PDR®

49 EDITION

1995

PHYSICIANS' DESK REFERENCE®

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ck
ck Drug Company, Inc.
N.J. 07302
s Product Identification Guide, page 325

arch Industries Corporation

ceutical Division
OUTH 300 WEST
LE, UTAH 84047

Rx

50

ethyl sulfoxide)

OVERVIEW

ponent of Rimso®-50 is sterile and pyrogen-
sulfoxide.

has been proved to be clinically effective for the
relief of patients with interstitial cystitis.

NFORMATION

instillation of Rimso®-50 may be harmful to
urinary tract malignancy because of dimethyl
ced vasodilation.
oxide can initiate the liberation of histamine
ave been occasional hypersensitivity reactions
administration.
oxide should be used during pregnancy only if
benefit justifies the potential risk to the fetus.

NG INFORMATION

50 Rx

ethyl sulfoxide)

TION
brand of dimethyl sulfoxide (DMSO)
queous Solution for intravesical instillation.
tains 0.54 gm dimethyl sulfoxide STERILE AND
GENIC.
instillation for the treatment of interstitial

M OR I.V. INJECTION

prohibits dispensing without a prescription.
mponent of RIMSO®-50 is dimethyl sulfoxide
e empirical formula C_2H_6OS.
oxide is a clear, colorless and essentially odor-
which is miscible with water and most organic
her physical characteristics include: molecular
melting point 18.4°C, and a specific gravity of

PHARMACOLOGY

oxide is metabolized in man by oxidation to
one or by reduction to dimethyl sulfide. Di-
ide and dimethyl sulfone are excreted in the
ss. Dimethyl sulfide is eliminated through the
n and is responsible for the characteristic odor
on dimethyl sulfoxide medication. Dimethyl
persist in serum for longer than two weeks after
vesical instillation. No residual accumulation
sulfoxide has occurred in man or lower animals
ved treatment for protracted periods of time.
cal application, dimethyl sulfoxide is absorbed
distributed in the tissues and body fluids.

NS AND USAGE

dimethyl sulfoxide) is indicated for the symp-
of patients with interstitial cystitis. RIMSO®-
n approved as being safe and effective for any
tion. There is no clinical evidence of effective-
yl sulfoxide in the treatment of bacterial infec-
inary tract.

DICATIONS

oxide can initiate the liberation of histamine
been an occasional hypersensitivity reaction
dministration of dimethyl sulfoxide. This hy-

lactoid symtoms develop, appropriate therapy should be instituted.

PRECAUTIONS

Changes in the refractive index and lens opacities have been seen in monkeys, dogs and rabbits given high doses of dimethyl sulfoxide chronically. Since lens changes were noted in animals, full eye evaluations, including slit lamp examinations are recommended prior to and periodically during treatment.

Approximately every six months patients receiving dimethyl sulfoxide should have a biochemical screening, particularly liver and renal function tests, and complete blood count. Intravesical instillation of RIMSO®-50 may be harmful to patients with urinary tract malignancy because of dimethyl sulfoxide-induced vasodilation.

Some data indicate that dimethyl sulfoxide potentiates other concomitantly administered medications.

Pregnancy Category C. Dimethyl sulfoxide caused teratogenic responses in hamsters, rats and mice when administered intraperitoneally at high doses (2.5–12 gm/kg). Oral or topical doses of dimethyl sulfoxide did not cause problems of reproduction in rats, mice and hamsters. Topical doses (5 gm/kg first two days, then 2.5 gm/kg-last eight days) produced terata in rabbits, but in another study, topical doses of 1.1 gm/kg days 3 through 16 of gestation failed to produce any abnormalities. There are no adequate and well controlled studies in pregnant women. Dimethyl sulfoxide should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus. It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when dimethyl sulfoxide is administered to a nursing woman.

Safety and effectiveness in children have not been established.

Information available to be given to the patient is reprinted at the end of this text.

