New products and services briefing

The new products and services listed below were selected by the editors based on potential interest to JAOA's *readers. Listings are prepared from information supplied by the companies cited or by their agents and are presented for informational value only. Publication in no way constitutes endorsement or warranty by the* JOURNAL OF THE AMERICAN OSTEOPATHIC ASSOCIATION *or by the American Osteopathic Association. In contacting companies, please mention* JAOA.

Warning aid for insulin reaction

A watch-like monitor emits an audible alarm when sensors detect perspiration or a drop in skin temperature on the wrist. The device is intended to awaken diabetics when either of these symptoms of hypoglycemia occur during sleep. It is the responsibility of the patient to determine by other means if hypoglycemia is occurring and needs to be treated. The monitor operates on 2 hearing aid type batteries. For more details on the Sleep Sentry®, contact Teledyne Avionics, P.O. Box 6098, Charlottesville, Virginia 22906 (216) 267-2700.

Broad-spectrum Primaxin

Primaxin® (imipenem-cilastatin sodium/MSD) is a broad spectrum antibiotic that is effective against gram-positive and gram-negative aerobic and anaerobic bacteria. The injectable drug also has a high degree of activity against organisms resistant to penicillin and cephalosporin. Primaxin belongs to the new class of beta-lactam antibiotics, and is intended for the intravenous treatment of serious infections in every major body site. For more information on Primaxin, contact Merck Sharp & Dohme, West Point, Pennsylvania 19486 (215) 661-6681.

Software that coordinates medication

A computer compares each drug in a patient's medication profile to other drugs, medical conditions, and allergies. Individual physicians maintain the program through their own computer terminals, and input medications being prescribed by the primary physician, dentist, specialists, and over-the-counter purchases. Special warnings are issued on such problems as sun exposure, urine/stool changes to be expected, and which foods or vitamin supplements to avoid. For more information on the Therapy Coordinator™, write to Lisjoy Computer Corporation, P.O. Box 25775, Tamarac, Florida 33320.

Home pregnancy test

An improved home pregnancy test can be performed as early as 1 day after a woman misses her menstrual period, and give results within 10 minutes. The original e.p.t. kit was a 9-day, 2-hour test. The test utilizes a monoclonal antibody technology to detect the presence of human chorionic gonadotropin (HCG) in the urine. Any color change in the intense red buffer solution indicates pregnancy. For more information on e.p.t. Plus, contact Warner-Lambert Consumer Health Products Division, 201 Tabor Road, Morris Plains, New Jersey 07950 (201) 540-2000.

Chewable calcium supplement

A chewable tablet has entered the Os-Cal® line of calcium supplements. Each chewable tablet contains 500 mg. of elemental calcium, and joins Os-Cal's 500 mg. and 250 mg. nonchewable supplements currently on the market. The tablets come in a 60-count bottle and are "Bavarian cream" flavored. For more information, write Marion Laboratories, P.O. Box 9627, Kansas City, Missouri 64137 (816) 966-5000.

Sulfanilamide cream

A new vaginal cream contains sulfanilamide as the sole ingredient, as per the Food and Drug Administration mandate that aminacrine and allantoin be removed from all vaginal cream and suppository products. The new formula is available in 4 oz. tubes. For more information on Vagitrol (sulfanilamide 15%) Vaginal Cream, call or write the Lemmon Company, P.O. Box 630, Sellersville, Pennsylvania 18960 (800) 523-6542.

Portable electrocardiograph

A portable single-channel electrocardiograph is designed for the private practitioner's office. The 12-lead unit features automatic stylus positioning and automatic sensitivity. The compact device weighs 4 lbs., runs on rechargeable batteries or AC current, and has an optional carrying case. For further details on the electrocardiograph, contact Circadian, Inc., 3960 North First Street, San Jose, California 95134 (408) 943-9222.

Familiar therapy in a convenient form

For acute otitis media in children*

*caused by susceptible strains of *Hemophilus influenzae* (including ampicillin-resistant strains)

ROSS LABORATORIES
COLUMBUS, OHIO 43216
Division of Abbott Laboratories, USA

B131/2810

Pediazole®

erythromycin ethylsuccinate and sulfisoxazole acetyl for oral suspension

(200 mg erythromycin activity and the equivalent of 600 mg sulfisoxazole per 5 ml)

Please see adjacent column for brief summary of prescribing information.

Pediazole®

erythromycin ethylsuccinate
and sulfisoxazole acetyl
for oral suspension

BRIEF SUMMARY:
Please see package enclosure for full prescribing information.

Indication
For treatment of ACUTE OTITIS MEDIA in children caused by susceptible strains of *Hemophilus influenzae.*

Contraindications
Known hypersensitivity to either erythromycin or sulfonamides.
Infants less than 2 months of age.
Pregnancy at term and during the nursing period, because sulfonamides pass into the placental circulation and are excreted in human breast milk and may cause kernicterus in the infant.

Warnings
Usage in Pregnancy (SEE ALSO: CONTRAINDICATIONS): The safe use of erythromycin or sulfonamides in pregnancy has not been established. The teratogenic potential of most sulfonamides has not been thoroughly investigated in either animals or humans. However, a significant increase in the incidence of cleft palate and other bony abnormalities of offspring has been observed when certain sulfonamides of the short, intermediate and long-acting types were given to pregnant rats and mice at high oral doses (7 to 25 times the human therapeutic dose).
Reports of deaths have been associated with sulfonamide administration from hypersensitivity reactions, agranulocytosis, aplastic anemia and other blood dyscrasias. The presence of clinical signs such as sore throat, fever, pallor, purpura or jaundice may be early indications of serious blood disorders. Complete blood counts should be done frequently in patients receiving sulfonamides.
The frequency of renal complications is considerably lower in patients receiving the most soluble sulfonamides such as sulfisoxazole. Urinalysis with careful microscopic examination should be obtained frequently in patients receiving sulfonamides.

