PDR®

46 EDITION

1992

PHYSICIANS' DESK REFERENCE®

PDR®

46 EDITION

1992

PHYSICIANS' DESK REFERENCE®

Director of Production:
MARJORIE A. DUFFY

Assistant Director of Production:
CARRIE WILLIAMS

Manager of Production Services:
ELIZABETH H. CARUSO

Format Editor:
MILDRED M. SCHUMACHER

Production Coordinator:
ELIZABETH A. KARST

Art Associate:
JOAN K. AKERLIND

Medical Consultant:
LOUIS V. NAPOLITANO, MD

Product Manager:
JOHN A. MALCZYNSKI

Sales Manager:
CHARLIE J. MEITNER

Account Managers:
CHAD E. ALCORN
MICHAEL S. SARAJIAN
JOANNE C. TERZIDES

Commercial Sales Manager:
ROBIN B. BARTLETT

Direct Marketing Manager:
ROBERT W. CHAPMAN

Manager, Professional Data:
MUKESH MEHTA, R.Ph.

Index Editor:
ADELE L. DOWD

Officers of Medical Economics Data, a division of Medical Economics Company Inc.: President and Chief Executive Officer: Norman R. Snesil; Senior Vice President and Chief Financial Officer: Joseph T. Deithorn; Senior Vice President of Business Development, Stephen J. Sorkenn; Senior Vice President of Operations: Mark L. Weinstein; Vice President, Sales and Marketing: Thomas F. Rice; Vice President of Circulation: Scott I. Rockman; Vice President of Information Services: Edward J. Zecchini.

ISBN 1-56363-003-6

Whitehall—Cont.

RIOPAN PLUS® OTC

[*rī'opan*]
magaldrate and simethicone
Antacid Plus Anti-Gas

DESCRIPTION

Riopan Plus is a buffer antacid plus anti-gas combination product containing the unique chemical entity Magaldrate. Each teaspoonful (5mL) of suspension contains Magaldrate, 540 mg and Simethicone, 40 mg. Each Chew Tablet contains Magaldrate, 480 mg and Simethicone, 20 mg. Riopan Plus is considered dietetically sodium-free [containing not more than 0.013 mEq. (0.3 mg.) sodium per teaspoonful or 0.004 mEq. (0.1 mg.) sodium per tablet.]

ACTIONS

The active antacid ingredient in Riopan Plus, Magaldrate, demonstrates a rapid and uniform buffering action. The acid-neutralizing capacity of Riopan Plus is 15.0 mEq per 5mL and 13.5 mEq per tablet. Riopan Plus does not produce acid rebound or alkalinization. Simethicone reduces the surface tension of gas bubbles so that the gas is more easily eliminated.

INDICATIONS

RIOPAN Plus is indicated for the relief of heartburn, sour stomach and acid indigestion accompanied by the symptoms of gas. For symptomatic relief of hyperacidity associated with the diagnosis of peptic ulcer, gastritis, peptic esophagitis, gastric hyperacidity, hiatal hernia, and postoperative gas pain.

DOSAGE AND ADMINISTRATION

RIOPAN PLUS (magaldrate and simethicone) Antacid Plus Anti-Gas *Suspension*—Take one or two teaspoonfuls between meals and at bedtime, or as directed by the physician.
RIOPAN PLUS Antacid Plus Anti-Gas *Chew Tablets*—Chew one or two tablets, between meals and at bedtime, or as directed by the physician.

WARNINGS

Patients should not take more than 12 teaspoonfuls, or 25 tablets, in a 24-hour period or use the maximum dosage for more than two weeks, except under the advice and supervision of a physician. If you have kidney disease, do not use this product except under the advice and supervision of a physician.

DRUG INTERACTION PRECAUTION

Do not use in patients presently taking a prescription antibiotic drug containing any form of tetracycline.

INACTIVE INGREDIENTS

Chew Tablets: Flavor, Magnesium Stearate, Methylcellulose, Polyethylene Glycol, Silica, Sorbitol, Starch, Sucrose, Titanium Dioxide. Suspension: Flavor, Glycerin, PEG-8 Stearate, Potassium Citrate, Saccharin, Sorbitan Stearate, Sorbitol, Xanthan Gum, Water.

