

1987

Lanier Brugh, Inc v. Steward : Unknown

Utah Court of Appeals

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UTAH COURT OF APPEALS
BRIEF

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APPENDIX V

1986 PHYSICIANS DESK REFERENCE
PRODUCT INFORMATION

PDR®
40
EDITION
1986

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maintained a normal TSH during those two to eight

Reactions: Adverse reactions, other than those of hyperthyroidism because of therapeutic over-, either initially or during the maintenance period are rare (see OVERDOSAGE).

Instances, allergic skin reactions have been reported with Cytomel (liothyronine sodium, SK&F) Tablets.

Overdose:

and Symptoms:—Headache, irritability, nervousness, tachycardia, increased bowel motility and men- irregularities. Angina pectoris or congestive heart may be induced or aggravated. Shock may also de- Massive overdose may result in symptoms resem- hyroid storm. Chronic excessive dosage will produce ns and symptoms of hyperthyroidism.

ment of Overdose:—Dosage should be reduced or temporarily discontinued if signs and symptoms of age appear. Treatment may be reinstituted at a dosage. In normal individuals, normal hypothalamic- thyroid axis function is restored in six to eight after thyroid suppression.

ent of acute massive thyroid hormone overdose is at reducing gastrointestinal absorption of the drugs interacting central and peripheral effects, mainly f increased sympathetic activity. Vomiting may be initially if further gastrointestinal absorption can bly be prevented and barring contraindications such , convulsions, or loss of the gagging reflex. Treatment omatic and supportive. Oxygen may be administered tilation maintained. Cardiac glycosides may be indi- congestive heart failure develops. Measures to con- , hypoglycemia, or fluid loss should be instituted if . Antiadrenergic agents, particularly propranolol, en used advantageously in the treatment of in- sympathetic activity. Propranolol may be adminis- travenously at a dosage of 1 to 3 mg. over a 10-minute r orally, 80 to 160 mg./day, especially when no con- ations exist for its use.

and Administration: The dosage of thyroid hor- s determined by the indication and must in every individualized according to patient response and ry findings.

hormones are given orally. In acute, emergency ns, injectable levothyroxine sodium may be given ously when oral administration is not feasible or , as in the treatment of myxedema coma or during enteral nutrition. Cytomel (liothyronine sodium) is able from Smith Kline & French Laboratories upon nder investigational status, for the treatment of a coma. Intramuscular administration of these two ions is not advisable because of reported poor ab-

tomel (liothyronine sodium, SK&F) Tablets once- age is recommended; although liothyronine sodium id cutoff, its metabolic effects persist for a few days f discontinuance.

hypothyroidism: Recommended starting dosage is . daily. Daily dosage then may be increased by 12.5 mcg. every one or two weeks. Usual maintenance 25-75 mcg. daily. Smaller doses may be fully effec- some patients, while dosage of 100 mcg. daily may ired in others.

pid onset and dissipation of action of liothyronine (T₃), as compared with levothyroxine sodium (T₄), some clinicians to prefer its use in patients who e more susceptible to the untoward effects of thy- adication. However, the wide swings in serum T₃ hat follow its administration and the possibility of onounced cardiovascular side effects tend to coun- nce the stated advantages.

l (liothyronine sodium, SK&F) Tablets may be used erence to levothyroxine (T₄) during radioisotope g procedures, since induction of hypothyroidism in uses is more abrupt and can be of shorter duration. also be preferred when impairment of peripheral ion of T₄ and T₃ is suspected.

ma: Recommended starting dosage is 5 mcg. his may be increased by 5 to 10 mcg. daily every wo weeks. When 25 mcg. daily is reached, dosage n be increased by 12.5 or 25 mcg. every one or two usual maintenance dose is 50 to 100 mcg. daily. **ma Coma:** Myxedema coma is usually precipi- the hypothyroid patient of long standing by inter- illness or drugs such as sedatives and anesthetics uld be considered a medical emergency. A 'Cyto- ection Kit for the emergency treatment of myx- oma is available from Smith Kline & French Labo- upon request, under investigational status. In- ns which accompany this kit provide information nistration.

tal Hypothyroidism: Recommended starting 5 mcg. daily, with a 5 mcg. increment every three ays until the desired response is achieved. Infants nths old may require only 20 mcg. daily for main- At one year, 50 mcg. daily may be required.

Above three years, full adult dosage may be necessary (See PRECAUTIONS, Pediatric Use).

Simple (non-toxic) Goiter: Recommended starting dosage is 5 mcg. daily. This dosage may be increased by 5 to 10 mcg. daily every one or two weeks. When 25 mcg. daily is reached, dosage may be increased every week or two by 12.5 or 25 mcg. Usual maintenance dosage is 75 mcg. daily.

In the elderly or in children, therapy should be started with 5 mcg. daily and increased only by 5 mcg. increments at the recommended intervals.

When switching a patient to Cytomel (liothyronine sodium, SK&F) Tablets from thyroid, L-thyroxine or thyroglobulin, discontinue the other medication, initiate 'Cytomel' at a low dosage, and increase gradually according to the patient's response. When selecting a starting dosage, bear in mind that this drug has a rapid onset of action, and that residual effects of the other thyroid preparation may persist for the first several weeks of therapy.

Thyroid Suppression Therapy: Administration of thyroid hormone in doses higher than those produced physiologi- cally by the gland results in suppression of the production of endogenous hormone. This is the basis for the thyroid sup- pression test and is used as an aid in the diagnosis of patients with signs of mild hyperthyroidism in whom baseline labora- tory tests appear normal or to demonstrate thyroid gland autonomy in patients with Graves' ophthalmopathy. ¹³¹I uptake is determined before and after the administration of the exogenous hormone. A 50 percent or greater suppression of uptake indicates a normal thyroid-pituitary axis and thus rules out thyroid gland autonomy.

