

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*APPLICATION NUMBER:*

**83-564**

**APPROVED DRAFT LABELING**

# DELCOBESF

## TABLETS—CAPSULES

(A SINGLE ENTITY AMPHETAMINE PREPARATION)

Supplied in:	5 mg.	10 mg.	15 mg.	20 mg.
Description:				
Dextroamphetamine sulfate	1.25 mg.	2.5 mg.	3.75 mg.	5 mg.
Dextroamphetamine adipate	1.25 mg.	2.5 mg.	3.75 mg.	5 mg.
Amphetamine adipate	1.25 mg.	2.5 mg.	3.75 mg.	5 mg.
Amphetamine sulfate	1.25 mg.	2.5 mg.	3.75 mg.	5 mg.

AMPHETAMINES HAVE A SIGNIFICANT POTENTIAL FOR ABUSE. IN VIEW OF THEIR LIMITED SHORT-TERM ANORECTIC EFFECT AND RAPID DEVELOPMENT OF TOLERANCE, THEY SHOULD BE USED WITH EXTREME CAUTION AND ONLY FOR LIMITED PERIODS OF TIME IN WEIGHT REDUCTION PROGRAMS.

**DESCRIPTION:** White, odorless crystalline powders, soluble in water. DEXTROAMPHETAMINE is the dextrorotatory isomer of amphetamine.

**ACTIONS:** Amphetamines are sympathomimetic amines with CNS stimulant activity. Peripheral actions include elevation of systolic and diastolic blood pressures and weak bronchodilator and respiratory stimulant action. The anorectic effect diminishes after a few weeks.

**INDICATIONS:** Narcolepsy.

Minimal brain dysfunction in children (hyperkinetic behavior disorders), as an aid to general management.

Exogenous obesity, as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction.

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

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.

Amphetamines 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:** Amphetamines have a significant potential for abuse. Tolerance and extreme psychological dependence have occurred. 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 amphetamines include severe dermatoses, marked insomnia, irritability, hyperactivity, and personality changes. The most severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

**Usage in Pregnancy:** Safe use in pregnancy has not been established. Reproduction studies in mammals at high multiples of the human dose have suggested both an embryotoxic and a teratogenic potential. Use of amphetamines by women who are or who may become pregnant, and especially 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:** Amphetamines are not recommended for use as anorectic agents in children under 12 years of age.

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

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

Amphetamines 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, other, gastrointestinal disturbances. Anorexia and weight loss may occur as undesirable effects when amphetamines are used for other than the anorectic effect.

**Allergies:** Urticaria.

**Endocrine:** Impotence, changes in libido.

**DOSAGE AND ADMINISTRATION:** Regardless of indication, amphetamines should be administered at the lowest effective dosage and dosage should be individually adjusted. Late evening medication should be avoided because of the resulting insomnia.

1. Narcolepsy: Usual dose 5 to 60 milligrams per day in divided doses.

2. Minimal brain dysfunction:

a. Not recommended for children under 3 years of age.

b. Children from 3 to 5 years of age: 2.5 milligrams daily, raised in increments of 2.5 milligrams at weekly intervals until optimal response is obtained.

c. Children 6 years of age and older: 5 milligrams once or twice daily, increased in increments of 5 milligrams at weekly intervals. Only in rare cases will it be necessary to exceed a total of 40 milligrams per day.

3. Obesity: Usual adult dose 5 to 30 milligrams per day in divided doses.

**OVERDOSAGE:** Manifestations of acute overdosage with amphetamines include restlessness, 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 amphetamine 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.

**DOSAGE: ADULTS:** Tablets or Capsules: One tablet or capsule three times a day 1/2 hour before meals. Third dose should not be taken after 4 P.M. to avoid insomnia.

**CAUTION: FEDERAL LAW PROHIBITS DISPENSING WITHOUT PRESCRIPTION.**

Available in bottles of 1,000 and 5,000.

JAN. 1973

# DELCOBESE

## EACH CAPSULE CONTAINS:

Amphetamine Sulfate	5 mg.
Dextroamphetamine Sulfate	5 mg.
Amphetamine Adipate	5 mg.
Dextroamphetamine Adipate	5 mg.

CAUTION: Federal law prohibits dispensing without prescription.

SEE INSERT FOR FULL INFORMATION

1000 CAPSULES NDC 697-2530-10

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5000 CAPSULES NDC 697-2530-51

# DELCOBESE

**EACH CAPSULE CONTAINS:**

Amphetamine Sulfate	2.5 mg.
Dextroamphetamine Sulfate	2.5 mg.
Amphetamine Adipate	2.5 mg.
Dextroamphetamine Adipate	2.5 mg.

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SEE INSERT FOR FULL INFORMATION

1000 CAPSULES NDC 697-2450-10

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**EACH CAPSULE CONTAINS:**

Amphetamine Sulfate	2.5 mg.
Dextroamphetamine Sulfate	2.5 mg.
Amphetamine Adipate	2.5 mg.
Dextroamphetamine Adipate	2.5 mg.

**CAUTION:** Federal law prohibits dispensing without prescription.

SEE INSERT FOR FULL INFORMATION

5000 CAPSULES NDC 697-2450-51

# DELCOBESSE

5 mg.

EACH CAPSULE CONTAINS:

Amphetamine Sulfate	1.25 mg.
Dextroamphetamine Sulfate	1.25 mg.
Amphetamine Adipate	1.25 mg.
Dextroamphetamine Adipate	1.25 mg.

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SEE INSERT FOR FULL INFORMATION

1000 CAPSULES NDC 697-2410-10

Distributed by  
Delco Chemical Co., Inc. M. Vernon, N.Y. 10550

# DELCOBESSE

5 mg.

EACH CAPSULE CONTAINS:

Amphetamine Sulfate	1.25 mg.
Dextroamphetamine Sulfate	1.25 mg.
Amphetamine Adipate	1.25 mg.
Dextroamphetamine Adipate	1.25 mg.

CAUTION: Federal law prohibits dispensing without prescription.

SEE INSERT FOR FULL INFORMATION

5000 CAPSULES NDC 697-2410-51

Distributed by  
Delco Chemical Co., Inc. M. Vernon, N.Y. 10550

# DELCOBESE

## EACH CAPSULE CONTAINS:

Amphetamine Sulfate	3.75 mg.
Dextroamphetamine Sulfate	3.75 mg.
Amphetamine Adipate	3.75 mg.
Dextroamphetamine Adipate	3.75 mg.

CAUTION: Federal law prohibits dispensing without prescription.

SEE INSERT FOR FULL INFORMATION

5000 CAPSULES NDC 697-2490-51

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## EACH CAPSULE CONTAINS:

Amphetamine Sulfate	3.75 mg.
Dextroamphetamine Sulfate	3.75 mg.
Amphetamine Adipate	3.75 mg.
Dextroamphetamine Adipate	3.75 mg.

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SEE INSERT FOR FULL INFORMATION

1000 CAPSULES NDC 697-2490-10

DELCOBES

NDA No. 13-504

12273

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Reviewed by

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