Precautions
Erythromycin is principally excreted by the liver. Caution should be exercised in administering the antibiotic to patients with impaired hepatic function. There have been reports of hepatic dysfunction, with or without jaundice occurring in patients receiving oral erythromycin products.
Recent data from studies of erythromycin reveal that its use in patients who are receiving high doses of theophylline may be associated with an increase of serum theophylline levels and potential theophylline toxicity. In case of theophylline toxicity and/or elevated serum theophylline levels, the dose of theophylline should be reduced while the patient is receiving concomitant erythromycin therapy.
Surgical procedures should be performed when indicated.
Sulfonamide therapy should be given with caution to patients with impaired renal or hepatic function and in those patients with a history of severe allergy or bronchial asthma. In the presence of a deficiency in the enzyme glucose-6-phosphate dehydrogenase, hemolysis may occur. This reaction is frequently dose-related. Adequate fluid intake must be maintained in order to prevent crystalluria and renal stone formation.

Adverse Reactions
The most frequent side effects of oral erythromycin preparations are gastrointestinal, such as abdominal cramping and discomfort, and are dose-related. Nausea, vomiting and diarrhea occur infrequently with usual oral doses. During prolonged or repeated therapy, there is a possibility of overgrowth of nonsusceptible bacteria or fungi. If such infections occur, the drug should be discontinued and appropriate therapy instituted. The overall incidence of these latter side effects reported for the combined administration of erythromycin and a sulfonamide is comparable to those observed in patients given erythromycin alone. Mild allergic reactions such as urticaria and other skin rashes have occurred. Serious allergic reactions, including anaphylaxis, have been reported with erythromycin.
The following untoward effects have been associated with the use of sulfonamides:
Blood dyscrasias: Agranulocytosis, aplastic anemia, thrombocytopenia, leukopenia, hemolytic anemia, purpura, hypoprothrombinemia and methemoglobinemia.
Allergic reactions: Erythema multiforme (Stevens-Johnson syndrome), generalized skin eruptions, epidermal necrolysis, urticaria, serum sickness, pruritus, exfoliative dermatitis, anaphylactoid reactions, periorbital edema, conjunctival and scleral injection, photosensitization, arthralgia and allergic myocarditis.
Gastrointestinal reactions: Nausea, emesis, abdominal pains, hepatitis, diarrhea, anorexia, pancreatitis and stomatitis.
C.N.S. reactions: Headache, peripheral neuritis, mental depression, convulsions, ataxia, hallucinations, tinnitus, vertigo and insomnia.
Miscellaneous reactions: Drug fever, chills and toxic nephrosis with oliguria or anuria. Periarteritis nodosa and L.E. phenomenon have occurred.
The sulfonamides bear certain chemical similarities to some goitrogens, diuretics (acetazolamide and the thiazides) and oral hypoglycemic agents. Goiter production, diuresis and hypoglycemia have occurred rarely in patients receiving sulfonamides. Cross-sensitivity may exist with these agents.
Rats appear to be especially susceptible to the goitrogenic effects of sulfonamides, and long-term administration has produced thyroid malignancies in the species.

Dosage and Administration
PEDIAZOLE SHOULD NOT BE ADMINISTERED TO INFANTS UNDER 2 MONTHS OF AGE BECAUSE OF CONTRAINDICATIONS OF SYSTEMIC SULFONAMIDES IN THIS AGE GROUP.
For Acute Otitis Media in Children: The dose of Pediazole can be calculated based on the erythromycin component (50 mg/kg/day) or the sulfisoxazole component (150 mg/kg/day to a maximum of 6 g/day). Pediazole should be administered in equally divided doses four times a day for 10 days. It may be administered without regard to meals.
The following approximate dosage schedule is recommended for using Pediazole:
Children: Two months of age or older.

Weight	Dose—every 6 hours
Less than 8 kg (less than 18 lb)	Adjust dosage by body weight
8 kg (18 lb)	½ teaspoonful (2.5 ml)
16 kg (35 lb)	1 teaspoonful (5 ml)
24 kg (53 lb)	1½ teaspoonfuls (7.5 ml)
Over 45 kg (over 100 lb)	2 teaspoonfuls (10 ml)

How Supplied
Pediazole Suspension is available for teaspoon dosage in 100 ml (**NDC** 0074-8030-13) and 200-ml (**NDC** 0074-8030-53) bottles, in the form of granules to be reconstituted with water. The suspension provides erythromycin ethylsuccinate equivalent to 200 mg erythromycin activity and sulfisoxazole acetyl equivalent to 600 mg sulfisoxazole per teaspoonful (5 ml).

ROSS LABORATORIES
COLUMBUS, OHIO 43216
Division of Abbott Laboratories, USA

B131/2810

Office supply catalog

A free medical office catalog features insurance aids, accounting records, marketing materials, appointment aids, and a wide variety of stationery and envelopes. To receive a complimentary catalog, call Sycom at (800) 356-8141 (in Wisconsin, (800) 356-9152) or write Sycom, West Beltline Highway, P.O. Box 7947, Madison, Wisconsin 53707-7947.