ADVERSE REACTIONS

A garlic-like taste may be noted by the patient within a few minutes after instillation of RIMSO®-50 (dimethyl sulfoxide). This taste may last several hours and because of the presence of metabolites an odor on the breath and skin may remain for 72 hours.

Transient chemical cystitis has been noted following instillation of dimethyl sulfoxide.

The patient may experience moderately severe discomfort on administration. Usually this becomes less prominent with repeated administration.

DRUG ABUSE AND DEPENDENCE

None known.

OVERDOSAGE

The oral LD_{50} of dimethyl sulfoxide in the dog is greater than 10 gm/kg. It is improbable that this dosage level could be obtained with intravesical instillation of RIMSO®-50 in the patient.

In case of accidental oral ingestion, specific measures should be taken to induce emesis. Additional measures which may be considered are gastric lavage, activated charcoal and forced diuresis.

DOSAGE AND ADMINISTRATION

Instillation of 50 ml of RIMSO®-50 (dimethyl sulfoxide) directly into the bladder may be accomplished by catheter or asepto syringe and allowed to remain for 15 minutes. Application of an analgesic lubricant gel such as lidocaine jelly to the urethra is suggested prior to insertion of the catheter to avoid spasm. The medication is expelled by spontaneous voiding. It is recommended that the treatment be repeated every two weeks until maximum symptomatic relief is obtained. Thereafter, time intervals between therapy may be increased appropriately.

Administration of oral analgesic medication or suppositories containing belladonna and opium prior to the instillation of RIMSO®-50 can reduce bladder spasm.

In patients with severe interstitial cystitis with very sensitive bladders, the initial treatment, and possibly the second and third (depending on patient response) should be done under anesthesia. (Saddle block has been suggested).

HOW SUPPLIED

Bottles contain 50 ml of sterile and nonpyrogenic RIMSO®-50 (50% w/w dimethyl sulfoxide aqueous solution).

Dimethyl sulfoxide is clear and colorless

Protect from strong light

Store at room temperature (59° to 86°F) (15° to 30°C)

If RIMSO®-50 becomes frozen, thaw at room temperature. Freezing and thawing does not affect drug stability.

Do not autoclave

NDC #0433-0433-05

RIMSO®-50 is manufactured by Tera Pharmaceuticals, Inc., Buena Park, California, for the Pharmaceutical Division, Research Industries Corp., Salt Lake City, Utah.

Rexar Pharmacal

A division Of Richwood Pharmaceutical Company Inc.
396 ROCKAWAY AVENUE
VALLEY STREAM, NY 11581

OBETROL™ TABLETS C II

See ADDERALL™ page # 1984.

DEXTROAMPHETAMINE SULFATE, USP C II
5 mg and 10 mg Tablets

OBY-TRIM Capsules C Rx
Phentermine Hydrochloride, USP, 30 mg
(equivalent to 24 mg phentermine base)

REXATAL Tablets Rx
Phenobarbital, USP, (1/4 gr) 16.2 mg
Hyoscyamine Sulfate, USP, 0.1037 mg
Atropine Sulfate, USP, 0.0194 mg
Scopolamine Hydrobromide, USP, 0.0065 mg

X-TROZINE Tablets C III Rx
X-TROZINE Capsules
Phendimetrazine Tartrate, USP, 35 mg

X-TROZINE L.A. Extended Release Capsules C III Rx
Phendimetrazine Tartrate, USP, 105 mg

Rhône-Poulenc Rorer Pharmaceuticals Inc.

500 ARCOLA ROAD
COLLEGEVILLE, PA 19426-0107

Following is a list of Rhône-Poulenc Rorer Pharmaceuticals Inc. products. Full prescribing information is provided on the following pages for those products indicated by an asterisk. For further information, please call the Rhône-Poulenc Rorer Medical Affairs Information Line at (610) 454-8110 or (610) 454-8000.

ACTHAR® for Injection Rx
25 USP Units and 40 USP Units
Corticotropin for injection available as a lyophilized powder in vials containing 25 USP Units or 40 USP Units per vial.

