PHENTERMINE HYDROCHLORIDE- phentermine hydrochloride tablet
Unit Dose Services

HIGHLIGHTS OF PRESCRIBING INFORMATION
These highlights do not include all the information needed to use phentermine hydrochloride tablets, USP safely and effectively. See full prescribing information for . phentermine hydrochloride tablets, USP

PHENTERMINE Hydrochloride Tablets, USP CIV for oral use
Initial U.S. Approval: 1959

INDICATIONS AND USAGE

Phentermine hydrochloride is a sympathomimetic amine anorectic indicated as a short-term adjunct (a few weeks) in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index ≥ 30 kg/m , or ≥ 27 kg/m in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). ( ) The limited usefulness of agents of this class, including phentermine hydrochloride, should be measured against possible risk factors inherent in their use. ( ) [22]1
1

DOSAGE AND ADMINISTRATION

- Dosage should be individualized to obtain an adequate response with the lowest effective dose. ( ) 2
- Late evening administration should be avoided (risk of insomnia). ( ) 2
- Phentermine hydrochloride tablets can be taken with or without food ( ) 12.3

DOSAGE FORMS AND STRENGTHS

- Tablets containing 37.5 mg phentermine hydrochloride. ( ) 3

CONTRAINDICATIONS

- History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension) ( ) 4
- During or within 14 days following the administration of monoamine oxidase inhibitors ( ) 4
- Hyperthyroidism ( ) 4
- Glaucoma ( ) 4
- Agitated states ( ) 4
- History of drug abuse ( ) 4
- Pregnancy (,) 48.1
- Nursing (,) 48.3
- Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines ( ) 4

WARNINGS AND PRECAUTIONS

- Coadministration with other drugs for weight loss is not recommended (safety and efficacy of combination not established). ( ) 5.1
- Rare cases of primary pulmonary hypertension have been reported. Phentermine should be discontinued in case of new, unexplained symptoms of dyspnea, angina pectoris, syncope or lower extremity edema. ( ) 5.2
- Rare cases of serious regurgitant cardiac valvular disease have been reported. ( ) 5.3
- Tolerance to the anorectic effect usually develops within a few weeks. If this occurs, phentermine should be discontinued. The recommended dose should not be exceeded. ( ) 5.4
- Phentermine may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle. ( ) 5.5
- Risk of abuse and dependence. The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdosage. ( ) 5.6
- Concomitant alcohol use may result in an adverse drug reaction. ( ) 5.7
- Use caution in patients with even mild hypertension (risk of increase in blood pressure). ( ) 5.8
- A reduction in dose of insulin or oral hypoglycemic medication may be required in some patients. ( ) 5.9

ADVERSE REACTIONS

Adverse events have been reported in the cardiovascular, central nervous, gastrointestinal, allergic, and endocrine systems. ( ) 6
To report SUSPECTED ADVERSE REACTIONS, contact Lannett Company, Inc. at 1-800-325-9994 or FDA at 1-800-FDA-1088 or . ***www.fda.gov/medwatch***

DRUG INTERACTIONS

- Monoamine oxidase inhibitors: Risk of hypertensive crisis. (,) 47.1
- Alcohol: Consider potential interaction ( ) 7.2
- Insulin and oral hypoglycemics: Requirements may be altered. ( ) 7.3
- Adrenergic neuron blocking drugs: Hypotensive effect may be decreased by phentermine. ( ) 7.4

USE IN SPECIFIC POPULATIONS

- Nursing mothers: Discontinue drug or nursing taking into consideration importance of drug to mother. (,) 48.3
- Pediatric use: Safety and effectiveness not established. ( ) 8.4
- Geriatric use: Due to substantial renal excretion, use with caution. ( ) 8.5
- Use caution when administering phentermine to patients with renal impairment ( ) 8.6

See 17 for PATIENT COUNSELING INFORMATION.

Revised: 5/2012

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FULL PRESCRIBING INFORMATION

1 INDICATIONS AND USAGE

Phentermine hydrochloride tablets are indicated as a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity for patients with an initial body mass index ≥ 30 kg/m , or ≥ 27 kg/m in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). [22]

Below is a chart of body mass index (BMI) based on various heights and weights.

BMI is calculated by taking the patient's weight, in kilograms (kg), divided by the patient's height, in meters (m), squared. Metric conversions are as follows: pounds ÷ 2.2 = kg; inches x 0.0254 = meters.

