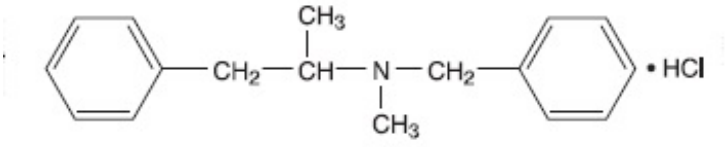
BENZPHETAMINE HYDROCHLORIDE- benzphetamine hydrochloride tablet
H. J. Harkins Company Inc.

Description

Benzphetamine Hydrochloride Tablets contain the anorectic agent benzphetamine hydrochloride. Benzphetamine hydrochloride is a white crystalline powder readily soluble in water and 95% ethanol. The chemical name for benzphetamine hydrochloride is d-N,α-Dimethyl-N -(phenylmethyl)-benzeneethanamine hydrochloride and its molecular weight is 275.82.

The structural formula (dextro form) is represented below:



Each Benzphetamine Hydrochloride Tablet, for oral administration, contains 50 mg of benzphetamine hydrochloride.

Inactive Ingredients: carnauba wax powder, colloidal silicon dioxide, FD&C red # 40 aluminum lake, FD&C yellow # 6 aluminum lake, lactose monohydrate, macrogol/polyethylene glycol 3350, magnesium stearate, microcrystalline cellulose 101, polyvinyl alcohol – partially hydrolyzed, sodium starch glycolate, talc and titanium dioxide.

Clinical Pharmacology

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

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

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 the 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 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 to be clinically limited.

Pharmacokinetic data in humans are not available.

Indications & Usage

Benzphetamine Hydrochloride Tablets are indicated in the management of exogenous obesity as a short term (a few weeks) adjunct in a regimen of weight reduction based on caloric restriction in patients with an initial body mass index (BMI) of 30 kg/m2 or higher who have not responded to appropriate weight reducing regimen (diet and/or exercise) alone. 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 × 0.0254 = meters. The limited usefulness of agents of this class (See CLINICAL PHARMACOLOGY) should be weighed against possible risks inherent in their use such as those described below.

BODY MASS INDEX (BMI), kg/m2
Weight
(pounds) Height (feet, inches)
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

Benzphetamine Hydrochloride Tablets are indicated for use as monotherapy only.

Contraindications

Benzphetamine Hydrochloride Tablets are contraindicated in patients with advanced arteriosclerosis, symptomatic cardiovascular disease, moderate to severe hypertension, hyperthyroidism, known hypersensitivity or idiosyncrasy to sympathomimetic amines, and glaucoma. Benzphetamine should not be given to patients who are in an agitated state or who have a history of drug abuse.

Hypertensive crises have resulted when sympathomimetic amines have been used concomitantly or within 14 days following use of monoamine oxidase inhibitors. Benzphetamine Hydrochloride Tablets should not be used concomitantly with other CNS stimulants.

Benzphetamine Hydrochloride Tablets may cause fetal harm when administered to a pregnant woman. Amphetamines have been shown to be teratogenic and embryotoxic in mammals at high multiples of the human dose. Benzphetamine Hydrochloride Tablets are contraindicated in women who are or may become pregnant. 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 the fetus.

Warnings

Precautions

Insulin requirements in diabetes mellitus may be altered in association with use of anorexigenic drugs and the concomitant dietary restrictions.

Psychological disturbances have been reported in patients who receive an anorectic agent together with a restrictive dietary regime.

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.

Information for Patients

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 Interactions

Efficacy of Benzphetamine Hydrochloride Tablets in combination with other anorectic agents has not been studied and the combined use may have the potential for serious cardiac problems.

Hypertensive crises have resulted when sympathomimetic amines have been used concomitantly or within 14 days following use of monoamine oxidase inhibitors. Benzphetamine Hydrochloride Tablets should not be used concomitantly with other CNS stimulants.

Amphetamines may decrease the hypotensive effect of antihypertensives. Amphetamines may enhance the effects of tricyclic antidepressants.

Urinary alkalinizing agents increase blood levels and decrease excretion of amphetamines. Urinary acidifying agents decrease blood levels and increase excretion of amphetamines.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Animal studies to evaluate the potential for carcinogenesis, mutagenesis or impairment of fertility have not been performed.

Pregnancy

Pregnancy Category X (see CONTRAINDICATIONS section).

Nursing Mothers

Amphetamines are excreted in human milk. Mothers taking amphetamines should be advised to refrain from nursing.

Pediatric Use

Safety and effectiveness in pediatric patients have not been established. Use of benzphetamine hydrochloride is not recommended in individuals under 12 years of age.