H.P. ACTHAR® GEL Rx
40 USP Units/mL and 80 USP Units/mL
Repository corticotropin injection available in strengths of 40 USP Units or 80 USP Units per mL.

***AZMACORT® Oral Inhaler** Rx
Each metered-dose inhaler contains 60 mg triamcinolone acetonide. Each oral inhaler unit delivers 240 actuations of approximately 100 mcg of triamcinolone acetonide.
Pictured in Product Identification Guide, page 325

BAROTRAST® Rx
This radiopaque contrast medium contains 92.5% barium

Rhône-Poulenc Rorer Consumer—Cont.

HOW SUPPLIED

Maalox® TC Suspension is available in a 12-fluid ounce (355 mL) plastic bottle (NDC 0067-0334-71).
(See PDR For Nonprescription Drugs.)

PERDIEM® OTC

[pĕr "dē 'ŭm]
Bulk-Forming Laxative
Rhône-Poulenc Rorer

ACTIONS

Perdiem®, with its 100% natural, gentle action provides comfortable, overnight relief from constipation. Perdiem® is a unique combination of bulk-forming fiber and natural stimulant. The vegetable mucilages of Perdiem® soften the stool and provide pain-free overnight evacuation of the bowel with no chemical stimulants. Perdiem® is effective as an aid to elimination for the hemorrhoid or fissure patient prior to and following surgery.

HOW SUPPLIED

250-gram (8.8 oz) (NDC 0067-0690-70) canisters.
6-6 g individual packets (NDC 0067-0690-16).
(See PDR For Nonprescription Drugs.)

PERDIEM® FIBER OTC

[pĕr "dē 'ŭm]
Bulk Forming Laxative
Rhône-Poulenc Rorer

ACTIONS

Perdiem® Fiber, is a 100% natural bulk-forming fiber that gently helps maintain regularity and prevents constipation. Perdiem® Fiber's unique form is easy to swallow and requires no mixing but must be followed by at least 8 ounces of cool liquid. Perdiem Fiber contains no chemical stimulants and may be used daily by those who may lack sufficient dietary fiber. When recommended by a doctor, Perdiem Fiber is also useful for the treatment of bowel disorders other than constipation.

HOW SUPPLIED

250-gram (8.8 oz) (NDC 0067-0795-70) canisters, 42-gram (1.4 oz) (NDC 0067-0795-42) and 42-gram sample (1.4 oz) (NDC 0067-0795-52).
(See PDR For Nonprescription Drugs.)

Richwood Pharmaceutical Company Inc.

7900 TANNER'S GATE DRIVE, SUITE 200
FLORENCE, KENTUCKY 41042

ACUPRIN 81™ Adult Low Dose Aspirin. OTC

Contains 81 mg of enteric coated aspirin.

81 mg 120's NDC 58521-081-01
81 mg 500's NDC 58521-081-05

ADDERALL™ TABLETS ℞

AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. THEY SHOULD THUS BE TRIED ONLY IN WEIGHT REDUCTION PROGRAMS FOR PATIENTS IN WHOM ALTERNATIVE THERAPY HAS BEEN INEFFECTIVE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME IN OBESITY MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBILITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.

DESCRIPTION

EACH TABLET CONTAINS:	10 mg	20 mg
Dextroamphetamine Saccharate	2.5 mg	5 mg
Amphetamine Aspartate	2.5 mg	5 mg
Dextroamphetamine Sulfate	2.5 mg	5 mg
Amphetamine Sulfate	2.5 mg	5 mg

Inactive ingredients: Sucrose, Lactose, Cornstarch, Acacia and Magnesium Stearate.
Colors: ADDERALL 10 mg contains FD&C Blue #1
Colors: ADDERALL 20 mg contains FD&C Yellow #6 as a color additive.

