

PDR®
49
EDITION
1995

PHYSICIANS'
DESK
REFERENCE®

Medical Consultant

Ronald Arky, MD, Charles S. Davidson Professor of Medicine and Master, Francis Weld Peabody Society, Harvard Medical School

President and Chief Operating Officer, Drug Information Services Group: William J. Gole

Senior Vice President and

General Manager: Thomas F. Rice

Product Manager: Stephen B. Greenberg

Associate Product Manager: Cy S. Caine

Sales Manager: James R. Pantaleo

Senior Account Manager: Michael S. Sarajian

Account Managers

Dik N. Barsamian

Donald V. Bruccoleri

Lawrence C. Keary

Jeffrey M. Keller

P. Anthony Pinsonault

Anthony Sorce

Commercial Sales Manager: Robin B. Bartlett

Direct Marketing Manager: Robert W. Chapman

Vice President of Production: Steven R. Andrezza

Manager, Professional Data: Mukesh Mehta, RPh

Manager, Database Administration: Lynne Handler

Contracts and Special Services Director: Marjorie A. Duffy

Director of Production: Carrie Williams

Production Managers: Kimberly Hiller-Vivas, Tara L. Walsh

Format Editor: Gregory J. Westley

Index Editor: Jeffrey Schaefer

Art Associate: Joan K. Akerlind

Director of Corporate Communications: Gregory J. Thomas

Digital Photography: Shawn W. Cahill

Digital Prepress Processing: Joanne McCloskey, Richard Weinstock

Editor, Special Projects: David W. Sifton



Copyright © 1995 and published by Medical Economics Data Production Company at Montvale, NJ 07645-1742. All rights reserved. None of the content of this publication may be reproduced, stored in a retrieval system, resold, redistributed, or transmitted in any form or by any means (electronic, mechanical, photocopying, recording, or otherwise) without the prior written permission of the publisher. PHYSICIANS' DESK REFERENCE®, PDR®, PDR For Nonprescription Drugs®, PDR For Ophthalmology®, and The PDR® Family Guide to Prescription Drugs® are trademarks of Medical Economics Data Production Company, registered in the United States Patent and Trademark Office. PDR Guide to Drug Interactions • Side Effects • Indications™, The PDR® Family Guide to Women's Health and Prescription Drugs™, PDR® Library on CD-ROM™, PDR® Drug Interactions/Side Effects/Indications Diskettes™, and Pocket PDR™ are trademarks of Medical Economics Data Production Company.

Officers of Medical Economics: President and Chief Executive Officer: Norman R. Snesil; Executive Vice President and Chief Financial Officer: J. Crispin Ashworth; Senior Vice President of Corporate Operations Group: John R. Ware; Senior Vice President of Corporate Business Development: Raymond M. Zoeller; Vice President of Information Services and Chief Information Officer: Edward J. Zecchini



ISBN: 1-56363-087-7

**DOCKET
ALARM**

Find authenticated court documents without watermarks at docketalarm.com.

Pratt—Cont.

to higher doses. Since steady-state plasma levels are achieved on the second day of dosing, if symptoms so warrant, titration may proceed more rapidly provided the patient is assessed frequently. Titration to doses above 120 mg is not recommended.

Angina patients controlled on Procardia capsules alone or in combination with other antianginal medications may be safely switched to PROCARDIA XL Extended Release Tablets at the nearest equivalent total daily dose (e.g., 30 mg t.i.d. of Procardia capsules may be changed to 90 mg once daily of PROCARDIA XL Extended Release Tablets). Subsequent titration to higher or lower doses may be necessary and should be initiated as clinically warranted. Experience with doses greater than 90 mg in patients with angina is limited. Therefore, doses greater than 90 mg should be used with caution and only when clinically warranted.

No "rebound effect" has been observed upon discontinuation of PROCARDIA XL Extended Release Tablets. However, if discontinuation of nifedipine is necessary, sound clinical practice suggests that the dosage should be decreased gradually with close physician supervision.

Care should be taken when dispensing PROCARDIA XL to assure that the extended release dosage form has been prescribed.

Co-Administration with Other Antianginal Drugs
Sublingual nitroglycerin may be taken as required for the control of acute manifestations of angina, particularly during nifedipine titration. See PRECAUTIONS, Drug Interactions, for information on co-administration of nifedipine with beta blockers or long acting nitrates.