Cytomel (liothyronine sodium, SK&F) Tablets are given in doses of 75-100 mcg./day for seven days, and radioactive io- dine uptake is determined before and after administration of the hormone. If thyroid function is under normal control, the radioiodine uptake will drop significantly after treatment. Cytomel (liothyronine sodium, SK&F) Tablets should be ad- ministered cautiously to patients in whom there is a strong suspicion of thyroid gland autonomy, in view of the fact that the exogenous hormone effects will be additive to the endoge- nous source.

How Supplied: Cytomel (liothyronine sodium, SK&F) tablets: 5 mcg. in bottles of 100; 25 mcg. in bottles of 100 and 1000; and 50 mcg. in bottles of 100.

CY:L30

Shown in Product Identification Section, page 429

DARBD® TABLETS, 5 mg.

[dahr'bid]

(brand of isopropamide iodide)

Description: Darbid (brand of isopropamide iodide) is avail- able as a tablet for oral administration. Each round, pink, coated tablet is imprinted SKF and D62 and contains isopro- pamide iodide equivalent to 5 mg. of isopropamide. Inactive ingredients consist of acacia, calcium sulfate, FD&C Red No. 3, FD&C Yellow No. 6, gelatin, iron oxide, mineral oil, starch, stearic acid, sucrose, talc, titanium dioxide and trace amounts of other inactive ingredients.

Chemically, Darbid (isopropamide iodide, SK&F) is (3-carbam- oyl-3, 3-diphenylpropyl) diisopropylmethyl ammonium io- dide.

Actions: Isopropamide iodide is a synthetic anticholinergic that produces 10- to 12-hour gastric acid antisecretory effect and gastrointestinal antispasmodic response in man.

Indications: 'Darbid' is effective as adjunctive therapy in the treatment of peptic ulcer.

'DARBD' HAS NOT BEEN SHOWN TO BE EFFECTIVE AS SOLE THERAPY IN CONTRIBUTING TO THE HEAL- ING OF PEPTIC ULCER, DECREASING THE RATE OF RECURRENCE OR PREVENTING COMPLICATIONS.

To be effective, dosage must be titrated to the individual pa- tient's needs.

Contraindications: Glaucoma; obstructive uropathy (e.g., bladder neck obstruction due to prostatic hypertrophy); ob- structive disease of the gastrointestinal tract (as in achal- sia, pyloroduodenal stenosis, etc.); obstructive or paralytic ileus, intestinal atony of the elderly or debilitated patient; unstable cardiovascular status in acute hemorrhage; severe ulcerative colitis; toxic megacolon complicating ulcerative colitis; myasthenia gravis.

Warnings: In the presence of a high environmental temper- ature, heat prostration (fever and heat stroke due to de- creased sweating) can occur.

In patients with diarrhea due to incomplete intestinal ob- struction (especially those with ileostomy or colostomy), treatment with Darbid (isopropamide iodide, SK&F) would be inappropriate and possibly harmful.

'Darbid' may produce drowsiness or blurred vision. In this event, the patient should be warned not to engage in activi- ties requiring mental alertness such as operating a motor vehicle or other machinery or perform hazardous work while taking this drug.

Usage in Pregnancy: In pregnancy, lactation, and in women who may bear children, the potential benefits of the drug must be weighed against possible hazards.

Precautions: Use cautiously in elderly patients.

Since the iodine in isopropamide iodide may alter PBI test results and will suppress ¹³¹I uptake, it is suggested that therapy be discontinued one week prior to these tests. Also, iodine skin rash may occur rarely.

Use with caution in patients with:

Autonomic neuropathy.

Hepatic or renal disease.

Ulcerative colitis (large doses may suppress intestinal motil- ity to the point of producing paralytic ileus, and the use of this drug may precipitate or aggravate the serious complica- tion of toxic megacolon).

Hyperthyroidism, coronary heart disease, congestive heart failure, cardiac arrhythmia, hypertension and nonobstruct- ing prostatic hypertrophy.

Hiatal hernia associated with reflux esophagitis (anticholin- ergic drugs may aggravate this condition).

It should be noted that the use of anticholinergic drugs in the treatment of gastric ulcer may produce a delay in gastric emptying time (antral stasis) and, thus, complicate therapy. Do not rely on the use of the drug in the presence of complica- tion of biliary tract disease.

Investigate any tachycardia before giving anticholinergic (atropine-like) drugs, since they may increase the heart rate.

With overdose, a curare-like action may occur.

Adverse Reactions: Anticholinergics produce certain phar- macological effects which may be desirable or undesirable, depending upon the individual patient's response. The physi- cian must delineate these.

Adverse reactions which have occurred with Darbid (isopro- pamide iodide, SK&F) include: xerostomia (dry mouth); uri- nary hesitancy and retention; blurred vision; tachycardia; palpitations; mydriasis (dilatation of the pupils); cycloplegia; constipation; bloated feeling; nausea; dysphagia; fever; and nasal congestion.