HOW SUPPLIED

RIOPAN PLUS Antacid Plus Anti-Gas *Suspension*—in 12 fl oz (355 mL) plastic bottles. Individual Cups, 1 fl oz (30 mL) ea., tray of 10—10 trays per packer.
Store at room temperature (approximately 25°C). Avoid freezing.
RIOPAN PLUS Antacid Plus Anti-Gas *Chew Tablets*—in bottles of 60 and 100. Also single rollpacks of 12 tablets and 3-roll rollpacks of 36 tablets.

Shown in Product Identification Section, page 434

RIOPAN PLUS® 2 OTC

[*rī'opan plus 2*]
magaldrate and simethicone Double Strength Antacid plus Anti-Gas

DESCRIPTION

Riopan Plus 2 is a double strength buffer antacid plus anti-gas combination product containing the unique chemical entity Magaldrate. Each teaspoonful (5 mL) of suspension contains Magaldrate, 1080 mg and Simethicone, 40 mg. Each Chew Tablet contains Magaldrate, 1080 mg and Simethicone, 20 mg. Riopan Plus 2 is considered dietetically sodium-free [containing not more than 0.013 mEq, (0.3) mg sodium per teaspoonful or 0.021 mEq, (0.5 mg) sodium per tablet.]

ACTIONS

The active antacid ingredient in Riopan Plus 2, Magaldrate, demonstrates a rapid and uniform buffering action. The acid-neutralizing capacity of Double Strength Riopan Plus 2

INDICATIONS

RIOPAN PLUS 2 is indicated for the relief of heartburn, sour stomach and acid indigestion accompanied by the symptoms of gas. For symptomatic relief of hyperacidity associated with the diagnosis of peptic ulcer, gastritis, peptic esophagitis, gastric hyperacidity, hiatal hernia, and postoperative gas pain.

DOSAGE AND ADMINISTRATION

RIOPAN PLUS 2 (magaldrate and simethicone) Antacid plus Anti-Gas *Suspension*—Take one or two teaspoonfuls between meals and at bedtime, or as directed by the physician.
RIOPAN PLUS 2 Antacid plus Anti-Gas *Chew Tablets*—Chew one or two tablets, between meals and at bedtime, or as directed by physician.

WARNINGS

Patients should not take more than 12 teaspoonfuls (or 25 tablets) in a 24-hour period nor use the maximum dosage for more than two weeks, nor use if they have kidney disease, except under the advice and supervision of a physician.

DRUG INTERACTION PRECAUTION

Do not use in patients presently taking a prescription antibiotic drug containing any form of tetracycline.

INACTIVE INGREDIENTS

Chew Tablets: Flavor, Magnesium Stearate, Methylcellulose, Polyethylene Glycol, Saccharin, Silica, Sorbitol, Starch, Sucrose, Titanium Dioxide. Suspension: Flavor, Glycerin, PEG-8 Stearate, Potassium Citrate, Saccharin, Sorbitan Stearate, Sorbitol, Xanthan Gum, Water.

HOW SUPPLIED

RIOPAN PLUS 2 *Suspension*—in 12 fl oz (355 mL) plastic bottles and 6 fl oz (176 mL) plastic bottles. Available in mint and cherry vanilla flavors.
Store at room temperature (approximately 25°C). Avoid freezing.
RIOPAN PLUS 2 Chew Tablets—in bottles of 60. Available in mint and cherry vanilla flavors.

Shown in Product Identification Section, page 435

SEMICID® OTC

[*sĕm'ĕ-sīd*]
Vaginal Contraceptive Inserts

DESCRIPTION

Semicid is a safe and effective, non-systemic, reversible method of birth control. Each vaginal contraceptive insert contains 100 mg of the spermicide nonoxynol-9. It contains no hormones and is odorless and non-messy.
When used consistently and according to directions, the effectiveness of Semicid is approximately equal to vaginal foam contraceptives, but less than the pill or diaphragm.
Semicid requires no applicator and has no unpleasant taste. Unlike foams, creams and jellies, Semicid does not drip or run, and Semicid inserts are easier to use than the diaphragm. Also, Semicid does not effervesce like some inserts, so it is not as likely to cause a burning feeling.