Access to rare analyses

The *Directory of Rare Analyses* is a handy book that tracks down which laboratories and professional societies are willing to perform rare diagnostic tests. The authors intend to update the compilation periodically, and make the lists available on diskette. The retail price of *DORA '86* is $34.50, and may be ordered from the Marketing Department of the American Association for Clinical Chemistry Press at (800) 892-1400 or (202) 857-0717.

Urine reagent strips

A multiple-test urine reagent strip is the first macroscopic screening test for specific gravity. Each strip simultaneously tests for leukocytes, nitrite, occult blood, protein, glucose, bilirubin, urobilinogen, ketone, and pH. The strips are designed to confirm, or in some cases replace, microscopic tests. For more details on Multistix® 10 SG, write the Ames Division of Miles Laboratories Inc., at P.O. Box 70, Elkhart, Indiana 46515 (219) 262-7617.

Spirometer

A computerized spirometer offers 10 vital tests including spirometry, smoking prognosis, cardiac risk, surgical risk, weight management, and hypertension diagnosis. Each system incorporates MVV (maximal voluntary ventilation) parameters, pediatric standards, and pre- and postbronchodilator comparisons. For further details on the Tiffenaire

continued on page **73**/22

Research
Commitment
Experience

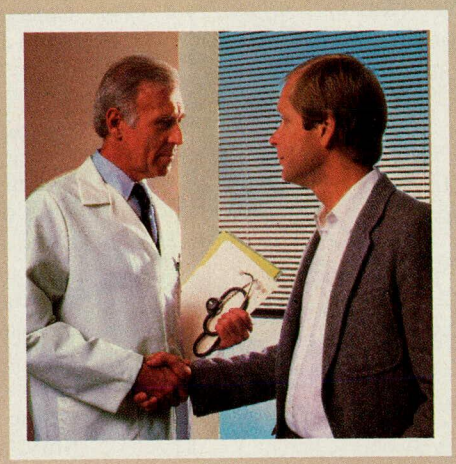
Research, commitment, experience...accurate descriptions of the anti-ulcer effort at Smith Kline &French...an endeavor that began 21 years ago, and focused on the then unknown field of receptor technology. An endeavor that stretched the known frontiers of knowledge, and in the ensuing years would become expertise.

It was SK&F scientists who discovered, described and characterized, for the first time, the H_2-receptor site on the parietal cell. And in the ten years that followed, they synthesized, then screened and discarded, thousands of compounds. Until the first clinically useful H_2-antagonist for ulcer disease was introduced.

Commercial introduction of that discovery, however, did not spell the end of research. Research continued. Research into new compounds... none of which proved more promising. Research into the appropriate amount of acid suppression, the concept of gastric mucosal defense, and the control of nocturnal acid secretion. Research into optimal dosage, and the optimal schedule of administration.

Those years of accumulated experience and acquired expertise in gastrointestinal medicine, and more basic receptor biology, are today at work in ongoing research projects...in gastroenterology, cardiology, respiratory conditions, and oncology.

Those decades of research, of commitment, of experience, are the very foundation for the future...for a future bright with promise.



Expertise.

SK&F

10, contact Jones Medical Instrument Company, 200 Windsor Drive, Oak Brook, Illinois 60521 (312) 654-1980 or (800) 323-7336.

Frameless chair

A back-sling has been designed to offer portable lumbar support. The "frameless chair" consists of 2-inch straps that are attached to a cushioned back pad. The straps loop over the knees to create a reverse pressure that holds the back erect. The device can be used in conjunction with a chair, or when sitting for long periods without support, such as on bleachers or in bed. For further details on this orthopedic device, contact Nada-Chair, 842 22nd Avenue S.E., Minneapolis, Minnesota 55414 (612) 623-4436.

Hydrocortisone lotion

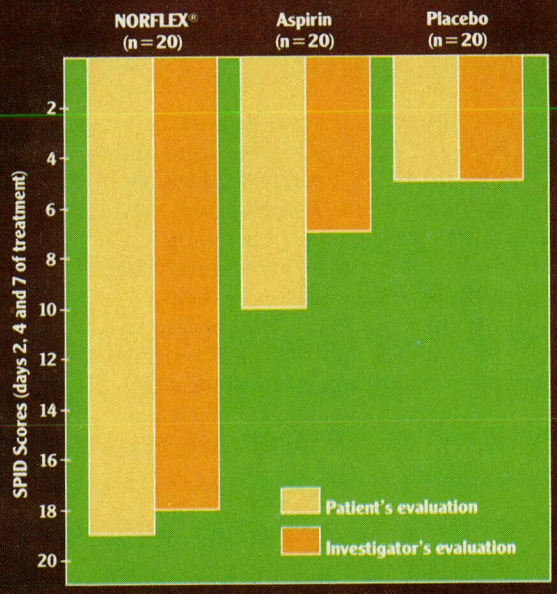
A moisturizing lotion with hydrocortisone has been formulated to relieve the dryness and itching of atopic and eczematous dermatoses. The anti-inflammatory medication is available in both 1 percent and 2½ percent hydrocortisone strengths. For more information on LactiCare-HC®, contact Stiefel Laboratories, Inc., 2801 Ponce de Leon Boulevard, Coral Gables, Florida 33134-6988 (305) 443-3807.

Software for scientists

A computer software package has been designed especially for scientists, engineers, and researchers. Logical commands replace computer languages so that no prior computer programming experience is necessary. The software can be used on almost any personal computer. Users can acquire, reduce, graphically display, and print hard copy of data produced by scientific instruments and experiments. Color graphics enhance and clarify data. For more information on the ASYSTANT™ Ready-to-Run Scientific Software, write the Macmillan Software Company, 630 Third Avenue, 8th floor, New York, New York 10017 or call (800)-348-0033.

