PHENTERMINE HYDROCHLORIDE- phentermine hydrochloride tablet
Northwind Pharmaceuticals

NDC: 51655-875-25

MFG: 53489-676-10

Phentermine HCL 37.5 MG C IV

60 tablets

Rx only

Lot#:

Exp. Date:

Each tablet contains: Phentermine hydrochloride, USP....37.5mg

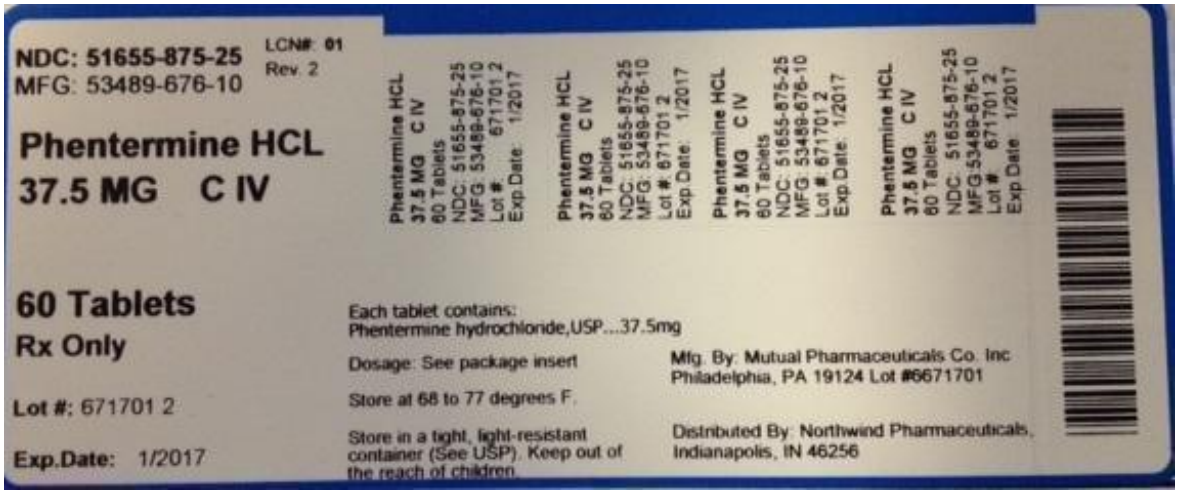
Dosage: See package insert

Store at 68 to 77 degrees F.

Store in a tight, light-resistance container (See USP) Keep out of the reach of children.

Mfg by: Mutual Pharmaceuticals Co., Inc Philadelphia, PA 19124 Lot #

Distributed by: Northwind Pharmaceuticals, Indianapolis, IN 46256



NDC: 51655-875-90

Phentermine HCL 37.5 MG C IV

45 Tablets Rx Only

Lot: Exp:

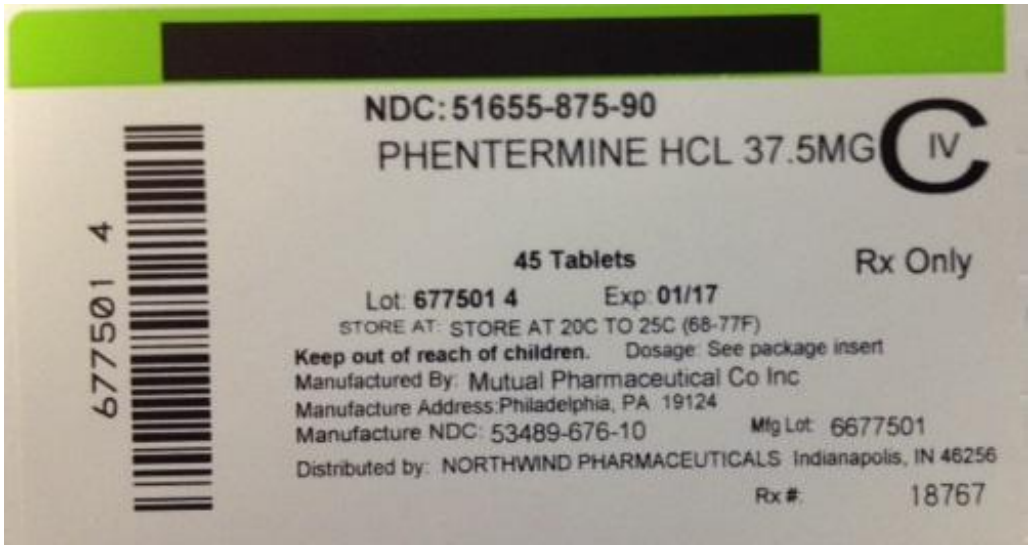
Store at 20C to 25C (68-77F)