BODY MASS INDEX (BMI), kg/m [2]

	Height (feet, inches)					
(pounds) **Weight**	**5'0"**	**5'3"**	**5'6"**	**5'9"**	**6'0"**	**6'3"**
140	27	25	23	21	19	18
150	29	27	24	22	20	19
160	31	28	26	24	22	20
170	33	30	28	25	23	21
180	35	32	29	27	25	23
190	37	34	31	28	26	24
200	39	36	32	30	27	25
210	41	37	34	31	29	26
220	43	39	36	33	30	28
230	45	41	37	34	31	29
240	47	43	39	36	33	30
250	49	44	40	37	34	31

The limited usefulness of agents of this class, including phentermine, [see] should be measured against possible risk factors inherent in their use such as those described below. *Clinical Pharmacology (,) 12.112.2*

2 DOSAGE AND ADMINISTRATION

Exogenous Obesity

Dosage should be individualized to obtain an adequate response with the lowest effective dose.

The usual adult dose is one tablet (37.5 mg) daily, as prescribed by the physician, administered before breakfast or 1 to 2 hours after breakfast. The dosage may be adjusted to the patient's need. For some patients, half tablet (18.75 mg) daily may be adequate, while in some cases it may be desirable to give half tablets (18.75 mg) two times a day. Phentermine is not recommended for use in pediatric patients ≤ 16 years of age.

Late evening medication should be avoided because of the possibility of resulting insomnia.

3 DOSAGE FORMS AND STRENGTHS

Phentermine hydrochloride tablets USP, 37.5 mg (equivalent to 30 mg phentermine base), blue speckled, capsule shaped, bisected tablets; debossed with "LCI" and "1445" on one side and plain on the other side.

4 CONTRAINDICATIONS

- History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congestive heart failure, uncontrolled hypertension)
- During or within 14 days following the administration of monoamine oxidase inhibitors
- Hyperthyroidism
- Glaucoma
- Agitated states
- History of drug abuse
- Pregnancy [see] *Use in Specific Populations ( ) 8.1*
- Nursing [see] *Use in Specific Populations ( ) 8.3*
- Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines

5 WARNINGS AND PRECAUTIONS

5.1 Coadministration with Other Drug Products for Weight Loss

Phentermine hydrochloride tablets are indicated only as short-term (a few weeks) monotherapy for the management of exogenous obesity. The safety and efficacy of combination therapy with phentermine and any other drug products for weight loss including prescribed drugs, over-the-counter preparations, and herbal products, or serotonergic agents such as selective serotonin reuptake inhibitors (e.g., fluoxetine, sertraline, fluvoxamine, paroxetine), have not been established. Therefore, coadministration of phentermine and these drug products is not recommended.

5.2 Primary Pulmonary Hypertension

The initial symptom of PPH is usually dyspnea. Other initial symptoms may include angina pectoris, syncope or lower extremity edema. Patients should be advised to report immediately any deterioration in exercise tolerance. Treatment should be discontinued in patients who develop new, unexplained symptoms of dyspnea, angina pectoris, syncope or lower extremity edema, and patients should be evaluated for the possible presence of pulmonary hypertension. **Primary Pulmonary Hypertension (PPH) - a rare, frequently fatal disease of the lungs - has been reported to occur in patients receiving a combination of phentermine with fenfluramine or dexfenfluramine. The possibility of an association between PPH and the use of phentermine alone cannot be ruled out; there have been rare cases of PPH in patients who reportedly have taken phentermine alone.**

5.3 Valvular Heart Disease

Serious regurgitant cardiac valvular disease, primarily affecting the mitral, aortic and/or tricuspid valves, has been reported in otherwise healthy persons who had taken a combination of

phentermine with fenfluramine or dexfenfluramine for weight loss. The possible role of phentermine in the etiology of these valvulopathies has not been established and their course in individuals after the drugs are stopped is not known. The possibility of an association between valvular heart disease and the use of phentermine alone cannot be ruled out; there have been rare cases of valvular heart disease in patients who reportedly have taken phentermine alone.

5.4 Development of Tolerance, Discontinuation in Case of Tolerance

When tolerance to the anorectant effect develops, the recommended dose should not be exceeded in an attempt to increase the effect; rather, the drug should be discontinued.

5.5 Effect on the Ability to Engage in Potentially Hazardous Tasks

Phentermine 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.

5.6 Risk of Abuse and Dependence

Phentermine is related chemically and pharmacologically to amphetamine (d- and d l-amphetamine) and other related stimulant drugs that have been extensively abused. The possibility of abuse of phentermine should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program. See and . *lDrug Abuse and Dependence ( ) 9Overdosage ( ) 10*

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

5.7 Usage with Alcohol

Concomitant use of alcohol with phentermine may result in an adverse drug reaction.

5.8 Use in Patients with Hypertension

Use caution in prescribing phentermine for patients with even mild hypertension (risk of increase in blood pressure).

5.9 Use in Patients on Insulin or Oral Hypoglycemic Medications for Diabetes Mellitus

A reduction in insulin or oral hypoglycemic medications in patients with diabetes mellitus may be required.