Back in shape.

Sum Pain Intensity Difference (SPID) scores, indicative of clinically significant pain relief.



Norflex delivers fast, potent relief of low back pain by breaking the pain-spasm-pain cycle.[1,2] A study comparing Norflex, aspirin and placebo found only Norflex to provide statistically significant pain relief.[3] And electromyographic data demonstrate rapid reversal of the associated muscle spasm after oral and parenteral administration of Norflex.[4-6]

Norflex has a unique nonsedating*/nonhabit-forming mode of action. Most patients can remain alert and on the job during treatment — without the potential for addiction or abuse. And a simple b.i.d. dosage schedule is easy to comply with. So they'll be back in shape fast.

NORFLEX®
(orphenadrine citrate) TABLETS and INJECTABLE

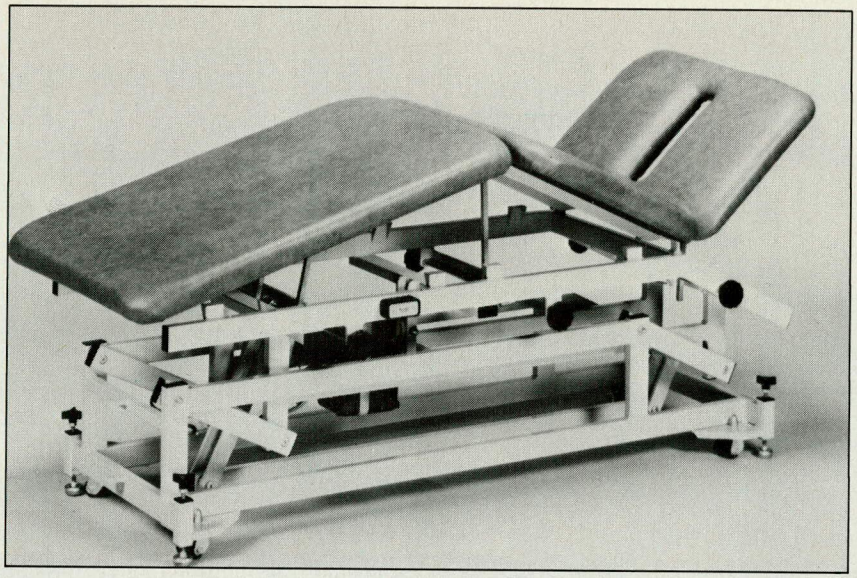
Breaks the pain-spasm-pain cycle.

Please see the following page for a summary of prescribing information.

*Some patients may experience transient episodes of light-headedness, dizziness or syncope, which may impair their ability to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; ambulatory patients should therefore be cautioned accordingly.

Riker Laboratories, Inc.
St. Paul, Minnesota 55144-1000

3M



Treatment table

A treatment table can be lowered to 22 inches for wheelchair access and then raised to a comfortable working height. The 3-section table adjusts to most standard positions, including postural drainage. The working surface is 28 x 78 inches. A breathing slot in the upholstered vinyl allows for patient comfort. For more information on the TRE-3 Triton® treatment table, call the Chattanooga Corporation at (800) 592-7329.

Injectable cephalosporin

Tazidime™ (ceftazidime) has been added to Eli Lilly's line of injectable cephalosporins. The antibiotic is especially active against Pseudomonas strains of bacteria. The drug may be used in combination with other antibiotics in certain severe and life-threatening infections. More information on Tazidime may be obtained by writing Eli Lilly and Company, 307 East McCarty Street, Indianapolis, Indiana 46285.

Antiviral for respiratory disease

Virazole™ (ribavirin) is a broad-spectrum antiviral drug designed to combat RNA and DNA viral diseases. Ribavirin is the only effective treatment to date against respiratory syncytial virus (RSV) infections. The medication is delivered directly to the lungs in a fine mist via a small-particle aerosol generator. The therapy has been found safe in infants, who are at high risk for RSV infections. For more information on Virazole, contact ICN Pharmaceuticals, Inc., 3300 Hyland Avenue, Costa Mesa, California 92626 (714) 545-0100.

Nonionic contrast agents

Nonionic contrast agents with improved patient tolerance have been released in the United States for diagnostic use in visualizing blood vessels. The nonionic agents cause fewer adverse reactions of pain on injection, headache, nausea, hot flushing, hallucination, and anxiety. Isovue™ (iopamidol injection, Squibb) is recommended for use in angiography throughout the vascular system; Isovue-M™ is indicated for lumbar, thoracic, cervical, and total columnar myelography. Omnipaque® (iohexol, Winthrop-Breon) is approved for both myelography and angiography. For more complete details on these respective contrast agents, contact Squibb Corporation, P.O. Box 4000, Princeton, New Jersey 08540 and Winthrop-Breon Lab-

olio \ō-lē-,ō\ *n* 1: a miscellaneous collection of literary selections 2: Osteopathic Literature Index/Online—the definitive online source to osteopathic literature

Osteopathic Literature Index/Online
Now available through AONET

For further information, contact AONET,
the American Osteopathic Network,
1500 Walnut Street, 7th floor,
Philadelphia, PA 19102

(215) 875-4650 or (800) 332-ICOA

oratories, 90 Park Avenue, New York, New York 10016.

Transdermal nitroglycerin

Improvements in a transdermal infusion system have yielded a nitroglycerin patch that is a mere 0.139 mm. thick. The thin, flexible patch attaches easily to the chest or upper arm and conforms to skin folds without loosening or buckling. Nitroglycerin is delivered through the skin for a full 24 hours. Five dosage strengths are available: 2.5, 5, 7.5, 10, and 15 mg./24 hours. For more details on the Nitro-Dur®II Transdermal Infusion System, contact Key Pharmaceuticals, Inc., 4400 Biscayne Boulevard, Miami, Florida 33137 (305) 578-5800.