Other adverse reactions possible with anticholinergics in- clude: increased ocular tension; loss of taste; headaches; ner- vousness; drowsiness; weakness; dizziness; insomnia; vomit- ing; impotence; suppression of lactation; severe allergic reac- tion or drug idiosyncrasies including anaphylaxis; urticaria and other dermal manifestations; some degree of mental confusion and/or excitement, especially in elderly persons. Decreased sweating may occur. It should be noted that ad- renergic innervation of the eccrine sweat glands on the palms and soles makes complete control of sweating impossi- ble. An end point of complete anhidrosis cannot occur be- cause large doses of drug would be required, and this would produce severe side effects from parasympathetic paralysis.

Dosage and Administration: Not for use in children under 12. Adults and children over 12—Usual starting dose is one 5 mg. tablet b.i.d. (every 12 hours). Patients with severe symptoms may require two 5 mg. tablets b.i.d., or more. Dosage should be individualized and titrated to the patient's need for greatest therapeutic effect.

Overdose: Involves the cardiovascular, respiratory, gas- trointestinal, central and peripheral nervous systems.

SYMPTOMS: May include dryness of mouth, dysphagia, thirst, blurred vision, dilated pupils, photophobia, fever, rapid pulse and respiration, disorientation. Depression and circulatory collapse may result from severe overdose.

TREATMENT:—Gastric lavage, repeated several times.

Respiratory depression should be promptly treated by the use of oxygen and stimulants. If marked excitement is pres- ent, one of the short-acting barbiturates, chloral hydrate, or gas anesthesia may be used. Otherwise do not administer sedation. Hyperpyrexia may be treated with physical cooling measures. Force fluids by mouth or, if necessary, by intrave- nous administration.

While pilocarpine or similar drugs are sometimes recom- mended for the relief of dry mouth, many authorities feel that these drugs are not indicated, since they relieve the minor peripheral effect but do not influence the more serious central effects and, thus, may merely mask signs of drug activity. If photophobia occurs, the patient should be kept in a darkened room.

How Supplied: Tablets, 5 mg., in bottles of 50.

Shown in Product Identification Section, page 429

DB:L16

DEXEDRINE®

[dex'eh-dreen]

(brand of dextroamphetamine sulfate)

SPANSULE® CAPSULES,

TABLETS and ELIXIR

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 AMPHETA- MINES FOR PROLONGED PERIODS OF TIME IN

Continued on next page

3 & French—Cont.

LEAD TO DRUG DEPENDENCE AND VOIDED PARTICULAR ATTENTION PAID TO THE POSSIBILITY OF SUBINING AMPHETAMINES FOR NON C USE OR DISTRIBUTION TO OTHER DRUGS SHOULD BE PRESCRIBED D SPARINGLY

Dexedrine (dextroamphetamine sulfate, dextro isomer of the compound *d,l*-amphetamine, sympathomimetic amine of the amphetamine, dextroamphetamine is *d*-alpha amine, and is present in all forms of 'Dexedrine' sulfate

The sustained release capsule is so prepared that it releases promptly and the remaining medication gradually over a prolonged period. Each brown cap and natural body, contains dextroamphetamine sulfate as follows: 5 mg. imprinted SKF and E13, 15 mg. imprinted cursive ingredients consist of acacia, benzyl sulfate, cetylpyridinium chloride, FD&C Red No. 40, FD&C Yellow No. 5 (tartrazine), No. 6 gelatin, glyceryl distearate, glyceryl sodium lauryl sulfate, starch, sucrose, and other inactive ingredients.

Each scored tablet is debossed SKF and dextroamphetamine sulfate, 5 mg. Inactive ingredients consist of calcium sulfate, FD&C Yellow No. 5, Yellow No. 6, gelatin, lactose, mineral oil, sucrose, talc and trace amounts of other

ingredients. Each clear, orange-colored, orange-impregnated dextroamphetamine sulfate, 5 mg., inactive ingredients consist of benzocaine, FD&C Yellow No. 5 (tartrazine), FD&C Yellow No. 6, water and wine.

Pharmacology. Amphetamines are non-catecholamine sympathomimetic amines with CNS stimulant actions. They include elevations of systolic and diastolic blood pressure and weak bronchodilator and respiratory

stimulant effects. Amphetamines clearly establish the efficacy of amphetamines in producing mental and physical effects in children, nor conclusive evidence relates to the condition of the central nervous system.

Amphetamines are commonly known as "recreational drugs." It has not been established whether the use of such drugs in treating obesity is effective. Other central nervous system effects, metabolic effects, may be involved, for

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blood level of 29.2 ng/ml at 2 hours post administration. The average half life was 10.25 hours. The average urinary recovery was 45% in 48 hours.

'Spansule' capsule.—Ingestion of a 'Spansule' capsule containing 15 mg. radiolabeled dextroamphetamine sulfate by healthy volunteers produced a peak blood level of radioactivity, on the average, at 8-10 hours post administration with peak urinary recovery seen at 12-24 hours.

Indications and Usage. Dexedrine (dextroamphetamine sulfate, SK&F) is indicated:

1 In Narcolepsy

2 In Attention Deficit Disorder with Hyperactivity. 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 a 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 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.

3 In 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 CLINICAL PHARMACOLOGY) should be weighed against possible risks inherent in use of the drug, 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).

Warning. 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.

Precautions

General. Caution is to be exercised in prescribing amphetamine to patients with even mild hypertension.

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

These products contain FD&C Yellow #5 (tartrazine), which may cause allergic type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C Yellow #5 (tartrazine) 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 (gastric acid, 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 ionized 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. d-amphetamine with desipramine or protriptyline and possibly other tricyclics cause striking and sustained increases in the 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 effect 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 neurological toxic effects and malignant hyperpyrexia can occur, sometimes with fatal results.

Antihistamines.—Amphetamines may counteract the sedative effect of antihistamines.