ACTIONS

Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant activity. Peripheral actions include elevation of systolic and diastolic blood pressures and weak bronchodilator and respiratory stimulant action. Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigenics". It has not been established, however, that the action of such drugs in treating obesity is primarily one of appetite suppression. Other central nervous system actions, or metabolic effect, 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 greater in the first weeks of therapy for both drug and placebo subjects and tends to decrease in succeeding weeks. The origins of the increased weight loss due to the various possible 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 drug 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.
There is neither specific evidence which clearly establishes the mechanism whereby Amphetamine produces mental and behavioral effects in children, nor conclusive evidence regarding how these effects relate to the condition of the central nervous system.

INDICATIONS

In Attention Deficit Disorder with Hyperactivity: Amphetamine is indicated as an integral part of a total treatment program which typically includes other remedial measures (psychological educational, social) for a stabilizing effect in children with behavioral syndrome characterized by the following group of developmentally inappropriate symptoms: moderate to severe distractibility, short attention span, hyperactivity, emotional liability, and impulsivity. The diagnosis of this symdrome should not be made with finality when these symptoms are only of comparatively recent origin. Nonlocalizing (soft) neurological signs, learning disability and abnormal EEG may or may not be present, and a diagnosis of central nervous system dysfunction may or may not be warranted.
Exogenous Obesity as a short-term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction, for patients refractory to alternative therapy, e.g., repeated diets, group programs, and other drugs. The limited usefulness of amphetamines (see ACTIONS) should be weighed against possible risks inherent in use of the drug, such as those described below.
Narcolepsy

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

When tolerance to the "anorectic" effect develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued. Clinical experience suggests that in psychotic children, administration of Amphetamine may exacerbate symptoms of behavior disturbance and thought disorder. Data are inadequate to determine whether chronic administration of Amphetamine may be associated with growth inhibition;

PRECAUTION

General: Caution is to be exercised in prescribing amphetamines for patients with even mild hypertension.
The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage.
ADDERALL 20 mg contains FD&C Yellow #6, which may cause allergic-type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow #6 sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.
Information for Patients: Amphetamines may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or vehicles; the patient should therefore be cautioned accordingly.
Drug Interactions: Acidifying agents—Gastrointestinal acidifying agents (guanethidine, reserpine, glutamic acid HCl, ascorbic acid, fruit juices, etc.) lower absorption of amphetamines.
Urinary acidifying agents (ammonium chloride, sodium acid phosphate, etc.) increase the concentration of the more active species of the amphetamine molecule, thereby increasing urinary excretion. Both groups of agents lower blood levels and efficacy of amphetamines.
Adrenergic blockers—Adrenergic blockers are inhibited by amphetamines.
Alkalinizing agents—Gastrointestinal alkalinizing agents (sodium bicarbonate, etc.) increase absorption of amphetamines. Urinary alkalinizing agents (acetazolamide, some thiazides) increase the concentration of the non-ionized species of the amphetamine molecule, thereby decreasing urinary excretion. Both groups of agents increase blood levels and therefore potentiate the actions of amphetamines.
Antidepressants, tricyclic—Amphetamines may enhance the activity of tricyclic or sympathomimetic agents (desipramine with desipramine of protriptyline and possibly other tricyclics cause striking and sustained increases in concentration of d-amphetamine in the brain; cardiovascular effects can be potentiated
MAO Inhibitors—MAOI antidepressants, as well as a metabolite of furazolidone, slow amphetamine metabolism. This slowing potentiates, amphetamines, increasing their effects on the release of *norepinephrine and other* monoamines from adrenergic nerve endings; this can cause headaches and other signs of hypertensive crisis. A variety of neurotoxic effects and malignant hyperpyrexia can occur, sometimes with fatal results.
Antihistamines—Amphetamines—Amphetamines counteract the sedative effect of antihistamines.
Antihypertensives—Amphetamines may antagonize hypotensive effects of antihypertensives.
Chlorpromazine—Chlorpromazine blocks dopamine and norepinephrine reuptake, thus inhibiting the central stimulant effects of amphetamines, and can be used to treat amphetamine poisoning.
Ethosuximide—Amphetamines may delay intestinal absorption of ethosuximide.
Haloperidol—Haloperidol blocks dopamine and norepinephrine reuptake, thus inhibiting the central stimulant effects of amphetamines.
Lithium carbonate—The antiobesity and stimulatory effects of amphetamines may be inhibited by lithium carbonate.
Meperidine—Amphetamines potentiate the analgesic action of meperidine.
Methenamine therapy—Urinary excretion of amphetamines is increased, and efficacy is reduced, by acidifying agents used in methenamine therapy.
Norepinephrine—Amphetamines enhance the stimulant effect of norepinephrine.
Phenobarbital—Amphetamines may delay intestinal absorption of phenobarbital; co-administration of phenobarbital may produce a synergistic anticonvulsant action.
Phenytoin—Amphetamines may delay intestinal absorption of phenytoin; co-administration of phenytoin may produce synergistic anticonvulsant action.
Propoxyphene—In cases of propoxyphene overdosage, amphetamine CNS stimulation is potentiated and fatal convulsions can occur.
Veratrum alkaloids—Amphetamines inhibit the hypertensive effect of veratrum alkaloids.
Drug/Laboratory Test Interactions:

- Amphetamines can cause a significant elevation in plasma corticosteroid levels. This increase is greatest in the evening.
- Amphetamines may interfere with urinary steroid determinations.

Carcinogenesis/Mutagenesis: Mutagenicity studies and long-term studies in animals to determine the carcinogenic potential of Amphetamine, have not been performed.
Pregnancy—Teratogenic Effects: Pregnancy Category C

...hite rabbits given the drug in doses 7 times the ...se nor in rats given 12.5 times the maximum hu... There are no adequate and well-controlled studies ...t women. Amphetamines should be used during ... only if the potential benefit justifies the potential ... fetus.

...nic Effects: Infants born to mothers dependent ...tamines have an increased risk of premature deliv... birth weight. Also, these infants may experience ... of withdrawal as demonstrated by dysphoria, in...itation, and significant lassitude.

...Use: Long-term effects of amphetamines in chil... not been well established. Amphetamines are not ...ded for use as anorectic agents in children under ... age, or in children under 3 years of age with At...Deficit Disorder with Hyperactivity described under ...TIONS AND USAGE.

...experience suggest that in psychotic children, ad...tion of amphetamines may exacerbate symptoms of ...disturbance and thought disorder.

...tamines have been reported to exacerbate motor and ...tics and Tourette's syndrome. Therefore, clinical ...n for tics and Tourette's syndrome in children and ...milies should precede use of stimulant medications.

...e inadequate to determine chronic administration of ...tamines may be associated with growth inhibition; ... growth should be monitored during treatment.

...tment is not indicated in all cases of Attention Def...der with Hyperactivity and should be considered ...ght of the complete history and evaluation of the ...The decision to prescribe amphetamines should de... the physician's assessment of the chronicity and ... of the child's symptoms and their appropriateness ...ker age. Prescription should not depend solely on ...ence of one or more of the behavioral characteris... when these symptoms are associated with acute stress ... treatment with amphetamines is usually not ...ed.

...RSE REACTIONS

...ascular: Palpitations, tachycardia, elevation of ...ressure.

...l Nervous System: Psychotic episodes at recom... doses (rare), overstimulation, restlessness, dizziness, ...a, euphoria, dyskinesia, dysphoria, tremor, head... exacerbation of motor and phonic tics and Tourette's ...me.

...estinal: Dryness of the mouth, unpleasant taste, ..., constipation, other gastrointestinal disturbances. ...ia and weight loss may occur as undesirable effects ...mphetamines are used for other than the anorectic ...

...: Urticaria.

...ic: Impotence, changes in libido.

...ABUSE AND DEPENDENCE

...mphetamine sulfate is a Schedule II controlled sub... Amphetamines have been extensively abused. Toler... extreme psychological dependence, and severe social ...y have occurred. There are reports of patients who ...creased the dosage to many times that recommended. ...t cessation following prolonged high dosage adminis... results in extreme fatigue and mental depression: ...s are also noted on the sleep EEG. Manifestations ...ic intoxication with amphetamines include severe ...ses, marked insomnia, irritability, hyperactivity, ...onality changes. The most severe manifestation of ...ic intoxication is psychosis, often clinically indistin...ble from schizophrenia. This is rare with oral amphet...