Antifungal cream

A once-a-day topical cream is available for the treatment of fungal infections. Nizoral® (ketoconazole) 2% Cream is indicated in the treatment of tinea corporis, tinea cruris, and tinea versicolor caused by *Trichophyton rubrum, T. mentagrophytes, Epidermophyton,* and *Malassezia furfur.* For more information on Nizoral, write Janssen Pharmaceutica, 40 Kingsbridge Road, Piscataway, New Jersey 08854 (201) 524-9591.

Examination lamp

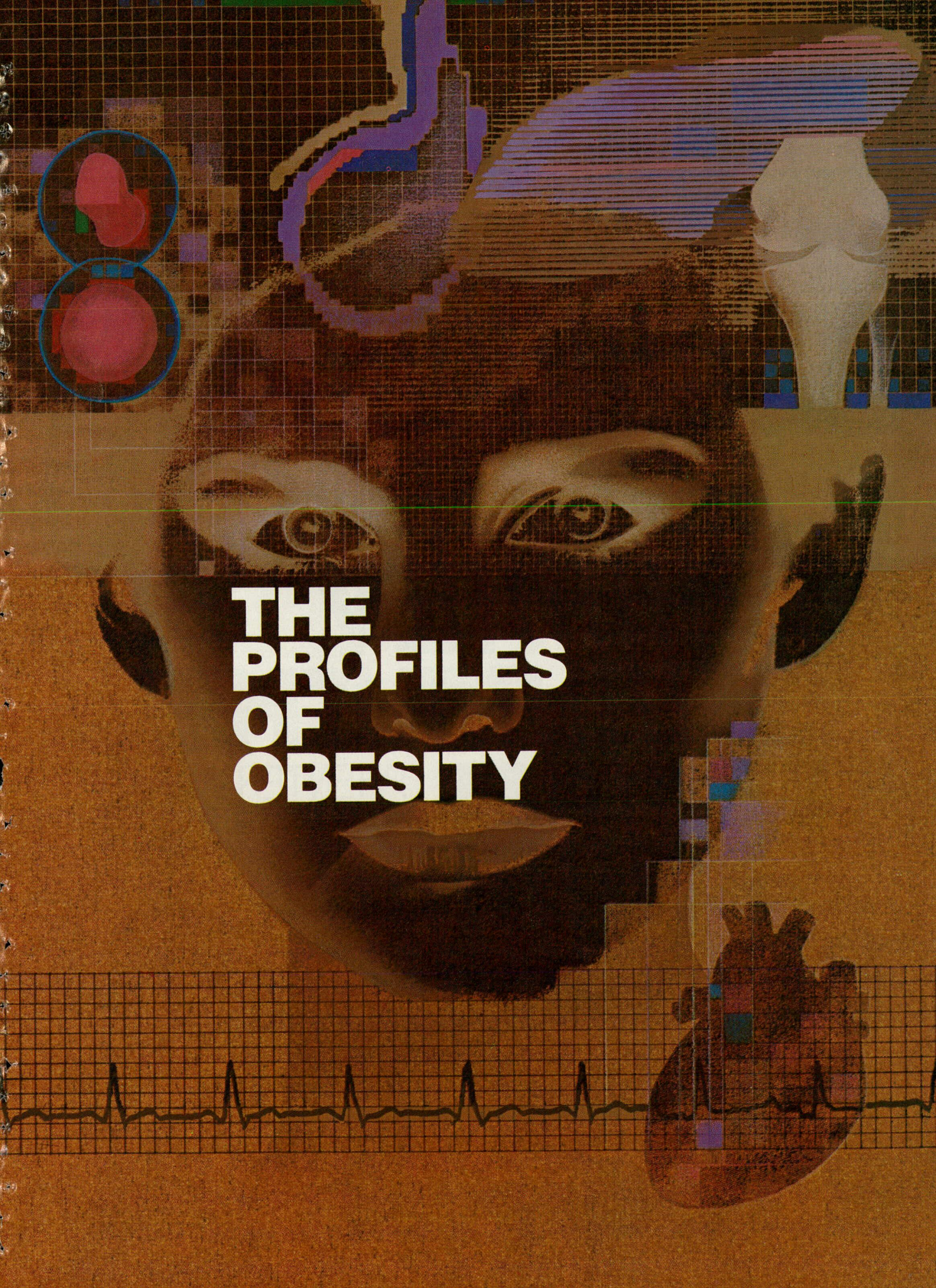
A high-intensity lamp provides localized light for close-up and general examinations. The low-voltage Halogen lamp is available with a mobile stand or bench, wall, or ceiling mount. A removable head for hand-held use is optional. For more information on the Tasklite™, contact Welch Allyn, Inc., 4341 State Street Road, P.O. Box 220, Skaneateles Falls, New York 13153-0220 (315) 685-8351.