Antihypertensives.—Amphetamines may antagonize the 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 anorectic and stimulatory effects of amphetamines may be inhibited by lithium carbonate.

Meperidine.—Amphetamines potentiate the analgesic effect of meperidine.

Methamphetamine therapy.—Urinary excretion of amphetamines is increased, and efficacy is reduced, by acidifying agents used in methamphetamine therapy.

Norepinephrine.—Amphetamines enhance the adrenergic 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 a synergistic anticonvulsant action.

Propoxyphene.—In cases of propoxyphene overdose, amphetamine CNS stimulation is potentiated and fatal convulsions can occur.

Veratrum alkaloids.—Amphetamines inhibit the hypotensive 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 Dexedrine (dextroamphetamine sulfate, SK&F) have not been performed.

Pregnancy—Teratogenic Effects. Pregnancy Category C. 'Dexedrine' has been shown to have embryotoxic and teratogenic effects when administered to A/Jax mice and C57BL mice in doses approximately 41 times the maximum human dose. Embryotoxic effects were not seen in New Zealand white rabbits given the drug in doses 1/10 times the human dose nor in rats given 1/25 times the maximum human dose. There are no adequate and well-controlled studies in pregnant women. 'Dexedrine' should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Nonteratogenic Effects. Infants born to mothers dependent on amphetamines have an increased risk of premature delivery and low birth weight. Also, these infants may experience symptoms of withdrawal as demonstrated by dysphoria, including agitation, and significant lassitude.

Nursing Mothers. It is not known whether this drug is excreted in breast milk; efforts to measure amphetamines in breast milk have been unsuccessful. Because many drugs are excreted in human milk, caution should be exercised when 'Dexedrine' is administered to a nursing woman.

Pediatric Use. Long term effects of amphetamines in children have not been well established.

Amphetamines are not recommended for use as anorectic agents in children under 12 years of age, or in children under 3 years of age with Attention Deficit Disorder with Hyperactivity described under INDICATIONS AND USAGE.

Clinical experience suggests that in psychotic children, administration of amphetamines may exacerbate symptoms of behavior disturbance and thought disorder.

Amphetamines have been reported to exacerbate motor and phonic tics and Tourette's syndrome. Therefore, clinical evaluation for tics and Tourette's syndrome in children and their families should precede use of stimulant medications. Data are inadequate to determine whether chronic administration of amphetamines may be associated with growth inhibition; therefore, growth should be monitored during treatment.

Drug treatment is not indicated in all cases of Attention Deficit Disorder with Hyperactivity and should be considered only in light of the complete history and evaluation of the child. The decision to prescribe amphetamines should depend on the physician's assessment of the chronicity and severity of the child's symptoms and their appropriateness for his/her age. Prescription should not depend solely on the presence of one or more of the behavioral characteristics. When these symptoms are associated with acute stress reactions, treatment with amphetamines is usually not indicated.

Adverse Reactions

Cardiovascular. Palpitations, tachycardia, elevation of blood pressure.

Central Nervous System. Psychotic episodes at recommended doses (rare), overstimulation, restlessness, dizziness, insomnia, euphoria, dyskinesia, dysphoria, tremor, head

Product Information

exacerbation of motor and phonic tics and Tourette's syndrome. Dryness of the mouth, unpleasant taste, heart constipation, other gastrointestinal disturbances, anorexia and weight loss may occur as undesirable effects. Amphetamines are used for other than the anorectic

gic Urticaria

crine Impotence, changes in libido

Abuse and Dependence Dextroamphetamine sulfate is a Schedule II controlled substance.

Amphetamines have been extensively abused. Tolerance, psychological dependence and severe social disability have occurred. There are reports of patients who have abused the dosage to many times that recommended. Cessation following prolonged high dosage administration results in extreme fatigue and mental depression, as are also noted on the sleep EEG.

Manifestations of chronic intoxication with amphetamines include severe dermatoses, marked insomnia, irritability, activity, and personality changes. The most severe manifestation of chronic intoxication is psychosis, often indistinguishable from schizophrenia. This is rare with amphetamines.

Individual patient response to amphetamine varies widely. While toxic symptoms occasionally occur, an idiosyncrasy at doses as low as 2 mg, they are rare. Doses of less than 15 mg, 30 mg can produce severe effects, yet doses of 400 to 500 mg are not necessarily fatal.

The oral LD₅₀ of dextroamphetamine sulfate is 96.8 g/kg.

TOMS—Manifestations of acute overdose with amphetamines include restlessness, tremor, hyperreflexia, hyperthermia, confusion, assaultiveness, hallucinations, states of depression usually follow the central stimulation.

vascular effects include arrhythmias, hypertension or hypotension and circulatory collapse. Gastrointestinal effects include nausea, vomiting, diarrhea and abdominal pain. Fatal poisoning is usually preceded by convulsions and coma.

Management—Management of acute amphetamine intoxication is largely symptomatic and includes gastric lavage, administration of a barbiturate. Experience with hemodialysis in this regard is inadequate to permit recommendation. Acidification of the urine increases amphetamine excretion. If acute, severe hypertension complicates amphetamine overdose, administration of intravenous phentolamine (Regitine®, CIBA) has been suggested. However, a gradual drop in blood pressure will usually result when sufficient sedation has been achieved. Diazepam antagonizes the central stimulant effects of amphetamines and can be used to treat amphetamine intoxication.

Each of the Spansule® capsule medication is coated for release therapy directed at reversing the effects of the drug and at supporting the patient should be required for as long as overdosage symptoms remain. Such capsules are useful for hastening the evacuation of the stomach, but have not already released medication.