ACTIONS

Semicid dissolves in the vagina and blends with natural vaginal secretions to provide double birth control protection: an effective sperm killing barrier plus a physical barrier that covers the cervical opening and adjoining vaginal walls.

INDICATION

For the prevention of pregnancy.

WARNINGS

Do not insert in urethra. Do not take orally. If irritation occurs, discontinue use. If irritation persists, consult a physician. Keep this and all contraceptives out of the reach of children.

PRECAUTIONS

As with all spermicides, some Semicid users may experience irritation in using the product, but most women can use Semicid safely and without irritation.
If douching is desired, one should wait at least six hours after intercourse before douching. If either partner experiences irritation, discontinue use. If irritation persists, consult a physician.
If a menstrual period is missed, a physician should be consulted.

DOSAGE AND ADMINISTRATION

To use, unwrap one insert and insert it deeply into the vagina. It is essential that Semicid be inserted at least 15 min-

INACTIVE INGREDIENTS

Benzethonium Chloride, Citric Acid, D&C Red #21 Lake, D&C Red #33 Lake, Methylparaben, Polyethylene Glycol, Water.

HOW SUPPLIED

Individually-wrapped inserts in Strip packaging of 10's and 20's.
Store at room temperature (not over 86°F or 30°C).

Shown in Product Identification Section, page 435

TODAY® OTC

[*tü-dā*]
Vaginal Contraceptive Sponge

DESCRIPTION

Today Vaginal Contraceptive Sponge is a soft polyurethane foam sponge containing nonoxynol-9, a spermicide used by millions of women for over 25 years.
Today Sponge is Effective, Safe, and Convenient. Today Sponge provides 24-hour contraceptive protection without hormones, allowing spontaneity. Today Sponge is easy to use, non-messy, and disposable.

ACTIVE INGREDIENT

Each Today Sponge contains nonoxynol-9, one gram.

INACTIVE INGREDIENTS

Benzoic acid, citric acid, sodium dihydrogen citrate, sodium metabisulfite, sorbic acid, water in a polyurethane foam sponge.

INDICATION

For the prevention of pregnancy.

ACTIONS

Used as directed, Today Vaginal Contraceptive Sponge prevents pregnancy in three ways: 1) the spermicide nonoxynol-9 kills sperm before they can reach the egg; 2) Today Sponge traps and absorbs sperm; 3) Today Sponge blocks the cervix so that sperm cannot enter.
Today Sponge is designed for easy insertion into the vagina. It is positioned against the cervix, and while in place provides protection against pregnancy for 24 hours. The soft polyurethane foam sponge is formulated to feel like normal vaginal tissue and has a specially-designed ribbon loop attached to an interior web for maximum strength.
In clinical trials of Today Sponge in over 1,800 women worldwide who completed over 12,000 cycles of use, the method-effectiveness, i.e., the level of effectiveness seen in women who followed the printed instructions exactly and who used Today Sponge every time that they had intercourse, was 89 to 91%.

INSTRUCTIONS

Remove one Today Sponge from airtight inner pack, wet thoroughly with clean tap water, and squeeze gently several times until it becomes very sudsy. The water activates the spermicide. Fold the sides of Today Sponge upward until it looks long and narrow and then insert it deeply into the vagina with the string loop dangling below. Protection begins immediately and continues for 24 hours. It is not necessary to add creams, jellies, foams, or any other additional spermicide as long as Today Sponge is in place, no matter how many acts of intercourse may occur during a 24-hour period. Always wait 6 hours after your last act of intercourse before removing Today Sponge. If you have intercourse when Today Sponge has been in place for 24 hours, it must be left in place an additional 6 hours after intercourse before removing it.
To remove Today Sponge, place a finger in the vagina and reach up and back to find the string loop. Hook a finger around the loop. Slowly and gently pull the Sponge out. Some women, especially first-time users, may have difficulty removing the Sponge. This situation may be due to tension or unusually strong muscular pressure. Simple relaxation of the vaginal muscles and bearing down should make it possible to remove the Sponge without difficulty. See User Instruction Booklet (Section 7) for details on removing Today Sponge or call the Today TalkLine 1-800-223-2329.