Asthma inhaler

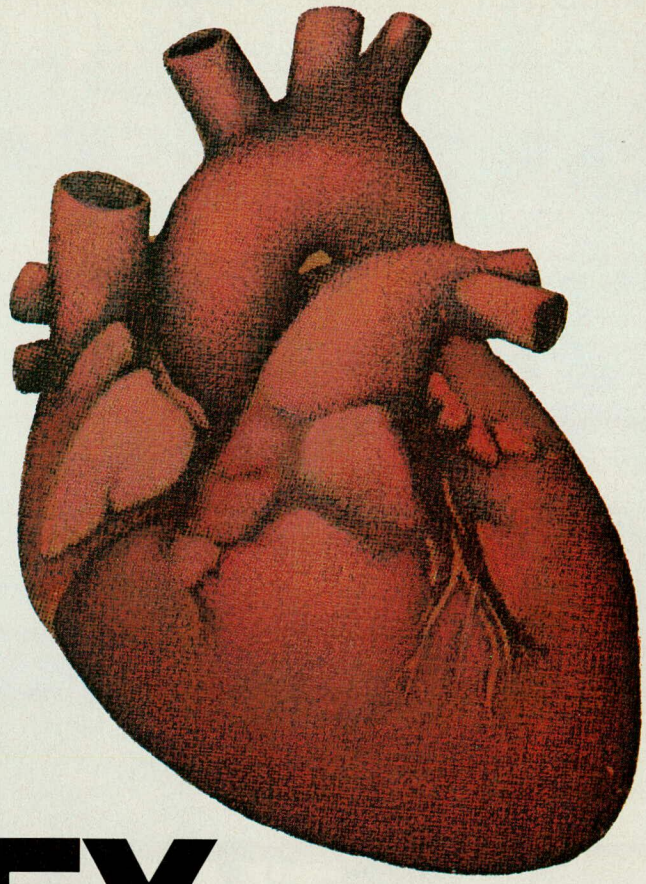
A new aerosol form of cromolyn sodium is available for the management of bronchial asthma. The active agent is not a steroid and exhibits no antihistamine activity; it prevents asthma and allergic reactions by stabilizing mast cells and preventing the release of chemical mediators into the respiratory tract. For more information on the Intal Inhaler, contact Fisons Corporation, Two Preston Court, Bedford, Massachusetts 01730 (617) 275-1000.

Low-sodium antacid

A low-sodium, high-potency antacid has been formulated for the treatment of reflux esophagitis. Magnesium alginate combines with the antacid to form a protective layer that prevents the reflux of stomach acid into the esophagus. The chewable tablets contain only 5 mg. sodium per minimum dose and provide 17.5 mEq. acid-neutralizing capacity. For more information on Algicon™, contact William H. Rorer, Inc., Fort Washington, Pennsylvania 19034.


THE
PROFILES
OF
OBESITY

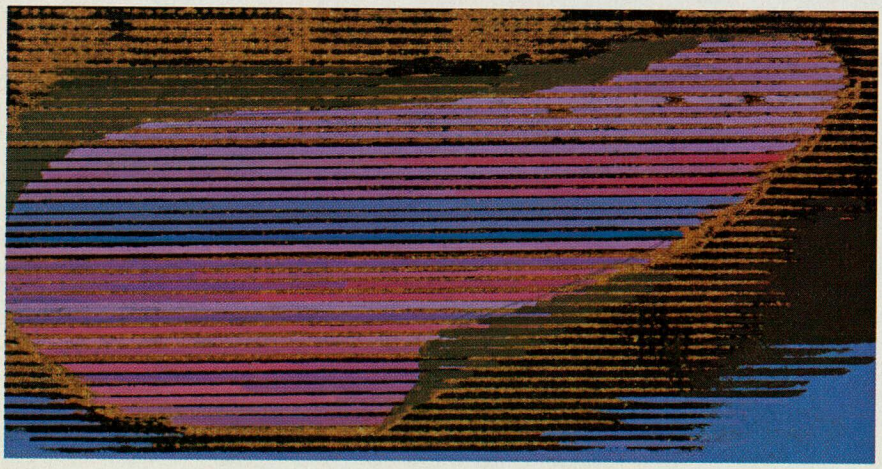
Organ systems at risk shape a clinical profile of serious dimension. Affecting over 34 million people, obesity has become America's most common chronic medical condition—associated either directly or indirectly with disorders responsible for approximately 20% of our total mortality.[1] In fact, the Concensus Panel on Obesity of the NIH has recently stated, "We want the average American and his physician to know that obesity is a disease...a killer."[2]



Measured risks

While obesity affects virtually every organ system in the body, nowhere is the evidence more compelling than in the *cardiovascular system*.[3] The increased risk of *sudden death*, *myocardial infarction* and *stroke* has been confirmed in 10 prospective studies involving over a quarter million people.[4] In women it is one of the best predictors of cardiovascular disease.[5] And when acquired between the ages of 20 and 40, obesity's effect on disease development may be even greater.[3] Adding further dimension to the problem is the association of weight with other risk factors—most notably its correlation with *hypertension* in any age group.[4]

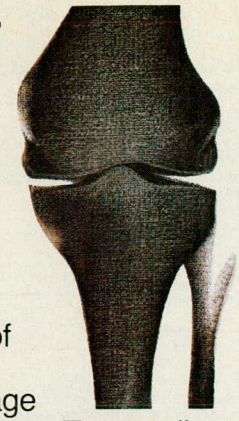
THEY SHAPE THE FASTIN® (PHENTERMINE HYDROCHLORIDE) PROFILE



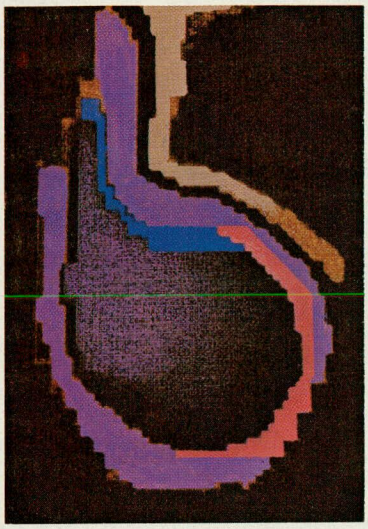
The association between obesity and *diabetes mellitus* is also very strong: the vast majority of diabetics are overweight; an estimated 25% of the obese are diabetic.[4] Furthermore, overweight affects the mortality rate of diabetes more than that of any other disease.[3]

The artist's interpretations of the pancreas, gall bladder and coronary artery are based on computer assisted diagnostic techniques.