HOW SUPPLIED

PROCARDIA XL® Extended Release Tablets are supplied as 30 mg, 60 mg and 90 mg round biconvex, rose-pink, film-coated tablets in:

Bottles of 100:

- 30 mg (NDC 59012-265-66) (NDC 0069-2650-66)
- 60 mg (NDC 59012-266-66) (NDC 0069-2660-66)
- 90 mg (NDC 59012-267-66) (NDC 0069-2670-66)

Bottles of 300:

- 30 mg (NDC 59012-265-72) (NDC 0069-2650-72)
- 60 mg (NDC 59012-266-72) (NDC 0069-2660-72)

Bottles of 5000:

- 30 mg (NDC 59012-265-94) (NDC 0069-2650-94)
- 60 mg (NDC 59012-266-94) (NDC 0069-2660-94)

Unit dose packages of 100:

- 30 mg (NDC 59012-265-41) (NDC 0069-2650-41)
- 60 mg (NDC 59012-266-41) (NDC 0069-2660-41)
- 90 mg (NDC 59012-267-41)

Store below 86°F (30°C).

Protect from moisture and humidity.

© 1992 PFIZER INC

Pfizer Pratt
Pharmaceuticals

Division of Pfizer Inc, NY, NY 10017

77-4848-00-9

Revised September 1993

Shown in Product Identification Guide, page 324

ZOLOFT®

(sertraline hydrochloride)
Tablets

This product is co-promoted by the Roerig and Pratt Pharmaceuticals Divisions, Pfizer Inc. Please refer to Roerig Division, Pfizer Inc for complete prescribing information, pages 2109-2112

Shown in Product Identification Section, page 327

Procter & Gamble
P.O. BOX 5516
CINCINNATI, OH 45201

ALEVE®

[əˈlev]

Naproxen Sodium Tablets, USP
Pain Reliever/Fever Reducer

ALLERGY WARNING

Do not take this product if you have had either hives or a severe allergic reaction after taking any pain reliever. Even though this product may not contain the same ingredient, ALEVE could cause similar reactions in patients allergic to other pain relieving drugs.

ALCOHOL WARNING

If you generally consume 3 or more alcohol-containing

ACTIVE INGREDIENT

Each [tablet] [caplet] contains naproxen sodium 220 mg (naproxen 200 mg and sodium 20 mg).

INACTIVE INGREDIENTS

Magnesium Stearate, Microcrystalline Cellulose, Povidone, Talc, Opadry YS-1-4215.

INDICATIONS

For the temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, for the minor pain of arthritis, for the pain of menstrual cramps and for the reduction of fever.

DOSAGE AND ADMINISTRATION

Adults: Take one [tablet] [caplet] every 8 to 12 hours while symptoms persist. With experience, some people may find that an initial dose of two [tablets] [caplets] followed by one [tablet] [caplet] 12 hours later, if necessary, will give better relief. Do not exceed three [tablets] [caplets] in 24 hours unless directed to do so by a doctor. The smallest effective dose should be used. A full glass of water or other liquid is recommended with each dose.

Adults over age 65: Do not take more than one [tablet] [caplet] every 12 hours, unless directed to do so by a doctor.

Children under age 12: Do not give this product to children under 12, except under the advice and supervision of a doctor.

GENERAL WARNINGS

Do not take ALEVE for more than 10 days for pain, or for more than 3 days for fever, unless directed by a doctor.

Consult a doctor if:

- * your pain or fever persists or gets worse
- * the painful area is red or swollen
- * you take any other drugs on a regular basis
- * you have had serious side effects from any pain reliever
- * you have any new or unusual symptoms
- * more than mild heartburn, upset stomach, or stomach pain occurs with use of this product or if even mild symptoms persist

Although naproxen sodium is indicated for the same conditions as aspirin, ibuprofen and acetaminophen, it should not be taken with them or other naproxen-containing products except under a doctor's direction. As with any drug, if you are pregnant or nursing a baby, seek the advice of a health professional before using this product. IT IS ESPECIALLY IMPORTANT NOT TO USE NAPROXEN SODIUM DURING THE LAST 3 MONTHS OF PREGNANCY UNLESS SPECIFICALLY DIRECTED TO DO SO BY A DOCTOR BECAUSE IT MAY CAUSE PROBLEMS IN THE UNBORN CHILD OR COMPLICATIONS DURING DELIVERY. KEEP THIS AND ALL DRUGS OUT OF THE REACH OF CHILDREN. In case of accidental overdose, seek professional assistance or contact a poison control center immediately. If you have questions, comments or problems, call 1-800-395-0689 to report them.