WARNINGS

Some cases of Toxic Shock Syndrome (TSS) have been reported in women using barrier contraceptives including Today® Sponge. Although the occurrence of TSS is uncommon, some studies indicate that there is an increased risk of non-menstrual TSS with the use of barrier contraceptives, including Today Sponge. Today Sponge should not be left in place for more than 30 hours after insertion. If you experience two or more of the warning signs of TSS including fever, vomiting, diarrhea, muscular pain, dizziness, and rash similar to sunburn, consult your physician or clinic immediately. If you have difficulty removing the sponge from your vagina

before using this product. If you have ever had Toxic Shock Syndrome do not use Today Sponge.
A small number of men and women may be sensitive to the spermicide in this product (nonoxynol-9) and should not use this product if irritation occurs and persists. If you or your partner have ever experienced an allergic reaction to the spermicide used in this product, it is best to consult a physician before using Today Vaginal Contraceptive Sponge. If either you or your partner develops burning or itching in the genital area, stop using this product and contact your physician.
A higher degree of protection against pregnancy will be afforded by using another method of contraception in addition to a spermicidal contraceptive. This is especially true during the first few months, until you become familiar with the method. In our clinical studies, approximately one-half of all accidental pregnancies occurred during the first three months of use. Where avoidance of pregnancy is essential, the choice of contraceptive should be made in consultation with a doctor or a family planning clinic Any delay in your menstrual period may be an early sign of pregnancy. If this happens, consult your physician or clinic as soon as possible.
In case of accidental ingestion of Today Sponge, call a poison control center, emergency medical facility or doctor (For most people ingestation of small quantities of spermicide alone should not be harmful.) As with any drug, if you are pregnant or nursing a baby, seek professional advice before using this product.

HOW TO STORE

Store at normal room temperature.

HOW SUPPLIED

Packages of 3s, 6s, and 12s.
Shown in Product Identification Section, page 435

EDUCATIONAL MATERIAL

Books—Booklets—Brochures
Today Sponge patient pamphlet available to physicians, pharmacists, and patients.
Pictures—Charts
8½× 11 laminated Instructions for Use chart available to physicians.
Write to: TalkLine, Whitehall Laboratories, 685 Third Ave., New York, NY 10017, or call toll-free 1-800-223-2329.

Willen Drug Company
18 NORTH HIGH STREET
BALTIMORE, MD 21202

BICITRA®—Sugar-Free ℞
[bye "si-trah]
(Sodium Citrate & Citric Acid
Oral Solution USP)

DESCRIPTION

BICITRA is a pleasant tasting oral alkalinizing agent and a fast-acting nonparticulate antacid.
BICITRA contains in each tablespoonful (15 mL):
SODIUM CITRATE Dihydrate ..... 1500 mg (0.34 Molar)
CITRIC ACID Monohydrate ..... 1002 mg (0.32 Molar)
Each mL contains 1 mEq Sodium ion and is equivalent to 1 mEq Bicarbonate (HCO_3).
BICITRA is sugar free and nonalcoholic. BICITRA is the highly palatable, improved SHOHL'S Solution.

CLINICAL PHARMACOLOGY

Sodium Citrate is absorbed and metabolized to sodium bicarbonate, thus acting as a systemic alkalizer. The effects are essentially those of chlorides before absorption and those of bicarbonates subsequently. Oxidation is virtually complete so that less than 5% of the citrate is excreted in the urine unchanged. BICITRA is a useful antacid for effectively buffering gastric acid, offering a maximum buffering capacity due to its equimolar ratio of Sodium Citrate to Citric Acid on a 1:1 basis.