Administration Regardless of indication, amphetamines should be administered at the lowest effective dose and dosage should be individually adjusted. Late doses—particularly with the Spansule® capsule—should be avoided because of the resulting insomnia. **Dosage** Usual dose 5 to 60 milligrams per day in divided doses depending on the individual patient response. Overdose seldom occurs in children under 12 years of age, when it does. Dextroamphetamine sulfate (Spansule®) may be used. The suggested initial dose for patients 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 starting daily dosage may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. If bothersome adverse reactions appear (e.g., insomnia, anorexia) dosage should be reduced. Spansule® capsules may be used for once-a-day dosage wherever appropriate. Tablets or elixir give first dose on awakening at intervals of 4 to 6 hours.

Deficit Disorder with Hyperactivity Not recommended in children under 3 years of age. Children from 3 to 5 years of age start with 2.5 mg daily or elixir. Daily dosage may be raised in increments of 2.5 mg at weekly intervals until optimal response is obtained.

Children 6 years of age and older start with 5 mg once or twice daily. Dosage may be raised in increments of 5 mg at weekly intervals until optimal response is obtained. In cases where it will be necessary to exceed a total of 40 mg per day.

With tablets or elixir, give first dose on awakening at intervals of 4 to 6 hours. Where possible, drug administration should be interrupted occasionally to determine if there is a recurrence of behavioral symptoms sufficient to require continued therapy.

Exogenous Obesity Usual dosage is one 10 or 15 mg 'Span' capsule daily, taken in the morning, or up to 30 mg daily by tablets or elixir, taken in divided doses of 5 to 10 mg 30 to 60 minutes before meals. Not recommended for this use in children under 12 years of age.

How Supplied

'Span' capsules available 5 mg, in bottles of 50, 10 mg and 15 mg, in bottles of 50 and 500.

Tablets, 5 mg, available in bottles of 100 and 1000.

Elixir, 5 mg/5 ml, available in 16 fl oz (473 ml) bottles.

Shown in Product Identification Section, page 429.

DX L34

DIBENZYLIN® Capsules

(dibenzylamine)

(brand of phenoxybenzamine hydrochloride)

Description Each 'Dibenzyl' capsule, with red cap and red body, is imprinted SKF and E33 and contains phenoxybenzamine hydrochloride, 10 mg. Inactive ingredients consist of benzyl alcohol, cetylpyridinium chloride, D&C Red No. 3, FD&C Red No. 3, FD&C Yellow No. 6, gelatin, lactose, sodium lauryl sulfate and trace amounts of other inactive ingredients.

'Dibenzyl' is N-(2-chloroethyl)-N-(1-methyl-2-phenoxylethyl) benzylamine hydrochloride. Phenoxybenzamine hydrochloride is a colorless, crystalline powder with a molecular weight of 340.3 which melts between 136° and 141°C. It is soluble in water, alcohol and chloroform, insoluble in ether.

Actions Dibenzyl (phenoxybenzamine hydrochloride, SKF) is a long acting adrenergic, α receptor blocking agent which can produce and maintain "chemical sympathectomy" by oral administration. It increases blood flow to the skin, mucosa and abdominal viscera, and lowers both supine and erect blood pressures. It has no effect on the parasympathetic system.

Indication Phentolamine, to control episodes of hypertension and sweating. If tachycardia is excessive, it may be necessary to use a beta blocking agent concomitantly.

Contraindications Conditions where a fall in blood pressure may be undesirable.

Warning 'Dibenzyl' induced α adrenergic blockade leaves beta adrenergic receptors unopposed. Compounds that stimulate both types of receptors may therefore produce an exaggerated hypotensive response and tachycardia.

Precautions Phenoxybenzamine hydrochloride has shown *in vitro* mutagenic activity in the Ames test and in the mouse lymphoma assay. It has not shown mutagenic activity in the micronucleus test in mice. In rats and mice repeated intraperitoneal administration of phenoxybenzamine hydrochloride resulted in peritoneal sarcomas. Chronic oral dosing in rats has produced malignant tumors of the gastrointestinal tract.

The clinical significance of such test results is not established. Nevertheless these results should be given consideration in determining the benefit risk ratio as it applies to the individual patient.

Administer with caution in patients with marked cerebral or coronary arteriosclerosis or renal damage. Adrenergic blocking effect may aggravate symptoms of respiratory infections.

Adverse Reactions Nasal congestion, miosis, postural hypotension, tachycardia and inhibition of ejaculation may occur. These so-called "side effects" are actually evidence of adrenergic blockade and vary according to the degree of blockade. Furthermore they tend to decrease as therapy is continued. Gastrointestinal irritation, drowsiness and fatigue have also been reported.

Dosage and Administration The dosage should be adjusted to fit the needs of each patient. Small initial doses should be slowly increased until the desired effect is obtained or the side effects from blockade become troublesome. After each increase the patient should be observed on that level before instituting another increase. The dosage should be carried to a point where symptomatic relief and/or objective improvement are obtained but not so high that the side effects from blockade become troublesome.

Initially 10 mg of Dibenzyl (phenoxybenzamine hydrochloride, SKF) twice a day. Dosage should be increased every other day usually to 20 to 40 mg two or three times a day until an optimal dosage is obtained as judged by blood pressure control.