Manufactured by Mutual Pharmaceuticals Co Inc

Manufacture Address: Philadelphia, PA 19124

Manufacture NDC: 53489-676-10 Mfg Lot: 6677501

Distributed by: Northwind Pharmaceuticals Indianapolis, IN 46256



NDC: 51655-875-24

Phentermine HCL 37.5 MG C IV

30 Tablets Rx Only

Lot: Exp:

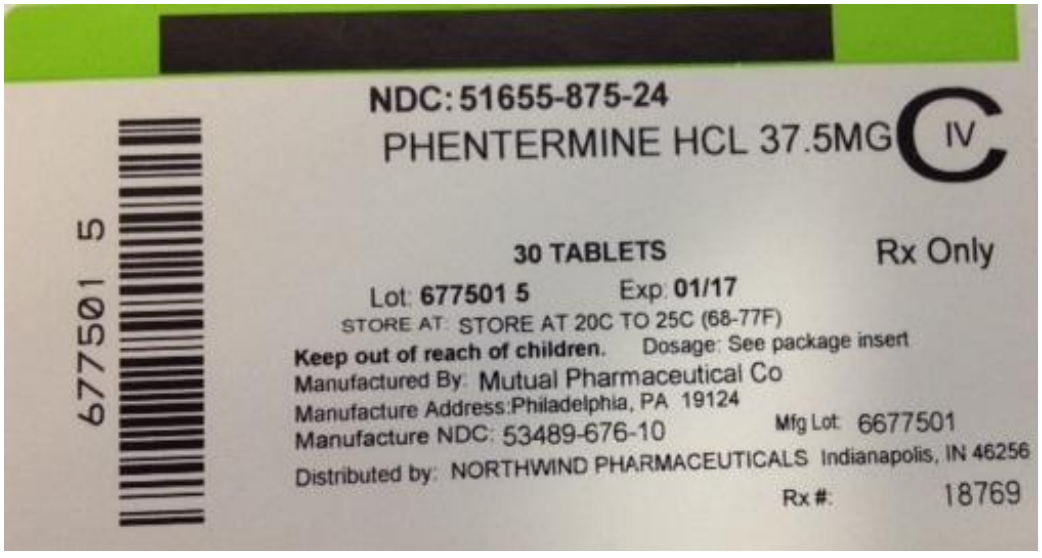
Store at 20C to 25C (68-77F)

Manufactured by Mutual Pharmaceuticals Co Inc

Manufacture Address: Philadelphia, PA 19124

Manufacture NDC: 53489-676-10 Mfg Lot: 6677501

Distributed by: Northwind Pharmaceuticals Indianapolis, IN 46256



NDC: 51655-875-25

Phentermine HCL 37.5 MG C IV

60 Tablets Rx Only

Lot: Exp:

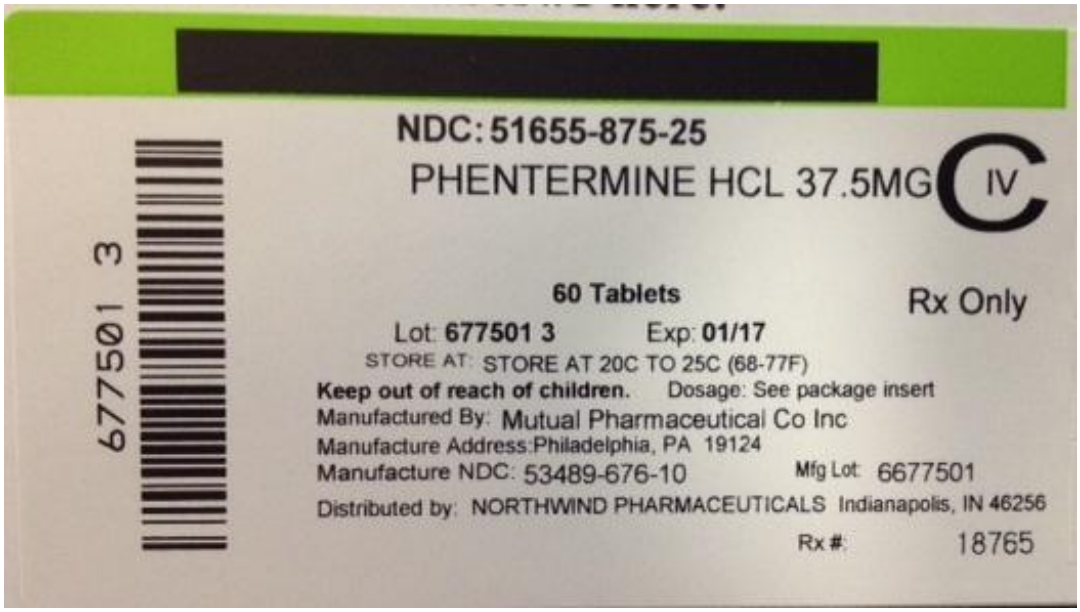
Store at 20C to 25C (68-77F)

Manufactured by Mutual Pharmaceuticals Co Inc

Manufacture Address: Philadelphia, PA 19124

Manufacture NDC: 53489-676-10 Mfg Lot: 6677501

Distributed by: Northwind Pharmaceuticals Indianapolis, IN 46256



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/m2, or ≥ 27 kg/m2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). (1)

The limited usefulness of agents of this class, including phentermine hydrochloride, should be measured against possible risk factors inherent in their use

Dosage and Administration

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

Late evening administration should be avoided (risk of insomnia).

Phentermine hydrochloride tablets can be taken with or without food

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

Nursing

Known hypersensitivity, or idiosyncrasy to the sympathomimetic amines

Warning and Precautions

Coadministration with other drugs for weight loss is not recommended (safety and efficacy of combination not established). 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. Rare cases of serious regurgitant cardiac valvular disease have been reported. 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. Phentermine may impair the ability of the patient to engage in potentially hazardous activities such as operating machinery or driving a motor vehicle. 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. Concomitant alcohol use may result in an adverse drug reaction. Use caution in patients with even mild hypertension (risk of increase in blood pressure). A reduction in dose of insulin or oral hypoglycemic medication may be required in some patients.

PHENTERMINE HYDROCHLORIDE

phentermine hydrochloride tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:51655-875(NDC:53489-676)
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	37.5 mg

Product Characteristics			
Color	white	**Score**	2 pieces
Shape	OVAL	**Size**	13mm
Flavor		**Imprint Code**	MP;273
Contains			

Packaging				
#	**Item Code**	**Package Description**	**Marketing Start Date**	**Marketing End Date**
1	NDC:51655-875-25	60 in 1 BOTTLE, DISPENSING		
2	NDC:51655-875-90	45 in 1 BOTTLE, DISPENSING		
3	NDC:51655-875-24	30 in 1 BOTTLE, DISPENSING		

Marketing Information			
Marketing Category	**Application Number or Monograph Citation**	**Marketing Start Date**	**Marketing End Date**
ANDA	ANDA040526	05/15/2014	

Labeler - Northwind Pharmaceuticals (036986393)

Registrant - Northwind Pharmaceuticals (036986393)

Establishment

Name	Address	ID/FEI	Business Operations
Northwind Pharmaceuticals		036986393	repack(51655-875)

Revised: 8/2014 Northwind Pharmaceuticals