INDICATIONS AND ADVANTAGES

BICITRA is useful for conditions requiring long-term maintenance of an alkaline urine, as in patients where dissolution and control of uric acid and cystine calculi of the urinary tract is indicated, especially when the administration of potassium salts is undesirable or contraindicated. It is highly valuable in preventing uric acid nephropathy when administered to patients with hyperuricosuria due to underlying metabolic defects (e.g. gout), or who are receiving drugs (e.g. may result from renal insufficiency or renal tubular acidosis, where the administration of Sodium Citrate may be preferable.
BICITRA is concentrated, and when administered after meals and before bedtime, maintains an alkaline pH without the need for a 2 A.M. dose. In the recommended dosage, BICITRA alkalinizes the urine without producing systemic alkalosis.
BICITRA is a fast-acting nonparticulate buffering agent and is useful for raising gastric pH. BICITRA has a rapid onset of action, and is decidedly advantageous over particulate aluminum-magnesium containing antacids as a preanesthesia medication. BICITRA offers these advantages over Shohl's Solution, while supplying equivalent alkalinizing effect and sodium content.
BICITRA is pleasant tasting and highly tolerable, even when administered for long periods.

CONTRAINDICATIONS

Patients on sodium-restricted diets or with severe renal impairment. POLYCITRA-K or POLYCITRA-K CRYSTALS is recommended in those clinical situations where administration of Potassium Citrate is preferred.

PRECAUTIONS

Should be used with caution by patients with low urinary output unless under the supervision of a physician. Patients with renal insufficiency should not ingest BICITRA concurrently with aluminum-based antacids used as phosphate binders. Patients should be directed to dilute adequately with water and preferably to take each dose after meals to avoid saline laxative effect. Sodium salts should be used cautiously in patients with cardiac failure, hypertension, impaired renal function, peripheral and pulmonary edema and toxemia of pregnancy. Periodic examinations of serum electrolytes, particularly serum bicarbonate level, should be carried out in those patients with renal disease in order to avoid these complications.

ADVERSE REACTIONS

BICITRA is generally well tolerated without any unpleasant side effects when given in recommended doses to patients with normal renal function and urinary output. However, as with any alkalinizing agent, caution must be used in certain patients with abnormal renal mechanisms to avoid development of alkalosis, especially in the presence of hypocalcemia.

DOSAGE AND ADMINISTRATION

BICITRA should be taken diluted in water followed by additional water, if desired.
For Systemic Alkalization: Usual Adult Prescribing Limits: Up to 150 mL daily. Occasional patients may require more or less to achieve the desired alkalinizing effect, and since 1 mEq Sodium and 1 mEq Citrate is supplied per each mL, dosage is easy to regulate. To check urinary pH, HYDRION Paper (pH 6.0-8.0) or NITRAZINE Paper (pH 4.5-7.5) are available and easy to use.
Usual Adult Dose: 10 to 30 mL, diluted in 1 to 3 ounces of water or juice, after meals and at bedtime.
Usual Pediatric Dose: 5 to 10 mL diluted in 1 to 3 ounces of water or juice, after meals and at bedtime.
As a Neutralizing Buffer: 15 mL to 30 mL, taken as a single dose, or diluted, if desired, with 15 mL to 30 mL water, or as directed by physician.

OVERDOSAGE

Overdosage with sodium salts may cause diarrhea, nausea and vomiting, hypernoia, and convulsions.

HOW SUPPLIED

BICITRA—
16 fl oz. (473 mL) (NDC 11414-207-01);
4 fl oz (120 mL) (NDC 11414-207-04);
1 gallon (3785 mL) (NDC 11414-207-08);
15 mL Unit-Dose (NDC 11414-207-15);
30 mL Unit-Dose (NDC 11414-207-30).

NEUTRA-PHOS® Powder, Packets & Capsules OTC
NEUTRA-PHOS®-K Powder, Packets & Capsules OTC
[new "trah foss']
Oral Phosphorus Dietary Supplement

NEUTRA-PHOS and NEUTRA-PHOS-K supply the physiologically important element—PHOSPHORUS—as inorganic orthophosphate, in a well tolerated oral compound. Each contains a chemically balanced combination of readily soluble inorganic phosphates, affording a very high source of elemental Phosphorus. Both products supply equal concentration of elemental Phosphorus.
NEUTRA-PHOS is a stable powder combination of monobasic and dibasic Sodium and Potassium Phosphates.
NEUTRA-PHOS-K is a stable sodium-free powder combination of monobasic and dibasic Potassium Phosphates intended for oral use in low sodium diets.

