, CAREFUL INQUIRY SHOULD BE MADE TO DETERMINE WHETHER THE PATIENT HAS HAD PREVIOUS HYPERSENSITIVITY REACTIONS TO CEPHALOSPORIN, PENCILLINS, OR OTHER DRUGS. IF THIS PRODUCT IS TO BE GIVEN TO PENCILLIN-SENSITIVE PATIENTS, CARE SHOULD BE EXERCISED BECAUSE CROSS HYPERSENSITIVITY AMONG β-LACTAM ANTIBIOTICS HAS BEEN DEMONSTRATED.**

**DOSAGE AND ADMINISTRATION:**

- Rules and administration of this drug to patients with kidney failure:
  - Adjusted dosage:
    - Patients with serum creatinine clearance of 10-50 mL/min: administer 250 mg every 12 hours.
    - Patients with serum creatinine clearance of <10 mL/min: administer 250 mg every 24 hours.
  - General dosage: administer 250 mg every 12 hours.

**ADVERSE REACTIONS:**

Most adverse reactions observed in clinical trials were of a mild and transient nature. Five percent (5%) of patients in the US trials discontinued therapy because of drug-related adverse reactions. The most commonly seen adverse reactions in US trials of the placebo-controlled trials, which were reported in 8.1% of patients, included nausea, vomiting, anorexia, constipation, and diarrhea. Other adverse reactions observed in clinical trials included alopecia, headache, dizziness, and pruritus.

**Hypersensitivity Reactions:**

- Skin rash, urticaria, pruritus, urticarial skin, and pruritus were the most common hypersensitivity reactions observed.

**CONTRAINDICATIONS:**

- Cefazime is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.

---

**References:**


---

**BRIEF SUMMARY**

**SUPRAX**

**CEFAXIME**

Oral

---

**INDICATIONS AND USAGE:**

SUPRAX is indicated in the treatment of the following infections when caused by susceptible strains of the designated microorganisms:

- **Uncomplicated Urinary Tract Infections:** caused by *Escherichia coli* and *Proteus mirabilis.*
- **Diatal Media:** caused by *Haemophilus influenzae* (beta-lactamase positive and negative strains), *Moraxella* (beta-lactamase negative, most of which are beta-lactamase positive), and *Staphylococcus aureus*.
- **Pharyngitis and Tonsillitis:** caused by *S. pneumoniae,* and *H. influenzae* (beta-lactamase positive and negative strains).
- **Uncomplicated Gonococcal (Cervical/Unithral):** caused by *Neisseria gonorrhoeae* in patients for whom opsonophagocytic assays have been performed.
- **Appropriate cultures and susceptibility studies should be performed to determine the causative organism and a susceptible to SUPRAX, however, therapy may be selected while awaiting the results of these studies.**

**Drug Interactions:**

- **No significant drug interactions have been reported to date.**

**DOSAGE AND ADMINISTRATION:**

- **Adults:** Begin with 500 mg orally every 12 hours.
- **Children:** Begin with 10 mg/kg/day in two divided doses.

---

**CONVENIENT QD DOSING**

<table>
<thead>
<tr>
<th>Tablet Size</th>
<th>Oral Suspension</th>
</tr>
</thead>
<tbody>
<tr>
<td>400 mg</td>
<td>8 mg/kg/day</td>
</tr>
<tr>
<td>100 mg</td>
<td>2 mg/kg/day</td>
</tr>
</tbody>
</table>

---

**CONTRAINdications:**

- Cefazime is contraindicated in patients with known allergy to the cephalosporin group of antibiotics.
24-Hour Delivery Means All Night, Too!

Theo-24®
(theophylline anhydrous)
Extended-release capsules 100, 200, 300 & 400 mg
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There are two sides to every story.

Except this one.

The Littmann™ Master technology stethoscope.
A comparison between 3M brand Littmann Master stethoscopes and traditional stethoscopes can be pretty one-sided.
That's because Littmann Master Classic and Master Cardiology stethoscopes, with their patented suspended diaphragms, combine both the bell and diaphragm into a single side of the chestpiece. So you can switch from low to high frequency sounds simply by varying the pressure. With no pressure, the bell mode picks up low frequency sounds. With moderate pressure, the diaphragm mode picks up high frequency sounds.

The rest of the story is the outstanding acoustic response you receive from Littmann Master stethoscopes. The patented soft-sealing earbuds provide superior comfort as well as an excellent acoustic seal.

The Master series is one more example of the high level of reliability and innovation that you've come to expect from Littmann.