6 ADVERSE REACTIONS

The following adverse reactions are described, or described in greater detail, in other sections:

- Primary pulmonary hypertension [see] - Valvular heart disease [see] - Effect on the ability to engage in potentially hazardous tasks [see] - Withdrawal effects following prolonged high dosage administration [see] *Warnings and Precautions ( ) 5.2*
Warnings and Precautions ( ) 5.3
Warnings and Precautions ( ) 5.5
Drug Abuse and Dependence ( ) 9.3

The following adverse reactions to phentermine have been identified:

Primary pulmonary hypertension and/or regurgitant cardiac valvular disease, palpitation, tachycardia, elevation of blood pressure, ischemic events. Cardiovascular

Overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache, psychosis. Central Nervous System

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

Gastrointestinal

Urticaria. Allergic

Impotence, changes in libido. Endocrine

7 DRUG INTERACTIONS

7.1 Monoamine Oxidase Inhibitors

Use of phentermine is contraindicated during or within 14 days following the administration of monoamine oxidase inhibitors because of the risk of hypertensive crisis.

7.2 Alcohol

Concomitant use of alcohol with phentermine may result in an adverse drug reaction.

7.3 Insulin and Oral Hypoglycemic Medications

Requirements may be altered [see]. *Warnings and Precautions ( ) 5.9*

7.4 Adrenergic Neuron Blocking Drugs

Phentermine may decrease the hypotensive effect of adrenergic neuron blocking drugs.

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Phentermine is contraindicated during pregnancy because weight loss offers no potential benefit to a pregnant woman and may result in fetal harm. A minimum weight gain, and no weight loss, is currently recommended for all pregnant women, including those who are already overweight or obese, due to obligatory weight gain that occurs in maternal tissues during pregnancy. Phentermine has pharmacologic activity similar to amphetamine (d- and d l-amphetamine) [see]. Animal reproduction studies have not been conducted with phentermine. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential hazard to a fetus. *Pregnancy Category X*
lClinical Pharmacology ( ) 12.1

8.3 Nursing Mothers

It is not known if phentermine is excreted in human milk; however, other amphetamines are present in human milk. Because of the potential for serious adverse reactions in nursing infants, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Because pediatric obesity is a chronic condition requiring long-term treatment, the use of this product, approved for short-term therapy, is not recommended.

8.5 Geriatric Use

In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be

taken in dose selection, and it may be useful to monitor renal function.

8.6 Renal Impairment

Phentermine was not studied in patients with renal impairment. Based on the reported excretion of phentermine in urine, exposure increases can be expected in patients with renal impairment. Use caution when administering phentermine to patients with renal impairment [see]. *Clinical Pharmacology ( ) 12.3*

9 DRUG ABUSE AND DEPENDENCE

9.1 Controlled Substance

Phentermine is a Schedule IV controlled substance.

9.2 Abuse

Phentermine is related chemically and pharmacologically to the amphetamines. Amphetamines and other stimulant drugs have been extensively abused and the possibility of abuse of phentermine should be kept in mind when evaluating the desirability of including a drug as part of a weight reduction program.

9.3 Dependence

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 of these drugs to many times than 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. A severe manifestation of chronic intoxication is psychosis, often clinically indistinguishable from schizophrenia.

10 OVERDOSAGE

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

10.1 Acute Overdosage

Manifestations of acute overdosage include restlessness, tremor, hyperreflexia, rapid respiration, confusion, assaultiveness, hallucinations, and panic states. Fatigue and depression usually follow the central stimulation. Cardiovascular effects include arrhythmia, hypertension or hypotension, and circulatory collapse. Gastrointestinal symptoms include nausea, vomiting, diarrhea and abdominal cramps. Overdosage of pharmacologically similar compounds has resulted in fatal poisoning usually terminates in convulsions and coma.

Management of acute phentermine hydrochloride 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 , CIBA) has been suggested on pharmacologic grounds for possible acute, severe hypertension, if this complicates overdosage. ®

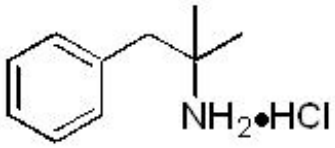
10.2 Chronic Intoxication

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. See . *Drug Abuse and Dependence ( ) 9.3*

11 DESCRIPTION

Phentermine hydrochloride is a sympathomimetic amine anorectic. Its chemical name is α,α,dimethylphenethylamine hydrochloride. The structural formula is as follows:

C H N • HCl M.W. 185.7



1015

Phentermine hydrochloride is a white, odorless, hygroscopic, crystalline powder which is soluble in water and lower alcohols, slightly soluble in chloroform and insoluble in ether.