INDICATIONS

NEUTRA-PHOS and NEUTRA-PHOS-K are recommended as oral Phosphorus supplements, particularly if the diet supplies an insufficient quantity of Phosphorus, or if metabolic requirements for Phosphorus are increased. In addition, NEUTRA-PHOS and NEUTRA-PHOS-K are useful in the treatment of children and adults with conditions associated with excessive renal phosphate loss or inadequate gastrointestinal absorption of phosphate. They are also useful as an adjunct supplement in the management of phosphate diabetes.

ADVANTAGES

NEUTRA-PHOS and NEUTRA-PHOS-K, reconstituted to an oral liquid, provide a chemically balanced supply of Phosphorus in a pH neutral solution that shows rapid absorption and utilization from the alimentary tract. These liquid products have the advantage over coated or uncoated tablets, as slowly dissolving tablets may cause local gastrointestinal irritation or inflammation in sensitive individuals. Both products are highly concentrated and thus economically provide inorganic Phosphate. They are especially useful for long term maintenance of an adequate daily supply of Phosphorus. NEUTRA-PHOS supplies Sodium and Potassium in equimolar proportions—a decided advantage over products which supply a high amount of sodium and a low amount of potassium per dose. NEUTRA-PHOS-K supplies only Potassium and is recommended when a low sodium intake is indicated.

ELECTROLYTES SUPPLIED

75 mL of the reconstituted solution or contents of 1 packet or 1 capsule supplies:

NEUTRA-PHOS

Electrolyte	mg	mEq	mg/mL
Phosphorus	250	14.25	3.33
Phosphate (PO_4)	765	—	10.20
Sodium	164	7.125	2.18
Potassium	278	7.125	3.70

NEUTRA-PHOS-K

Electrolyte	mg	mEq	mg/mL
Phosphorus	250	14.25	3.33
Phosphate (PO_4)	765	—	10.20
Sodium	none	none	none
Potassium	556	14.25	7.41

OSMOLALITY

NEUTRA-PHOS Solution*: 223–236 milliosmols per kg (mOsm/kg)
NEUTRA-PHOS-K Solution*: 240–244 milliosmols per kg (mOsm/kg)
(*reconstituted in water as per label directions. Refer to Packets and Capsules description.)

AVERAGE DIRECTIONS FOR ADULTS AND CHILDREN

4 or more years of age: 75 mL of the oral solution, or contents of 1 packet or capsule, equivalent to 250 mg Phosphorus, taken 4 times a day. (See Packets and Capsules description.)

PEDIATRIC DOSE

Infants and children under 4 years of age: 60 mL of the oral solution, equivalent to 200 mg of Phosphorus, taken 4 times a day.

USUAL DOSE RANGE

75 mL to 600 mL of the oral solution, or contents of 1 to 8 packets or capsules (equivalent from 250 mg to 2 grams of Phosphorus) taken daily in divided doses, after meals and at bedtime.*
75 mL of the reconstituted solution, 1 packet, or 1 capsule, 4 times a day, supplies 1 g Phosphorus. 150 mL of the reconstituted solution, 2 packets, or 2 capsules, 3 times a day, supplies 1.5 g Phosphorus. Phosphorus. (See Packets and Capsules description).*

PRECAUTIONS AND SIDE EFFECTS

Reconstitute powder and contents of packets and capsules as directed before taking. Occasionally some individuals may experience a mild laxative effect for the first day or two when beginning to use NEUTRA-PHOS. If this persists to an unpleasant degree, reduce the daily intake until this effect subsides or, if necessary, discontinue its use. NEUTRA-PHOS-K contains FD&C Yellow #6.

(*This U.S. R.D.A. for Phosphorus is 0.8 g for children 1 to 10