Overdosage Symptoms—These are largely the result of block of the sympathetic nervous system and of the circulating epinephrine. They may include postural hypotension resulting in dizziness or fainting, tachycardia, particularly postural vomiting, lethargy, shock. **Treatment**—When

consideration. In cases of mild overdosage, recumbent position with legs elevated usually restores cerebral circulation. In the more severe cases the usual measures to combat shock should be instituted. Usual pressor agents are not effective. Epinephrine is contraindicated because it stimulates both α and β receptors, since α receptors are blocked, the net effect of epinephrine administration is vasodilation and further drop in blood pressure (epinephrine reversal).

The patient may have to be kept flat for 24 hours or more in the case of overdosage, as the effect of the drug is prolonged. Leg bandages and an abdominal binder may shorten the period of disability.

IV infusion of levarterenol bitartrate* may be used to combat severe hypotensive reactions, because it stimulates receptors primarily. Although Dibenzyl (phenoxybenzamine hydrochloride, SKF) is an α adrenergic blocking agent, a sufficient dose of levarterenol bitartrate will overcome the effect.

How Supplied Dibenzyl (phenoxybenzamine hydrochloride, SKF) capsules, 10 mg, in bottles of 100.

*Available as Levophed® Bitartrate (brand of levarterenol bitartrate) from Winthrop Laboratories.

Shown in Product Identification Section, page 429.

DI L2

DYAZIDE® Capsules

(dye uh zide')

('Dyazide' is a product of SK&F Co., Carolina, P.R. 00631. Subsidiary of SmithKline Beckman Corporation, Philadelphia, Pa.)

Warning

This fixed combination drug is not indicated for initial therapy of edema or hypertension. Edema or hypertension requires therapy titrated to the individual patient. If the fixed combination represents the dosage so determined, its use may be more convenient in patient management. The treatment of hypertension and edema is not static, but must be reevaluated as conditions in each patient warrant.

Description Each red and white 'Dyazide' capsule contains 50 mg of Dyrenum® (brand of triamterene), a potassium-sparing agent, and 25 mg of hydrochlorothiazide. 'Dyrenum' is 2, 4, 7 triamino-6-phenylpteridine. Hydrochlorothiazide is 6-chloro-3, 4-dihydro-2H, 1, 2, 4 benzothiadiazine-7-sulfonamide 1,1-dioxide.

At 50°C, triamterene is practically insoluble in water (less than 0.1%). It is soluble in formic acid, sparingly soluble in methoxyethanol, and very slightly soluble in alcohol. Hydrochlorothiazide is slightly soluble in water. It is soluble in dilute ammonia, dilute aqueous sodium hydroxide, and dimethylformamide. It is sparingly soluble in methanol. **Action** 'Dyazide' is a diuretic/antihypertensive drug product that combines the natriuretic hydrochlorothiazide, and the potassium-sparing natriuretic, triamterene, each of which complements the action of the other. The hydrochlorothiazide component blocks the reabsorption of sodium and chloride ions, and thereby increases the quantity of sodium traversing the distal tubule and the volume of water excreted. A portion of the additional sodium presented to the distal tubule is exchanged there for potassium and hydrogen ions. With continued use of hydrochlorothiazide and depletion of sodium, compensatory mechanisms tend to increase this exchange and may produce excessive loss of potassium, hydrogen and chloride ions. Hydrochlorothiazide also decreases the excretion of calcium and uric acid, may increase the excretion of iodide and may reduce glomerular filtration rate. The exact mechanism of the antihypertensive effect of hydrochlorothiazide is not known.

The triamterene component of 'Dyazide' exerts its diuretic effect on the distal renal tubule to inhibit the reabsorption of sodium in exchange for potassium and hydrogen ions. Its natriuretic activity is limited by the amount of sodium reaching its site of action. Although it blocks the increase in this exchange that is stimulated by mineralocorticoids (chiefly aldosterone) it is not a competitive antagonist of aldosterone and its activity can be demonstrated in adrenalectomized rats and patients with Addison's disease. As a result the dose of triamterene required is not proportionally related to the level of mineralocorticoid activity but is dictated by the response of the individual patient and the kaliuretic effect of concomitantly administered drugs. By inhibiting the distal tubular exchange mechanism triamterene maintains or increases the sodium excretion and reduces the excess loss of potassium, hydrogen and chloride ions induced by hydrochlorothiazide. As with hydrochlorothiazide triamterene may reduce glomerular filtration and renal plasma flow. Via this mechanism it may reduce uric acid excretion although it has no tubular effect on uric acid reabsorption or secretion. Triamterene does not affect calcium

organism is not likely to be eradicated from the na-
 nx of asymptomatic carriers
 applied Capsules, 300 mg (opaque scarlet and cara-
 tles of 30, 60, and 100 Also available, Rimac
 (NH (isoniazid USP) Dual Pack containing 60 Rimac-
 psules and 30 INH 300-mg Tablets

ice
 er, A W, Kirby, W M M, Sherris, J C, and Turck,
 otic susceptibility testing by a standardized single
 thod Am J Clin Path 45 493-496, 1966

C83-8 (Rev 7/83)

own in Product Identification Section, page 408

IN® hydrochloride @
 in]®
 phenidate hydrochloride USP)

IN-SR® @
 phenidate hydrochloride)
 d release tablets

tion: Ritalin is a white, odorless, fine crystalline
 solutions of which are acid to litmus It is freely solu-
 ation