...DOSAGE

...al patient response to amphetamines varies widely. ...ic symptoms occasionally occur as an idiosyncrasy ...as low as 2 mg, they are rare with doses of less than ...0 mg can produce severe reactions, yet doses of 400 to ... area not necessarily fatal.

...the oral LD_{50} of dextroamphetamine sulfate is 96.8 ...

...OMS—Manisfestations of acute overdosage with ...mines include restlessness, tremor, hyperreflexia ...spiration, confusion, assaultiveness, hallucinations, ...ales, hyperpyrexia and rhabdomolysis. ... and depresssion usually follow the central ...ion.

...scular effects include arrhythmias, hypertension ...latory collapse.

...estinal symptoms include nausea, vomiting, diar... abdominal cramps. Fatal poisoning is usually pre... convulsions and coma.

...MENT—Management of acute amphetamine intoxi... is largely symptomatic and includes gastric lavage ...ion with a barbiturate. Experience with hemodialy... nous phentolamine (Regitine®, CIBA) has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Chlorpromazine antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine intoxication.

Saline cathartics are useful for hastening the evacuation of pellets that have not already released medication.

DOSAGE AND ADMINISTRATION

Regardless of indication, amphetamines should be administered at the lowest effective dosage and dosage should be individually adjusted. Late evening doses should be avoided because of the resulting insomnia.

Narcolepsy: Usual dose 5 to 60 milligrams per day in divided doses, depending on the individual patient response. Narcolepsy seldom occurs in children under 12 years of age; however, when it does, dextroamphetamine sulfate, may be used. The suggested initial dose for patients aged 6–12 is 5 mg daily; daily dose may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. In patients 12 years of age and older, start with 10 mg daily; daily dosage may be raised in increments of 10 mg at weekly intervals until optimal response is obtained. If bothersome adverse reactions appear (e.g., insomnia or anorexia), dosage should be reduced. Give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours.

Attention Deficit Disorder with Hyperactivity: Not recommended for children under 3 years of age. In children from 3 to 5 years of age, start with 2.5 mg daily, daily dosage may be raised in increments of 2.5 mg at weekly intervals until optimal response is obtained.

In children 6 years of age and older, start with 5 mg once or twice daily; daily doage may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. Only in rare cases will it be necessary to exceed a total of 40 milligrams per day. Give first dose on awakening; additional doses (1 or 2) at intervals of 4 to 6 hours.

Where possible, drug administration should be interrupted occasionaly to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

Exogenous Obesity: Usual adult dose if 5 to 30 mg per day in divided doses, taken 30 to 60 minutes before meals. Not recommended for use in children under 12 years of age.

HOW SUPPLIED

ADDERALL 10 mg Blue scored tablet IMPRINTED OP-32 (NDC 58521-032-01)

ADDERALL 20 mg Orange scored tablet IMPRINTED OP-33 (NDC 58521-033-01)

In bottles of 100 Tablets.

Dispense in a tight container as defined in the USP.

Store in controlled room Temperature 15°–30°C (59°–86°F).

CAUTION: Federal law prohibits dispensing without prescription.

Manufactured for:
Richwood Pharmaceutical Company, Inc.
Florence, KY 41042
Manufactured by:
Rexar Pharmacal
Valley Stream, NY 11581

Revised: April 1994 MG#10185

Shown in Product Identification Guide, page 325

BELLATAL™ ℞

DESCRIPTION

Each scored, white, compressed, oral tablet contains:

Phenobarbital USP	16.2 mg

Warning: May be habit forming.

From:

Hyoscyamine Sulfate USP	0.1037 mg
Atropine Sulfate USP	0.0194 mg
Scopolamine Hydrobromide USP	0.0065 mg

Inactive Ingredients: Lactose, Magnesium Stearate, Microcrystalline Cellulose, Starch, Stearic Acid.