Geriatric Use

Clinical studies of Benzphetamine Hydrochloride Tablets did not include sufficient numbers of subjects aged 65 and over to establish safety and efficacy in this population. 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.

Adverse reactions

The following have been associated with the use of benzphetamine hydrochloride:

Cardiovascular

Palpitation, tachycardia, elevation of blood pressure.

There have been isolated reports of cardiomyopathy and ischemic cardiac events associated with chronic amphetamine use.

Valvular heart disease associated with the use of some anorectic agents such as fenfluramine and dexfenfluramine, both independently and especially when used in combination with other anorectic drugs, have been reported. However, no cases of this valvulopathy have been reported when Benzphetamine Hydrochloride tablets have been used alone.

CNS

Overstimulation, restlessness, dizziness, insomnia, tremor, sweating, headache; rarely, psychotic episodes at recommended doses; depression following withdrawal of the drug.

Gastrointestinal

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

Allergic

Urticaria and other allergic reactions involving the skin.

Endocrine

Changes in libido.

Drug Abuse and Dependence

Benzphetamine is a controlled substance under the Controlled Substance Act by the Drug Enforcement Administration and has been assigned to Schedule III.

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

Overdosage

Manifestations of Overdosage

Acute overdosage with amphetamines may result in restlessness, tremor, tachypnea, confusion, assaultiveness and 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. Hyperpyrexia and rhabdomyolysis have been reported and can lead to a number of associated complications. Fatal poisoning is usually preceded by convulsions and coma.

Treatment of Overdosage

(See WARNINGS)--- Information concerning the effects of overdosage with Benzphetamine Hydrochloride Tablets is extremely limited. The following is based on experience with other anorexiants.

Management of acute amphetamine intoxication is largely symptomatic and includes sedation with a barbiturate. If hypertension is marked, the use of a nitrite or rapidly acting alpha receptor blocking agent should be considered. Experience with hemodialysis or peritoneal dialysis is inadequate to permit recommendations in this regard.

Acidification of the urine increases amphetamine excretion.

The oral LD50 is 174 mg/kg in mice and 104 mg/kg in rats. The intraperitoneal LD50 in mice is 153 mg/kg.

Dosage and Administration

Dosage should be individualized according to the response of the patient. The suggested dosage ranges from 25 to 50 mg one to three times daily. Treatment should begin with 25 to 50 mg once daily with subsequent increase in individual dose or frequency according to response. A single daily dose is preferably given in mid-morning or mid-afternoon, according to the patient's eating habits. In an occasional patient it may be desirable to avoid late afternoon administration. Use of benzphetamine hydrochloride is not recommended in individuals under 12 years of age.

How Supplied

Benzphetamine Hydrochloride Tablets are available as follows:

Benzphetamine Hydrochloride Tablets, 50 mg are supplied as peach, round, biconvex, film coated tablets debossed with "K" on left of the score and the number "40" debossed right of the score and plain on other side.

Bottles of 30 NDC 10702-040-03

Bottles of 100 NDC 10702-040-01

Bottles of 500 NDC 10702-040-50

Bottles of 1000 NDC 10702-040-10

Dispense in a tight container as defined in the USP, with a child-resistant closure (as required).

Store at 20° to 25°C with excursions permitted between 15° to 30°C (59° to 86°F) [See USP Controlled Room Temperature].