Pharmacology: Ritalin is a mild central nervous
 stimulant
 e of action in man is not completely understood, but
 presumably activates the brain stem arousal system
 ex to produce its stimulant effect

neither specific evidence which clearly establishes
 hanism whereby Ritalin produces its mental and
 al effects in children, nor conclusive evidence re-
 how these effects relate to the condition of the cen-
 ous system

n the SR tablets is more slowly but as extensively
 as in the regular tablets Relative bioavailability of
 ablet compared to the Ritalin tablet, measured by
 ary excretion of Ritalin major metabolite (α phenyl
 line acetic acid) was 105% (49-168%) in children
 % (85-152%) in adults The time to peak rate in chil-
 , 4-7 hours (1-3-8-2 hours) for the SR tablets and 1-9
 3-4-4 hours) for the tablets An average of 67% of SR
 se was excreted in children as compared to 86% in

ons
 n Deficit Disorder: Narcolepsy (previously known
 nal Brain Dysfunction in Children) Other terms
 ed to describe the behavioral syndrome: low in
 yperkinetic Child Syndrome, Minimal Brain Dys-
 nimal Cerebral Dysfunction, Minor Cerebral Dys-

s indicated as an integral part of a total treatment
 which typically includes other remedial measures
 gical, educational, social) for a stabilizing effect in
 with a behavioral syndrome characterized by the
 group of developmentally inappropriate symp-
 omerate-to-severe distractibility, short attention
 peractivity, emotional lability, and impulsivity The
 of this syndrome should not be made with finality
 ese symptoms are only of comparatively recent ori-
 calizing (soft) neurological signs, learning disabil-
 abnormal EEG may or may not be present, and a
 of central nervous system dysfunction may or may
 arranged

Diagnostic Considerations

etiology of this syndrome is unknown, and there is
 diagnostic test Adequate diagnosis requires the use
 of medical but of special psychological, educational,
 il resources

istics commonly reported include chronic history
 attention span, distractibility, emotional lability,
 ity, and moderate-to-severe hyperactivity, minor
 ical signs and abnormal EEG Learning may or may
 paired The diagnosis must be based upon a com-
 ory and evaluation of the child and not solely on the
 of one or more of these characteristics

atment is not indicated for all children with this
 e Stimulants are not intended for use in the child
 bts symptoms secondary to environmental factors
 rimary psychiatric disorders, including psychosis
 ate educational placement is essential and psycho-
 ervention is generally necessary When remedial
 alone are insufficient, the decision to prescribe
 t medication will depend upon the physician's as-
 of the chronicity and severity of the child's symp-

ications: Marked anxiety, tension, and agita-
 contraindications to Ritalin, since the drug may
 e these symptoms Ritalin is contraindicated also in
 known to be hypersensitive to the drug, in patients
 coma, and in patients with motor tics or with a fam-
 y or diagnosis of Tourette's syndrome
 s Ritalin should not be used in children under six
 ice safety and efficacy in this age group have not
 blished

Sufficient data on safety and efficacy of long term use of Rit-
 alin in children are not yet available Although a causal rela-
 tionship has not been established, suppression of growth (ie,
 weight gain, and/or height) has been reported with the long-
 term use of stimulants in children Therefore, patients re-
 quiring long term therapy should be carefully monitored
 Ritalin should not be used for severe depression of either
 exogenous or endogenous origin Clinical experience sug-
 gests that in psychotic children, administration of Ritalin
 may exacerbate symptoms of behavior disturbance and
 thought disorder

Ritalin should not be used for the prevention or treatment of
 normal fatigue states

There is some clinical evidence that Ritalin may lower the
 convulsive threshold in patients with prior history of sei-
 zures, with prior EEG abnormalities in absence of seizures,
 and, very rarely, in absence of history of seizures and no
 prior EEG evidence of seizures Safe concomitant use of anti-
 convulsants and Ritalin has not been established In the
 presence of seizures, the drug should be discontinued

Use cautiously in patients with hypertension Blood pressure
 should be monitored at appropriate intervals in all patients
 taking Ritalin, especially those with hypertension

Symptoms of visual disturbances have been encountered in
 rare cases Difficulties with accommodation and blurring of
 vision have been reported

Drug Interactions

Ritalin may decrease the hypotensive effect of guanethidine
 Use cautiously with pressor agents and MAO inhibitors
 Human pharmacologic studies have shown that Ritalin may
 inhibit the metabolism of coumarin anticoagulants, anticon-
 vulsants (phenobarbital, diphenylhydantoin, primidone),
 phenylbutazone, and tricyclic antidepressants (imipramine,
 desipramine) Downward dosage adjustments of these drugs
 may be required when given concomitantly with Ritalin

Use in Pregnancy

Adequate animal reproduction studies to establish safe use
 of Ritalin during pregnancy have not been conducted There-
 fore, until more information is available, Ritalin should not
 be prescribed for women of childbearing age unless, in the
 opinion of the physician, the potential benefits outweigh the
 possible risks

Drug Dependence

Ritalin should be given cautiously to emotionally unsta-
 ble patients, such as those with a history of drug depen-
 dence or alcoholism, because such patients may in-
 crease dosage on their own initiative

Chronically abusive use can lead to marked tolerance
 and psychic dependence with varying degrees of abnor-
 mal behavior Frank psychotic episodes can occur, espe-
 cially with parenteral abuse Careful supervision is re-
 quired during drug withdrawal, since severe depression
 as well as the effects of chronic overactivity can be un-
 masked Long term follow up may be required because
 of the patient's basic personality disturbances

Precautions: Patients with an element of agitation may
 react adversely, discontinue therapy if necessary
 Periodic CBC, differential, and platelet counts are advised
 during prolonged therapy