Phentermine hydrochloride tablets, USP are available as oral tablets containing 37.5 mg of phentermine hydrochloride (equivalent to 30 mg of phentermine base). Each phentermine hydrochloride tablet also contains the following inactive ingredients: corn starch, lactose (anhydrous), magnesium stearate, microcrystalline cellulose, pregelatinized starch, compressible sugar, and FD&C Blue # 1 aluminum lake.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Phentermine is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, amphetamine (d- and d l-amphetamine). Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigenics." It has not been established that the primary action of such drugs in treating obesity is one of appetite suppression since other central nervous system actions, or metabolic effects, may also be involved. *l*

12.2 Pharmacodynamics

Typical of amphetamines 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.

12.3 Pharmacokinetics

Following the administration of phentermine, phentermine reaches peak concentrations (C) after 3 to 4.4 hours. max

Specific Populations

Phentermine was not studied in patients with renal impairment. The literature reported cumulative urinary excretion of phentermine under uncontrolled urinary pH conditions is 62%-85%. Exposure increases can be expected in patients with renal impairment. Use caution when administering phentermine to patients with renal impairment. *Renal Impairment*

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Studies have not been performed with phentermine to determine the potential for carcinogenesis, mutagenesis or impairment of fertility.

14 CLINICAL STUDIES

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

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 over several 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.

17 PATIENT COUNSELING INFORMATION

Patients must be informed that phentermine hydrochloride is a (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and caloric restriction in the management of exogenous obesity, and that coadministration of phentermine with other drugs for weight loss is not recommended [see and]. *short-termIndications and Usage ( ) 1Warnings and Precautions ( ) 5.1*

Patients must be instructed on how much phentermine to take, and when and how to take it [see]. *Dosage and Administration ( ) 3*

Advise pregnant women and nursing mothers not to use phentermine [see]. *Use in Specific Populations (,) 8.18.3*

Patients must be informed about the risks of use of phentermine (including the risks discussed in Warnings and Precautions), about the symptoms of potential adverse reactions and when to contact a physician and/or take other action. The risks include, but are not limited to:

- Development of primary pulmonary hypertension [see] *Warnings and Precautions ( ) 5.2*
- Development of serious valvular heart disease [see Warnings and Precautions ( )] 5.3
- Effects on the ability to engage in potentially hazardous tasks [see] *Warnings and Precautions ( ) 5.5*
- The risk of an increase in blood pressure [see and] *Warnings and Precautions ( ) 5.8Adverse Reactions ( ) 6*
- The risk of interactions [see , and] *Contraindications ( ) 4Warnings and Precautions (,) 5.75.9Drug Interactions ( ) 7*

See also, for example, and . *Adverse Reactions ( ) 6Use in Specific Populations ( ) 8*

The patients must also be informed about

- the potential for developing tolerance and actions if they suspect development of tolerance [see] and *Warnings and Precautions ( ) 5.4*
- the risk of dependence and the potential consequences of abuse [see , , and]. *Warnings and Precautions ( ) 5.6Drug Abuse and Dependence ( ) 9Overdosage ( ) 10*

Tell patients to keep phentermine in a safe place to prevent theft, accidental overdose, misuse or abuse. Selling or giving away phentermine may harm others and is against the law.

Manufactured by: Philadelphia, PA 19136 Made in the USA
LANNETT COMPANY, INC.

Revised 05/2012, Revision 3

10-069

PHENTERMINE HYDROCHLORIDE TABLET

PHENTERMINE HYDROCHLORIDE

phentermine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:50436-6744(NDC:0527-1445)
Route of Administration	ORAL	**DEA Schedule**	CIV

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
PHENTERMINE HYDROCHLORIDE (UNII: 0K2I505OTV) (PHENTERMINE - UNII:C045TQL4WP)	PHENTERMINE HYDROCHLORIDE	37.5 mg

Inactive Ingredients

Ingredient Name	Strength
STARCH, CORN (UNII: O8232NY3SJ)	
ANHYDROUS LACTOSE (UNII: 3SY5LH9PMK)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
CELLULOSE, MICROCRYSTALLINE (UNII: OP1R32D61U)	
SUCROSE (UNII: C151H8M554)	
FD&C BLUE NO. 1 (UNII: H3R47K3TBD)	
ALUMINUM OXIDE (UNII: LMI26O6933)	

Product Characteristics

Color	BLUE (Blue-speckled)	**Score**	2 pieces
Shape	OVAL (Capsule-shaped)	**Size**	10mm
Flavor		**Imprint Code**	LCI;1445

Contains	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:50436-6744-1	14 in 1 BOTTLE		
2	NDC:50436-6744-2	7 in 1 BOTTLE		
3	NDC:50436-6744-3	30 in 1 BOTTLE		
4	NDC:50436-6744-4	28 in 1 BOTTLE		

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA040555	04/15/2005	

Labeler - Unit Dose Services (831995316)

Registrant - Unit Dose Services (831995316)

Establishment

Name	Address	ID/FEI	Business Operations
Unit Dose Services		831995316	REPACK(50436-6744)

Revised: 5/2012 Unit Dose Services