In the musculoskeletal system, disability is a particular problem among obese women with *osteoarthritis* of weight-bearing joints like the knees. *Gouty arthritis* also occurs more frequently,[1] and the distribution of excess fat may aggravate or create postural faults.[3]

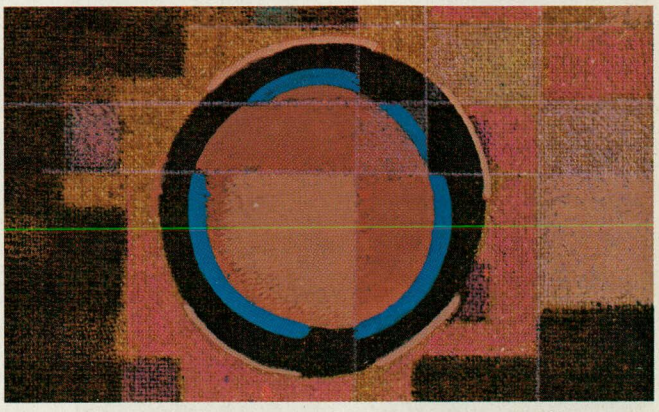


In the gallbladder, the level of body weight parallels the frequency of disease within any age group. To complicate matters, obese patients exhibit more resistance to drug therapy for *cholelithiasis*.[3]



Proven benefits

Used as a therapeutic tool, weight loss can greatly benefit patients with hypertension, maturity onset diabetes, gout and gallstones.[1,3] A 10% change in relative weight, for example, can effect a 6.5 mmHg change in systolic blood pressure, a 12.5 mg/dl change in plasma cholesterol and a 2 mg/dl change in fasting blood sugar.[3] And long before normal weight is restored, insulin responsiveness is improved.[1] In fact, workers in the Framingham study have concluded that "reduction of overweight is probably the most important hygienic measure (aside from avoidance of cigarettes) available for the control of cardiovascular disease."[5]



Fastin: a good start in a long fight

When risks shape the therapeutic rationale for weight loss, early motivation can often be the key to long-term success. As a short-term adjunct to your weight loss regimen, Fastin can help provide that motivation. One capsule daily at 10 A.M. helps curb hunger and achieve *greater initial weight loss*. In a six-week, double-blind study,[7] patients given 1,000 calorie/day diets, nutritional counseling and FASTIN lost an average of 8.27 pounds, *2½ times more* than patients on the same diet, counsel and placebo.

Help get your overweight patients off to a good start.

References:

1. Weiss SR: Obesity: Pathogenesis, consequences, and approaches to treatment. *Psychiatric Clinics of North America* 7(2):307-319, June 1984.
2. Eastman P: Call obesity 'a killer', costing U.S. $30.6 billion a year. *Medical Tribune* 26(8):7, March 20, 1985.
3. Van Italie TB: Obesity: adverse effects on health and longevity. *American Journal of Clinical Nutrition* 32:2723-2733, December 1979.
4. Halstead CH, Stern JS: ASCN workshop on obesity and its treatments. *American Journal of Clinical Nutrition* 33:1326-1327, June 1980.
5. Hubert HB: The nature of the relationship between obesity and cardiovascular disease. *International Journal of Cardiology* 6:268-274, 1984.
6. Kannel WB, Gordon T: Physiological and medical concomitants of obesity: the Framingham Study. In: *Obesity in America*, edited by G.A. Bray, NIH Publication No. 79-359, 1979, pp. 125-163.
7. Wise PJ: Clinical experience with a new dosage form of phentermine hydrochloride. *Obesity/Bariatric Medicine* 4(3):102-105, 1975.

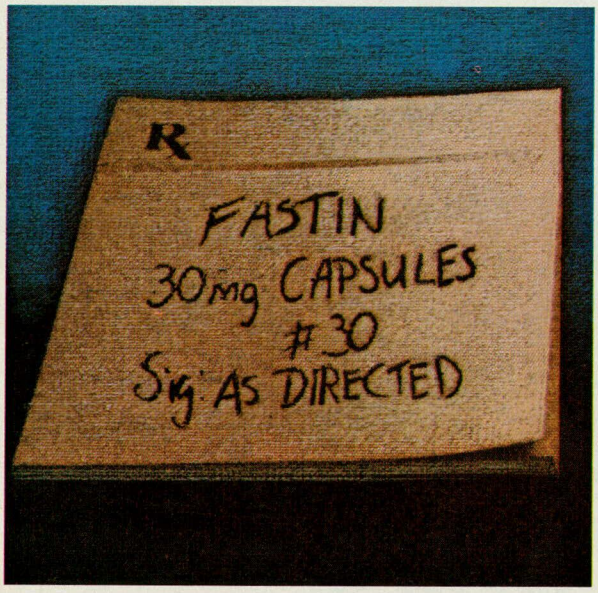
Fastin® 30 mg Ⓒ Ⓘⓥ Capsules
(phentermine HCl)

The First Step

A good start in a long fight

Fastin® 30 mg Ⓒ Ⓘ Ⓥ Capsules (phentermine HCl)

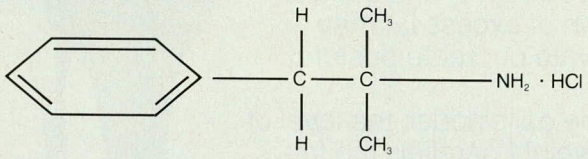
The First Step



Indicated only for use as a short-term adjunct in the management of exogenous obesity.