For more information, call the 3M Health Care Customer Helpline toll-free, 1-800-228-3957.

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Antihypertensive Efficacy Equivalent to 2.5 mg*

With the benefits of a lower once-daily dose

Favorable metabolic profile—no adverse effect on lipids; only 2% incidence of clinical hypokalemia

Safe and effective for step-down therapy

Side-effect profile compatible with other antihypertensive agents

LOZOL 1.25 mg once daily is now the recommended starting dose for indapamide

---

LOZOL® (indapamide) 1.25 mg and 2.5 mg tablets

BRIEF SUMMARY

INDICATIONS: LOZOL (indapamide) is indicated for the treatment of hypertension, alone or in combination with other antihypertensive drugs, and for the treatment of salt and fluid retention associated with congestive heart failure.

USAGE IN HYPERTENSION:

CONTRAINDICATIONS: LOZOL is contraindicated in patients with history of sulfonamide allergy; severe hepatic, renal, or cardiac disease. LOZOL should not be used concomitantly with other antihypertensive agents that result in decreased renal function.

WARNINGS: Infrequent cases of severe hypokalemia, accompanied by hyperkalemia, have been reported. Do not use in patients with chronic renal disease, or in those with severe hepatic disease. The use of LOZOL in patients with moderate to severe hepatic disease is not recommended.

PRECAUTIONS: Perform serum electrolyte determinations at appropriate intervals, especially in patients who are vomiting excessively or receiving parenteral fluids. In patients subjected to electrolyte imbalance, or in patients on a salt-restricted diet. In addition, patients should be observed for clinical signs of fluid or electrolyte imbalance, such as hypokalemia, hyperkalemia, or hypernatremia. The risk of hyperkalemia may increase with use of other diuretics or potassium-sparing agents, such as spironolactone. The use of other diuretics is not recommended in patients with moderate to severe renal disease. The use of LOZOL in patients with moderate to severe renal disease is not recommended.

DIAGNOSTIC TESTS: Serum electrolytes should be monitored periodically. Use with caution in patients with severe renal disease. Serum potassium level should be monitored periodically. Use with caution in patients with impaired hepatic function or prerenal disease, since minor alterations in fluid and electrolyte balance may precipitate hepatic coma.

ADVERSE REACTIONS: Most adverse effects have been mild and transient. From Phase III placebo-controlled studies with indapamide 1.25 mg, adverse reactions 6% cumulative incidence: headache, infection, back pain, diarrhea, nausea, vomiting, abdominal pain, chest pain, constipation, dizziness, glossitis, hyperkalemia, cough, pharyngitis, sinusitis, conjunctivitis. Other adverse reactions occurred in less than 1% of patients receiving indapamide 1.25 mg: hypokalemia, 6% of patients receiving indapamide 5.0 mg, and 8% of patients receiving indapamide 10.0 mg. In the indapamide 1.25 mg group, about 40% of patients who reported hypokalemia had no laboratory evidence of hypokalemia. In 1% of patients receiving indapamide 1.25 mg. From Phase II placebo-controlled studies and long-term controlled clinical trials with LOZOL 2.5 mg and 5.0 mg, adverse reactions 1% cumulative incidence: headache, back pain, diarrhea, nausea, vomiting, abdominal pain or cramps, nausea, abdominal pain, diarrhea, hyperkalemia, cough, pharyngitis, sinusitis, conjunctivitis. Other adverse reactions occurred in less than 1% of patients receiving indapamide 5.0 mg, and 4% of patients receiving indapamide 10.0 mg. In the indapamide 2.5 mg group, about 40% of patients who reported hypokalemia had no laboratory evidence of hypokalemia. In 1% of patients receiving indapamide 2.5 mg. From Phase III placebo-controlled studies and long-term controlled clinical trials with LOZOL 2.5 mg and 5.0 mg, adverse reactions 1% cumulative incidence: headache, back pain, diarrhea, nausea, vomiting, abdominal pain or cramps, nausea, abdominal pain, diarrhea, hyperkalemia, cough, pharyngitis, sinusitis, conjunctivitis. Other adverse reactions occurred in less than 1% of patients receiving indapamide 5.0 mg, and 4% of patients receiving indapamide 10.0 mg. In the indapamide 2.5 mg group, about 40% of patients who reported hypokalemia had no laboratory evidence of hypokalemia. In 1% of patients receiving indapamide 2.5 mg.
JAMA Medical Rounds

News you need from the name you trust. Tune-in to American Medical Television every weekend for JAMA Medical Rounds.