Drug treatment is not indicated in all cases of this behavioral
 syndrome and should be considered only in light of the com-
 plete history and evaluation of the child The decision to pre-
 scribe Ritalin should depend on the physician's assessment
 of the chronicity and severity of the child's symptoms and
 their appropriateness for his/her age Prescription should
 not depend solely on the presence of one or more of the be-
 havioral characteristics

When these symptoms are associated with acute stress reac-
 tions, treatment with Ritalin is usually not indicated
 Long term effects of Ritalin in children have not been well
 established

Adverse Reactions: Nervousness and insomnia are the
 most common adverse reactions but are usually controlled
 by reducing dosage and omitting the drug in the afternoon or
 evening Other reactions include hypersensitivity (including
 skin rash, urticaria, fever, arthralgia, exfoliative dermatitis,
 erythema multiforme with histopathological findings of
 necrotizing vasculitis, and thrombocytopenic purpura), ano-
 rexia, nausea, dizziness, palpitations, headache, dyskinesia,
 drowsiness, blood pressure and pulse changes, both up and
 down, tachycardia, angina, cardiac arrhythmia, abdominal
 pain, weight loss during prolonged therapy There have
 been rare reports of Tourette's syndrome Toxic psychosis
 has been reported Although a definite causal relationship
 has not been established, the following have been reported in
 patients taking this drug leukopenia and/or anemia, a few
 instances of scalp hair loss

In children, loss of appetite, abdominal pain, weight loss
 during prolonged therapy, insomnia, and tachycardia may
 occur more frequently, however, any of the other adverse
 reactions listed above may also occur

Dosage and Administration Dosage should be individu-
 alized according to the needs and responses of the patient

Adults

Tablets Administer in divided doses 2 or 3 times daily,
 preferably 30 to 45 minutes before meals Average dosage is
 20 to 30 mg daily Some patients may require 40 to 60 mg
 daily In others, 10 to 15 mg daily will be adequate Patients
 who are unable to sleep if medication is taken late in the day
 should take the last dose before 6 p m

SR Tablets Ritalin SR Tablets have a duration of action of
 approximately 8 hours Therefore, Ritalin SR tablets may be
 used in place of Ritalin tablets when the 8 hour dosage of
 Ritalin SR corresponds to the titrated 8 hour dosage of Rita-
 lin

Children (6 years and over)

Ritalin should be initiated in small doses, with gradual
 weekly increments Daily dosage above 60 mg is not recom-
 mended

If improvement is not observed after appropriate dosage
 adjustments over a one-month period, the drug should be
 discontinued

Tablets Start with 5 mg twice daily (before breakfast and
 lunch) with gradual increments of 5 to 10 mg weekly

SR Tablets Ritalin SR tablets have a duration of action of
 approximately 8 hours Therefore, Ritalin SR tablets may be
 used in place of Ritalin tablets when the 8 hour dosage of
 Ritalin SR corresponds to the titrated 8 hour dosage of Rita-
 lin

If paradoxical aggravation of symptoms or other adverse
 effects occur, reduce dosage, or, if necessary, discontinue the
 drug

Ritalin should be periodically discontinued to assess the
 child's condition Improvement may be sustained when the
 drug is either temporarily or permanently discontinued

Drug treatment should not and need not be indefinite and
 usually may be discontinued after puberty

Overdosage Signs and symptoms of acute overdosage,
 resulting principally from overstimulation of the central
 nervous system and from excessive sympathomimetic ef-
 fects, may include the following: vomiting, agitation, trem-
 ors, hyperreflexia, muscle twitching, convulsions (may be
 followed by coma), euphoria, confusion, hallucinations, delir-
 ium, sweating, flushing, headache, hyperpyrexia, tachycar-
 dia, palpitations, cardiac arrhythmias, hypertension, mydri-
 asis, and dryness of mucous membranes

Treatment consists of appropriate supp. ve measures The
 patient must be protected against self injury and against
 external stimuli that would aggravate overstimulation al-
 ready present If signs and symptoms are not too severe and
 the patient is conscious, gastric contents may be evacuated
 by induction of emesis or gastric lavage In the presence of
 severe intoxication, use a carefully titrated dosage of a short
 acting barbiturate before performing gastric lavage

Intensive care must be provided to maintain adequate circula-
 tion and respiratory exchange, external cooling proce-
 dures may be required for hyperpyrexia

Efficacy of peritoneal dialysis or extracorporeal hemodialy-
 sis for Ritalin overdosage has not been established

How Supplied

Tablets 20 mg—round, pale yellow, scored (imprinted CIBA
 34)

Bottles of 100 NDC 0083-0034-30
 Bottles of 1000 NDC 0083-0034-40

Tablets 10 mg—round, pale green, scored (imprinted CIBA
 3)

Bottles of 100 NDC 0083-0003-30
 Bottles of 500 NDC 0083-0003-35
 Bottles of 1000 NDC 0083-0003-40

Accu Pak® Unit Dose (blister pack)
 Box of 100 (strips of 10) NDC 0083-0003-32

Tablets 5 mg—round, yellow (imprinted CIBA 7)

Bottles of 100 NDC 0083-0007-30
 Bottles of 500 NDC 0083-0007-35
 Bottles of 1000 NDC 0083-0007-40

SR Tablets 20 mg—round, white, coated (imprinted CIBA
 16)

Bottles of 100 NDC 0083-0016-30

Note SR Tablets are color additive free
 Do not store above 86°F (30°C) Protect from moisture

Dispense in tight, light resistant container (USP)
 C84-29 (Rev 6/84)

Shown in Product Identification Section, page 408

Continued on next page

The full prescribing information for each CIBA drug is
 contained herein and is that in effect as of September 1,
 1985