HOW SUPPLIED

Light blue round tablets or oval-shaped caplets debossed with "ALEVE". Child-resistant "Safety SquEASE" bottles of 24, 50, and 100 tablets or caplets, with fold-out back label on the 24 and 50 count bottles containing important information.

STORAGE

Store at room temperature (typically 59–85°F or 15–30°C). Avoid excessive heat (104°F or 40°C).

CHILDREN'S VICKS® CHLORASEPTIC® SORE THROAT LOZENGES
Benzocaine/Oral Anesthetic

(See PDR For Nonprescription Drugs.)

CHILDREN'S VICKS® CHLORASEPTIC® SORE THROAT SPRAY
Phenol/Oral Anesthetic/Antiseptic

(See PDR For Nonprescription Drugs.)

CHILDREN'S VICKS® DAYQUIL®
Allergy Relief
Nasal Decongestant/Antihistamine

CHILDREN'S VICKS® NYQUIL®
Cold/Cough Relief
Antihistamine/Nasal Decongestant/Cough Suppressant

(See PDR For Nonprescription Drugs.)

HEAD & SHOULDERS® DANDRUFF SHAMPOO

(See PDR For Nonprescription Drugs.)

HEAD & SHOULDERS® DRY SCALP DANDRUFF SHAMPOO

(See PDR For Nonprescription Drugs.)

HEAD & SHOULDERS® INTENSIVE TREATMENT DANDRUFF AND SEBORRHEIC DERMATITIS SHAMPOO

(See PDR For Nonprescription Drugs.)

METAMUCIL®
[met uh-mu si]
(psyllium hydrophilic mucilloid)

DESCRIPTION

Metamucil contains a bulk forming natural therapeutic for restoring and maintaining regularity as recommended by a physician. It contains psyllium hydrophilic mucilloid, a highly efficient fiber derived from the husk of the psyllium seed (*Plantago ovata*). Metamucil contains chemical stimulants and does not disrupt normal bowel function. Each dose contains approximately 3.4 grams of psyllium hydrophilic mucilloid. Inactive ingredients, sodium potassium, calories, carbohydrate, fat and phenylalanine content are shown in Table 1 for all forms and flavors. traSweet® brand sweetener (aspartame) is used in flavo sugar-free Metamucil powdered products. Phenylketonou should be aware that phenylalanine is present in Metamucil products that contain Nutrasweet®. Metamucil Sugar-I Regular Flavor contains no sugar and no artificial sweeteners.

Metamucil in powdered forms is gluten-free. Wafers contain: Apple Crisp contains 0.7g/dose, Cinnamon S contains 0.5g/dose.

ACTIONS

The active ingredient in Metamucil is psyllium, a natural fiber which promotes elimination due to its bulking effect on the colon. This bulking effect is due to both the water-holding capacity of undigested fiber and the increased bacterial fermentation following partial fiber digestion. These actions result in enlargement of the lumen of the colon, and softer stool, thereby decreasing intraluminal pressure and straining, and speeding colonic transit in constipated patients.

INDICATIONS

Metamucil is indicated in the management of chronic constipation, in irritable bowel syndrome, as adjunctive therapy in the constipation of diverticular disease, in the bowel management of patients with hemorrhoids, and for constipation associated with convalescence and senility and for occasional constipation during pregnancy when under the care of a physician. Pregnancy: Category B.

CONTRAINDICATIONS

Intestinal obstruction, fecal impaction.
Known allergy to any component.

WARNINGS

Patients are advised they should not use the product without consulting a doctor when abdominal pain, nausea, or vomiting are present or if they have noticed a sudden change in bowel habits that persists over a period of 2 weeks, or rectal bleeding. Patients are advised to consult a physician if constipation persists for longer than one week, as this may be a sign of a serious medical condition. PATIENTS ARE CAUTIONED THAT TAKING THIS PRODUCT WITHOUT ADEQUATE FLUID MAY CAUSE IT TO SWELL AND BLOCK THE THROAT OR ESOPHAGUS AND MAY CAUSE CHOKING. THEY SHOULD NOT TAKE THE PRODUCT IF THEY HAVE DIFFICULTY IN SWALLOWING. IF THEY EXPERIENCE CHEST PAIN, VOMITING, OR DIFFICULT SWALLOWING OR BREATHING AFTER TAKING THIS PRODUCT, THEY ARE ADVISED TO SEEK IMMEDIATE MEDICAL ATTENTION. Psyllium products may cause a allergic reaction in people sensitive to inhaled or ingested