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Ismo
(isosorbide mononitrate)
Activity You Can Count On

Antianginal activity
during the active hours**

Effective day after day2
- Ismo patients were able to exercise at least as well on Day 14 as on Day 1

Predictable pharmacokinetics
- Nearly 100% bioavailable
- No first-pass hepatic metabolism
- Consistent blood levels from patient to patient

*Ismo is active for at least 12 hours after the first dose (ie, 5 hours after the second dose) of each day. The dosing recommendation for Ismo is 20 mg, twice daily, 7 hours apart (with a 17-hour dose-free interval) to maintain efficacy and to avoid tolerance.

Ismo is not recommended for use in aborting acute anginal episodes. The most common side effect, headache, may be managed with simple analgesics. As with other long-acting nitrates, Ismo is not recommended in patients with acute myocardial infarction or congestive heart failure.

Please see brief summary of prescribing information on adjacent page.

This study measured improvement in exercise performance to moderately severe anginal pain in patients given Ismo 20 mg (N = 56) or placebo (N = 60) dosed at 8 AM and 3 PM for 2 weeks following a 1-week washout period.
HOW MUCH HAVE YOUR MIGRAINE PATIENTS TOLD YOU LATELY ABOUT THEIR CURRENT TREATMENT?

“My medicine knocks the pain out, but it knocks me out too...
I guess it's probably the best I can hope for.”
MORE OF YOUR PATIENTS MAY

Because it works fast.¹

The most frequently reported adverse events associated with IMITREX are injection-site reactions (59%), atypical sensations (e.g., tingling, warm/hot sensation) (42%), and dizziness/vertigo (12%). IMITREX is contraindicated in patients with ischemic heart disease, symptoms or signs consistent with ischemic heart disease, or Prinzmetal's angina because of the potential to cause coronary vasospasm. IMITREX is contraindicated in patients with uncontrolled hypertension because it can give rise to increases in blood pressure (usually small). IMITREX should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. (Please see Precautions.) IMITREX should not be administered to patients with basilar or hemiplegic migraine.

BENEFIT FROM IMITREX

Because it works well.¹

Because it is nonsedating.

SUBCUTANEOUS IMITREX
SUMATRIPTAN SUCCINATE

MIGRAINE RELIEF THAT CAN CHANGE PATIENTS' LIVES

Please consult Brief Summary of Prescribing Information on last page of this advertisement.
Intermittent report of altered mental status, including delirium, disorientation, or confusion. Other adverse reactions that have occurred with the use of Sumatriptan injection include: pain or redness at the injection site, atypical sensations (such as sensations of warmth, cold, tingling, or pain), paresthesia, numbness, tingling sensations, or aching, cramping, or tingling sensations in the arms, legs, or trunk (which may be localized or generalized), flushing, chest discomfort (pressure, pain, or tightness), fatigue, dizziness, and flushing. These sensations usually last for several minutes and may occur several times a day.

Treatment- Emergent Adverse Experience: In two large placebo-controlled clinical trials, events reported by at least 1% of patients receiving Imitrex Injection:。。
Just how powerful is it?

The vast majority of patients on PLENDIL receive prescriptions for 5 mg, once daily.*

PLENDIL provides a gradual onset of action for continuous 24-hour blood-pressure control in many patients.

And, PLENDIL is suited to a broad range of your hypertensive patients — including many with concomitant disorders, such as: hypercholesterolemia, diabetes, impaired renal function, COPD, or asthma.

PLENDIL. A highly effective calcium channel blocker for blood pressure control.

Generally well tolerated at usual doses.†

Plendil®

(felodipine) Tablets, 5 mg, 10 mg

Because you consider the whole patient.

*1993 IMS NDTI Prescription Data.
†Peripheral edema, generally mild, was the most common adverse event in clinical trials.
PLENDIL is contraindicated in patients who are hypersensitive to this product. Please see brief summary of Prescribing Information on page following next page.
**BRIEF SUMMARY**

**TABLES**

PLENDEL® (Felodipine) EXTRUDES-RELEASE TABLETS

**INDICATIONS AND USAGE**

PLENDEL® is indicated for the treatment of hypertension. PLENDEL® may be used alone or concomitantly with other antihypertensive agents.

**CONTRAINDICATIONS**

PLENDEL is contraindicated in patients who are hypersensitive to this product.

**PRECAUTIONS**

**General**

Hypotension: Felodipine, like other calcium antagonists, may occasionally precipitate significant hypotension and rarely syncope. It may lead to reflex tachycardia which is susceptible individuals may precipitate significant hypotension and possibly syncope. No specific treatment is necessary. Safety in pregnant patients has not been established. Caution therefore should be exercised when using PLENDEL in pregnant women due to the inherent risk of an intrauterine feto-toxic effect in any animal test.
Here we go again. Another new NSAID.