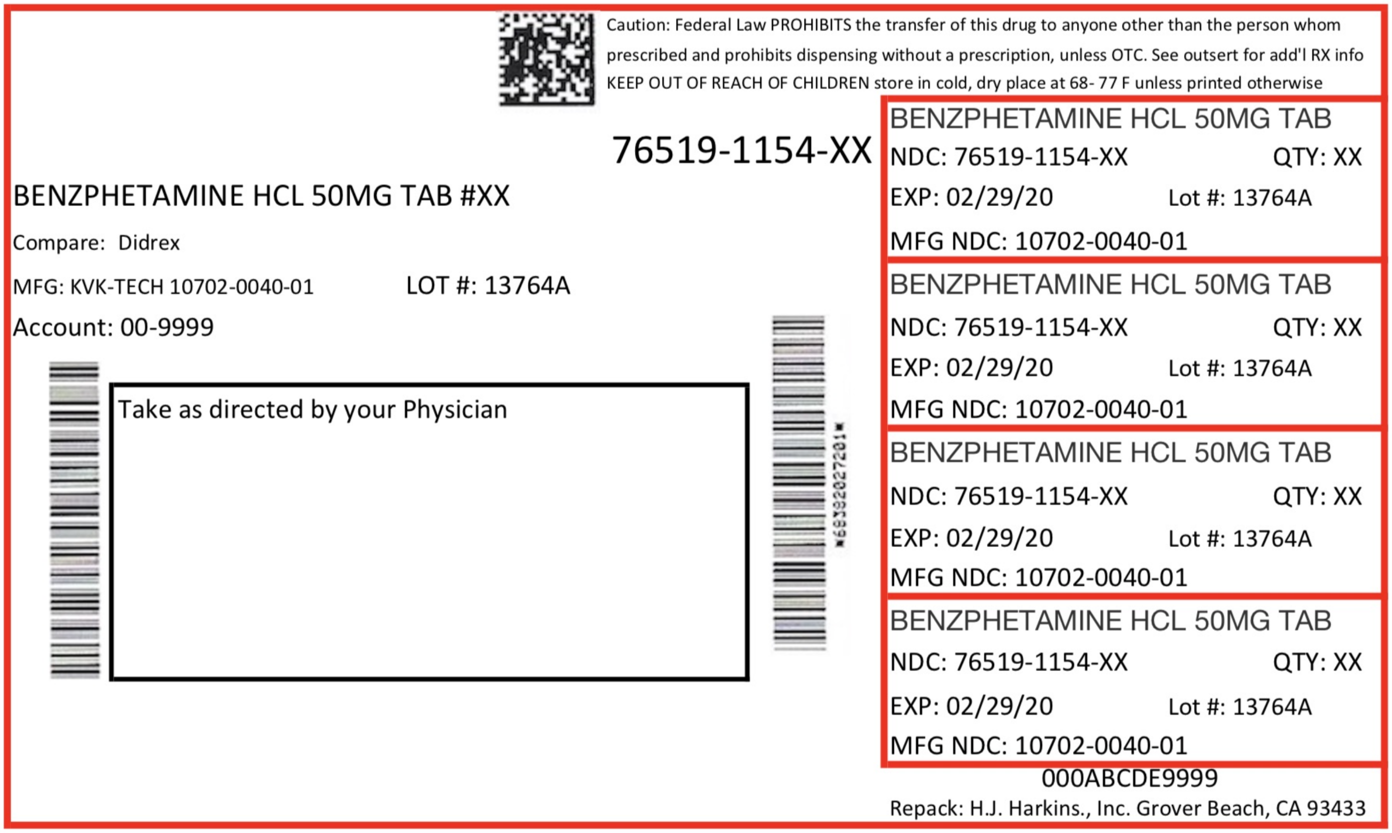
Rx only

Manufactured by:
KVK-Tech, INC.
110 Terry Dr. Suite 200
Newtown, PA 18940-1850

[company logo]

Item ID # 6077/03 07/10
Manufacturer's Code: 10702

Package Label.Principal Display Panel



BENZPHETAMINE HYDROCHLORIDE

benzphetamine hydrochloride tablet

Product Information

Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:76519-1154
Route of Administration	ORAL	**DEA Schedule**	CIII

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
BENZPHETAMINE HYDROCHLORIDE (UNII: 43DWT87QT7) (BENZPHETAMINE - UNII:0M3S43XK27)	BENZPHETAMINE HYDROCHLORIDE	50 mg

Inactive Ingredients

Ingredient Name	Strength
FD&C YELLOW NO. 6 (UNII: H77VEI93A8)	
MAGNESIUM STEARATE (UNII: 70097M6I30)	
POLYVINYL ALCOHOL, UNSPECIFIED (UNII: 532B59J990)	
CARNAUBA WAX (UNII: R12CBM0EIZ)	
FD&C RED NO. 40 (UNII: WZB9127XOA)	
SODIUM STARCH GLYCOLATE TYPE A POTATO (UNII: 5856J3G2A2)	
TITANIUM DIOXIDE (UNII: 15FIX9V2JP)	
TALC (UNII: 7SEV7J4R1U)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
POLYETHYLENE GLYCOL 3350 (UNII: G2M7P15E5P)	

LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
MICROCRYSTALLINE CELLULOSE (UNII: OP1R32D61U)	

Product Characteristics			
Color	orange	**Score**	2 pieces
Shape	ROUND	**Size**	10mm
Flavor		**Imprint Code**	K;40
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:76519-1154-1	100 in 1 CONTAINER; Type 0: Not a Combination Product	06/07/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA090968	06/07/2017	

Labeler - H. J. Harkins Company Inc. (147681894)

Establishment

Name	Address	ID/FEI	Business Operations
H. J. Harkins Company Inc.		147681894	manufacture(76519-1154) , repack(76519-1154) , relabel(76519-1154)

Revised: 12/2017 H. J. Harkins Company Inc.