PHENTERMINE HYDROCHLORIDE- phentermine hydrochloride tablet
H.J. Harkins Company, Inc.

Indications & Usage

Phentermine hydrochloride tablets USP 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 greater than or equal to 30 kg/m , or greater than or equal to 27 kg/m in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia).
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)

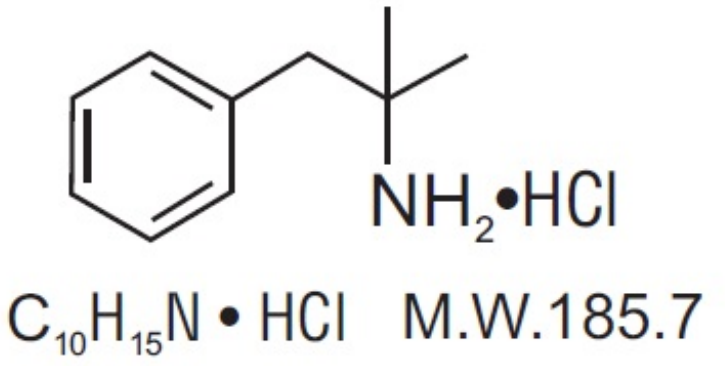
Weight (pounds)	5'0"	5'3"	5'6"	5'9"	6'0"	6'3"
140	27	25	23	21	19	18
150	29	27	24	22	20	19
160	31	28	26	24	22	20
170	33	30	28	25	23	21
180	35	32	29	27	25	23
190	37	34	31	28	26	24
200	39	36	32	30	27	25
210	41	37	34	31	29	26
220	43	39	36	33	30	28
230	45	41	37	34	31	29
240	47	43	39	36	33	30
250	49	44	40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

Description

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

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

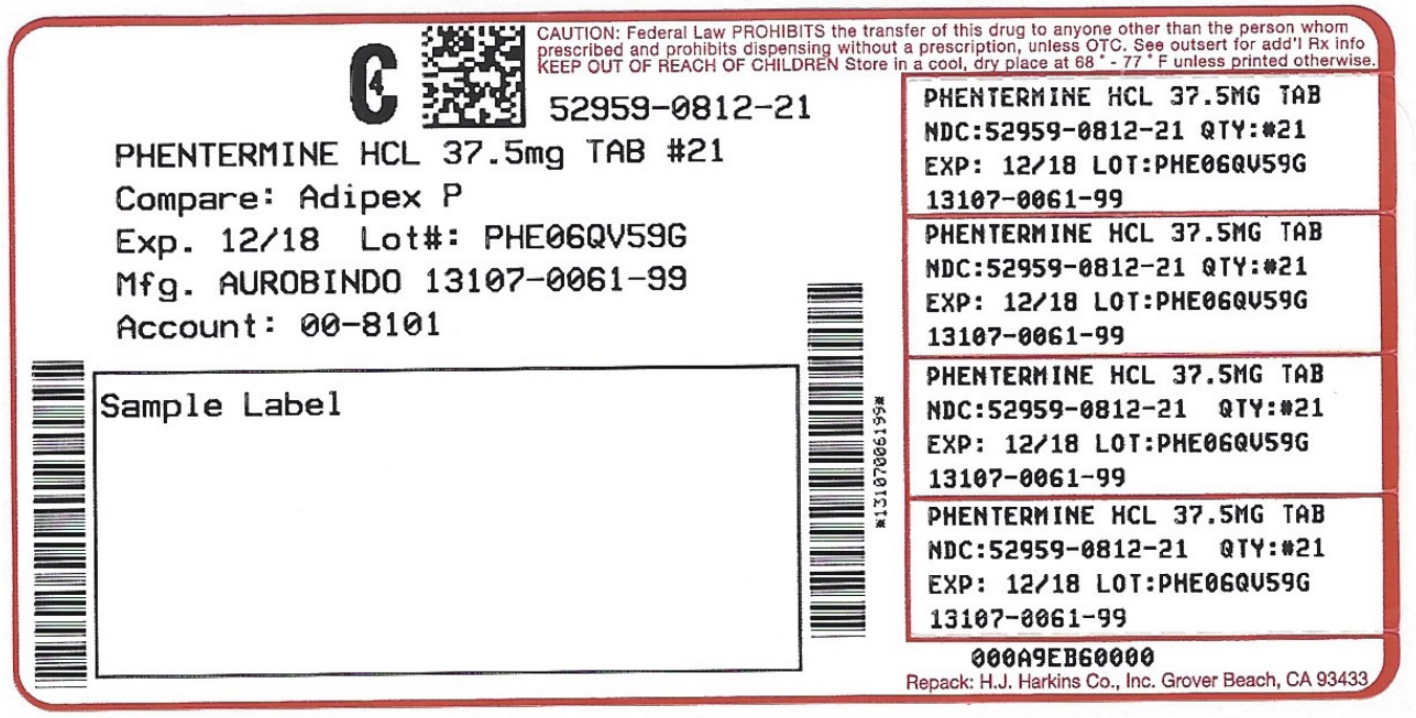
Phentermine hydrochloride tablets USP are available as an oral tablet containing 37.5 mg of phentermine hydrochloride USP (equivalent to 30 mg of phentermine base). Each phentermine hydrochloride tablet USP also contains the inactive ingredients microcrystalline cellulose, pregelatinized starch, anhydrous lactose, crospovidone, colloidal silicon dioxide, magnesium stearate, sucrose, corn starch and FD&C



$C_{10}H_{15}N \bullet HCl$ M.W.185.7

Blue #1.

Package and Display



PHENTERMINE HYDROCHLORIDE

phentermine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:52959-812
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

Product Characteristics			
Color	white (Off-white with blue specks)	**Score**	no score
Shape	OVAL	**Size**	10mm
Flavor		**Imprint Code**	MP;273
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:52959-812-21	21 in 1 BOTTLE; Type 0: Not a Combination Product	07/18/2017	
2	NDC:52959-812-45	45 in 1 CONTAINER; Type 0: Not a Combination Product	07/18/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA203068	07/18/2017	

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

Establishment

Name	Address	ID/FEI	Business Operations
H.J. Harkins Comapny., Inc.		147681894	repack(52959-812) , relabel(52959-812) , manufacture(52959-812)

Revised: 1/2018 H.J. Harkins Company, Inc.