Is it stronger? Safer? Based on what?

I've heard about micro-this and endo-

that. But if it's not clinically significant,

I'm not interested. I've seen the proof

in my practice. I see it every day.

*keep doing it with NAPROSYN*®
(NAPROXEN) 500 mg tablets

Also available in 375 and 230 mg tablets and in suspension 125 mg/5 mL.

Please see brief summary of full prescribing information on adjacent page.

©1994 Syntax Puerto Rico, Inc. NP94016

Contraindicated in patients hypersensitive to naproxen, aspirin, or other NSAIDs. As with other NSAIDs, the most frequent adverse events are gastrointestinal. With chronic NSAID therapy, serious GI toxicity such as bleeding, ulceration, and perforation can occur. Rare hepatic and renal reactions have been reported.
Government-approved AMA claim forms give you flexibility and value

Whatever your insurance claim form needs, you can count on the AMA for affordability, selection and quality. We have everything from convenience packs for small volume users to special forms for large volume users.

Order #: OP050092IZ
AMA member price: $17.95/package Nonmember price: $21.95/package

Order #: OP050192IZ
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Snap-out Form. 2-part NCR, 1000 carton, Kodak bar code.
Order #: OP050292IZ
AMA member price: $49.95/carton Nonmember price: $59.95/carton

Continuous Form with Bar Code. 2-part NCR with pinfeeds for computer printers, 1000 carton, Kodak bar code.
Order #: OP050392IZ
AMA member price: $55.95/carton Nonmember price: $67.95/carton

To order, call toll free 800 621-8335
MasterCard, VISA, American Express, and Optimia accepted.
State sales taxes and shipping/handling charges apply.

American Medical Association
Physicians dedicated to the health of America
Real Value for Real People with Hypertension

Real Therapeutic Value
• The benefits of long-acting nifedipine therapy for hypertension*1

Real Economic Value
• Lower price (AWP) than Procardia XL® 30 mg, 60 mg and 90 mg—potential 25% savings12

*Not indicated for angina. Take on an empty stomach. Careful titration may be necessary when switching between Procardia XL® and Adalat® CC. Procardia XL is a registered trademark of Pfizer Labs Division, Pfizer Inc.

†Calculations based on suggested Average Wholesale Price (AWP). Please see brief summary of Prescribing Information on back of this page.

Candidate Profile
Name: Steven P.
Age: 67
Residence: Minneapolis
Pretreatment BP: 172/94
Marital Status: Single
Health Ins: Medicare

“Save as much as $111† a year? I could afford to paint the apartment.”
**Adalat CC**

**nifedipine**

**EXTENDED RELEASE TABLETS**

30mg, 60mg & 90mg

---

**BRIEF SUMMARY**

**CONSULT PACKAGE INSERT FOR FULL PRESCRIBING INFORMATION**

For Oral Use

PZ1004748S 5/93

**INDICATION AND USAGE:** ADALAT CC is indicated for the treatment of hypertension. It may be used alone or in combination with other antihypertensive agents.

**CONTRAINDICATIONS:** Known hypersensitivity to nifedipine.

**WARNINGS:** Excessive Hypotension: Although in most patients the hypertensive effect of nifedipine is either absent or poorly tolerated, in patients with severe hypertension, this may be exacerbated. In these patients, an initial reduction of blood pressure must be avoided. Patients with severe uncontrolled hypertension should be treated with caution. Significant hypotension may occur resulting in symptoms such as dizziness, nausea, and headache. If hypotension is severe, discontinuation of nifedipine may be necessary.

**PRECAUTIONS:** General: Hypotension: Nifedipine may cause dizziness or syncope, especially when initiated in patients with severe uncontrolled hypertension. In patients with severe uncontrolled hypertension, nifedipine may cause symptoms such as dizziness, nausea, and headache. If hypotension is severe, discontinuation of nifedipine may be necessary.

**ADVERSE REACTIONS:** The most frequent adverse reactions reported with nifedipine therapy are dizziness, headache, flushing, and flushing.

---

**Real People, Real Needs, Real Value**

---

**Titrate, if necessary**

---

**References:**

1. Data on file, Miles Inc.

---

**MILES Pharmaceutical Division**

Distributed by: Miles Inc.

360 Smith Street

Miles Inc.