DESCRIPTION: Each FASTIN (Phentermine Hydrochloride) capsule contains Phentermine Hydrochloride, 30 mg (equivalent to 24 mg Phentermine).

Phentermine Hydrochloride is a white crystalline powder, very soluble in water and alcohol. Chemically, the product is phenyl-tertiary-butylamine hydrochloride. *Inactive Ingredients:* F D & C Blue 1, Methylcellulose, Polyethylene Glycol and Starch.



ACTIONS: FASTIN is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, the amphetamines. Actions include central nervous system stimulation and elevation of blood pressure. Tachyphylaxis and tolerance have been demonstrated with all drugs of this class in which these phenomena have been looked for.

Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigenics." It has not been established that the action of such drugs in treating obesity is primarily one of appetite suppression. Other central nervous system actions, or metabolic effects may be involved, for example.

Adult obese subjects instructed in dietary management and treated with "anorectic" drugs, lose more weight on the average than those treated with placebo and diet, as determined in relatively short-term clinical trials.

The magnitude of increased weight loss of drug-treated patients over placebo-treated patients is only a fraction of a pound a week. The rate of weight loss is greatest in the first weeks of therapy for both drug and placebo subjects and tends to decrease in succeeding weeks. The possible origins of the increased weight loss due to the various drug effects are not established. The amount of weight loss associated with the use of an "anorectic" drug varies from trial to trial, and the increased weight loss appears to be related in part to variables other than the drugs prescribed, such as the physician-investigator, the population treated, and the diet prescribed. Studies do not permit conclusions as to the relative importance of the drug and non-drug factors on weight loss.

The natural history of obesity is measured in years, whereas the studies cited are restricted to a few weeks duration; thus, the total impact of drug-induced weight loss over that of diet alone must be considered clinically limited.

INDICATION: FASTIN is indicated in the management of exogenous obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class (see ACTIONS) should be measured against possible risk factors inherent in their use such as those described below.

CONTRAINDICATIONS: Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity, or idiosyncrasy to the sympathomimetic amines, glaucoma.

Agitated states. Patients with a history of drug abuse. During or within 14 days following the administration of monoamine oxidase inhibitors (hypertensive crises may result).

WARNINGS: Tolerance to the anorectic effect usually develops within a few weeks. When this occurs, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

FASTIN may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle; the patient should therefore be cautioned accordingly.

DRUG DEPENDENCE: FASTIN is related chemically and pharmacologically to the amphetamines. Amphetamines and related stimulant drugs have been extensively abused, and the possibility of abuse of FASTIN should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. Abuse of amphetamines and related drugs may be associated with intense psychological dependence and severe social dysfunction. There are reports of patients who have increased the dosage to many times that recommended. Abrupt cessation following prolonged high dosage administration results in extreme fatigue and mental depression; changes are also noted on the sleep EEG. Manifestations of chronic intoxication with anorectic drugs include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxications is psychosis, often clinically indistinguishable from schizophrenia.

Usage in Pregnancy: Safe use in pregnancy has not been established. Use of FASTIN by women who are or who may become pregnant, and those in the first trimester of pregnancy, requires that the potential benefit be weighed against the possible hazard to mother and infant.

Usage in Children: FASTIN is not recommended for use in children under 12 years of age.

Usage with Alcohol: Concomitant use of alcohol with FASTIN may result in an adverse drug interaction.

PRECAUTIONS: Caution is to be exercised in prescribing FASTIN for patients with even mild hypertension.

Insulin requirements in diabetes mellitus may be altered in association with the use of FASTIN and the concomitant dietary regimen.

FASTIN may decrease the hypotensive effect of guanethidine.

The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage.

ADVERSE REACTIONS: Cardiovascular: Palpitation, tachycardia, elevation of blood pressure.

Central Nervous System: Overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache; rarely psychotic episodes at recommended doses.

Gastrointestinal: Dryness of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances.

Allergic: Urticaria.

Endocrine: Impotence, changes in libido.

DOSAGE AND ADMINISTRATION: Exogenous Obesity: One capsule at approximately 2 hours after breakfast for appetite control. Late evening medication should be avoided because of the possibility of resulting insomnia.

Administration of one capsule (30 mg) daily has been found to be adequate in depression of the appetite for twelve to fourteen hours.

FASTIN is not recommended for use in children under 12 years of age.

OVERDOSAGE: Manifestations of acute overdosage with phentermine include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmias, hypertension or hypotension, and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea, and abdominal cramps. Fatal poisoning usually terminates in convulsions and coma.

Management of acute phentermine intoxication is largely symptomatic and includes lavage and sedation with a barbiturate. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendations in this regard. Acidification of the urine increases phentermine excretion. Intravenous phentolamine (REGITINE) has been suggested for possible acute, severe hypertension, if this complicates phentermine overdosage.

CAUTION: Federal law prohibits dispensing without prescription.

HOW SUPPLIED: Blue and clear capsules with blue and white beads containing 30 mg phentermine hydrochloride (equivalent to 24 mg phentermine).

NDC 0029-2205-30 . . . . . bottles of 100
NDC 0029-2205-39 . . . . . bottles of 450
NDC 0029-2205-31 . . . . . pack of 30

Beecham
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