ACTIONS

This drug combination provides natural belladonna alkaloids in a specific, fixed ratio combined with phenobarbital to provide peripheral anticholinergic/antispasmodic action and mild sedation.

INDICATIONS

Based on a review of this drug by the National Academy of Sciences-National Research Council and/or other information, FDA has classified the following indications as "possibly" effective: For use as adjunctive therapy in the treatment of irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis.

OF A DUODENAL ULCER, DECREASE THE RATE OF RECURRENCES OR PREVENT COMPLICATIONS. Final classification of the less-than-effective indications requires further investigation.

DOSAGE AND ADMINISTRATION

Dosage should be adjusted to the needs of the individual patient to assure symptomatic control with a minimum of adverse effects.

Oral, Adults: One or two tablets three or four times a day according to condition and severity of symptoms.

Overdosage: The signs and symptoms of overdose are headache, nausea, vomiting, blurred vision, dilated pupils, hot and dry skin, dizziness, dryness of mouth, difficulty in swallowing, CNS stimulation. Treatment should consist of gastric lavage, emetics, and activated charcoal. If indicated, parenteral cholinergic agents such as physostigmine or bethanechol chloride should be added.

CAUTION

Federal law prohibits dispensing without prescription.

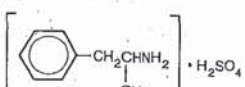
HOW SUPPLIED

Scored, white, compressed oral tablets imprinted.
0478/5477
Bottle of 100 NDC 58521-162-01
Bottle of 500 NDC 58521-162-05
Dispense in a tight container as defined in the USP.
Manufactured For:
RICHWOOD PHARMACEUTICAL COMPANY INC.
FLORENCE, KY 41042
Manufactured by:
REXAR PHARMACAL
VALLEY STREAM, N.Y. 11581
March 1994 MG#10179

Shown in Product Identification Guide, page 325

DEXTROSTAT™ ℞

DEXTROAMPHETAMINE SULFATE TABLETS, USP



WARNING: AMPHETAMINES HAVE A HIGH POTENTIAL FOR ABUSE. THEY SHOULD THUS BE TRIED ONLY IN WEIGHT REDUCTION PROGRAMS FOR PATIENTS IN WHOM ALTERNATIVE THERAPY HAS BEEN INEFFECTIVE. ADMINISTRATION OF AMPHETAMINES FOR PROLONGED PERIODS OF TIME IN OBESITY MAY LEAD TO DRUG DEPENDENCE AND MUST BE AVOIDED. PARTICULAR ATTENTION SHOULD BE PAID TO THE POSSIBLITY OF SUBJECTS OBTAINING AMPHETAMINES FOR NON-THERAPEUTIC USE OR DISTRIBUTION TO OTHERS, AND THE DRUGS SHOULD BE PRESCRIBED OR DISPENSED SPARINGLY.

DESCRIPTION

Dextroamphetamine Sulfate is the dextro isomer of the compound d, l-Amphetamine Sulfate, a sympathomimetic amine of the amphetamine group. Chemically, dextroamphetamine is d-alpha-methylphenethylamine, and is present as the neutral sulfate. Has a Chemical formula of $(C_9H_{13}N)_2H_2SO_4$ and a molecular weight of 368.49.

Each tablet for oral administration contains 5 mg of Dextroamphetamine Sulfate. Inactive ingredients consist of Sucrose, Lactose, Corn Starch, Acacia, Magnesium Sterate and FD&C Yellow #5.

INDICATIONS AND USAGE

In Attention Deficit Disorder with Hyperactivity: Amphetamine is indicated as a integral part of a total treatment program which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with behavioral syndrome characterized by the following group of developmentally inappropriate symptoms, moderate to severe distractibility, short attention span, hyperactivity, emotional lability, and impulsivity. The diagnosis of this syndrome should not be made with finality when these symptoms are only of compartively recent origin. Nonlocalizing (soft) neurological signs, learning disability and abnormal EEG may or may not be present, and a