Pharmaceutical Division

400 Morgan Lane

West Haven, CT 06516 USA

Made in Germany

© November 1993, Miles Inc., Pharmaceutical Division

XO8903

M-12518
Now for Angina

The One

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

Once a day

Proven 24-hour control of both Angina and Hypertension¹,²

©1993, Marion Merrell Dow Inc.

Please see brief summary of prescribing information on adjacent page.

0115A3
Brief Summary of
Prescribing Information as of October 1992 (2)

CARDIZEM® CD
(diltiazem HCl)

Contraindications

Cardiovascular: Use with caution in patients with cardiogenic shock syndrome, including those with hypotension, severe ventricular dysfunction, or significant atrioventricular block. Use is contraindicated in patients with sinus node dysfunction or complete heart block. Use of CARDIZEM CD in patients with PR-interval prolongation greater than 0.25 seconds or complete atrioventricular block is not recommended. Use with caution in patients with history of prolonged QT interval. Use with caution in patients with sick sinus syndrome. Use with caution in patients with heart failure. Use with caution in patients with peripheral vascular disease, Raynaud's phenomenon, or severe aortic stenosis. Use with caution in patients with ischemic heart disease and cocaine use. Use with caution in patients with aortic stenosis and aortic regurgitation. Use with caution in patients with atrial fibrillation and atrial flutter. Use with caution in patients with angina pectoris and myocardial infarction.

Pregnancy

Category C: Reproduction studies have been conducted in mice, rats, and rabbits. No adverse effects were observed in animals. However, as with other drugs, there is no adequate and well-controlled study in pregnant women. Use only if the potential benefit justifies the potential risk to the fetus.

Nursing Mothers

Cardizem is excreted in human milk. One report suggests that concentrations in breast milk may approximate serum levels. If use of Cardizem is deemed necessary, 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 CARDIZEM CD up to 360 mg with notes in placebo patients shown for comparison.

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>CARDIZEM CD</th>
<th>Placebo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Headache</td>
<td>4.4%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Dizziness</td>
<td>3.7%</td>
<td>3.0%</td>
</tr>
<tr>
<td>Bradycardia</td>
<td>2.9%</td>
<td>1.9%</td>
</tr>
<tr>
<td>AV Block First Degree</td>
<td>3.4%</td>
<td>0.9%</td>
</tr>
<tr>
<td>Edema</td>
<td>2.6%</td>
<td>1.3%</td>
</tr>
<tr>
<td>CG Abnormality</td>
<td>1.6%</td>
<td>1.3%</td>
</tr>
<tr>
<td>Anemia</td>
<td>1.8%</td>
<td>1.7%</td>
</tr>
</tbody>
</table>

In clinical trials of CARDIZEM CD Capsules, CARDIZEM Tablets, and CARDIZEM SR Capsules involving over 300 patients, the most common events (ie, greater than 1%) were edema (4.6%), headache (4.7%), dizziness (3.8%), diarrhea (2.5%), first-degree AV block (2.4%), infections (1.7%), flushing (1.7%), rash (1.7%), and upper respiratory tract infections (1.7%). In addition, the following events were reported infrequently (less than 1%): angina or hypertension.

Cardiovascular: Arrhythmia, edema, AV block (second- or third-degree), bundle branch block, congestive heart failure, ECG abnormalities, hypotension, palpitations, syncpe, arthralgia, urticaria, blurred vision, dizziness, syncope, diaphoresis, flushing, rash, pruritus, hives, angioedema.

Gastrointestinal: Abdominal pain, constipation, diarrhea, dry mouth, dyspepsia, flatulence, nausea, vomiting, anorexia.

Other: Amblyopia, color vision, dry mouth, eye irritation, hyperglycemia, hypothyroidism, impotence, muscle cramps, nasopharyngitis, otitis externa, osteoarthritis, polyuria, urinary difficulties.

The following postmarketing events have been reported infrequently in patients receiving CARDIZEM: alopecia, rashes, urticaria, angioedema, dermatitis, erythema multiforme, exfoliative dermatitis, erythematous rash, hypotension, hypovolemia, hypothyroidism, hyperglycemia, hypertrichosis, impotence, melena, myalgia, oral ulcers, pancreatitis, pruritus, erythema, pruritus, urticaria, and thrombophlebitis. In addition, patients with atrial fibrillation have been observed who are not readily distinguishable from the natural history of the disease in these patients. A number of well-controlled cases of generalized rash, characterized as maculopapular eruptions, have been reported.

A definitive cause and effect relationship between these events and CARDIZEM therapy is yet to be established.

Prescribing Information as of October 1992 (2)

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References:

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