PHENDIMETRAZINE TARTRATE- phendimetrazine tartrate tablet
NuCare Pharmaceuticals, Inc.

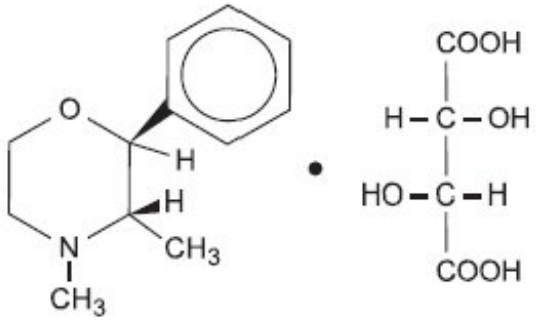
Phendimetrazine Tartrate Tablets USP, 35 mg

Rx only

DESCRIPTION

Phendimetrazine tartrate, as the dextro isomer, has the chemical name of (2 *s*, 3 *s*,)-3,4-dimethyl-2-phenylmorpholine L-(+)-tartrate (1:1).

The structural formula is as follows:



$C_{12}H_{17}NO.C_4H_6O_6$
M.W. 341.36

Phendimetrazine tartrate is a white, odorless crystalline powder. It is freely soluble in water; sparingly soluble in warm alcohol; insoluble in chloroform, acetone, ether and benzene.

Each tablet, for oral administration, contains 35 mg of phendimetrazine tartrate.

Inactive Ingredients: confectioner's sugar (sucrose and corn starch), lactose monohydrate, povidone, pregelatinized starch, silicon dioxide and stearic acid.

The pink, white and blue tablets also contain: FD&C blue No. 1 and FD&C red No. 3.

The pink tablets also contain: FD&C red No. 3 and FD&C yellow No. 5 (see PRECAUTIONS).

The yellow tablets also contain: FD&C yellow No. 5 (see PRECAUTIONS).

CLINICAL PHARMACOLOGY

Phendimetrazine tartrate is a phenylalkylamine sympathomimetic amine with pharmacological 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, for example.

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 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 clinically limited.

INDICATIONS AND USAGE

Phendimetrazine tartrate tablets are indicated in the management of exogenous obesity as a short term adjunct (a few weeks) in a regimen of weight reduction based on caloric restriction. The limited usefulness of agents of this class (see CLINICAL PHARMACOLOGY) should be measured against possible risk factors inherent in their use such as those described below.

CONTRAINDICATIONS

Known hypersensitivity or idiosyncratic reactions to sympathomimetics.

Advanced arteriosclerosis, symptomatic cardiovascular disease, moderate and severe hypertension, hyperthyroidism and glaucoma.

Highly nervous or agitated patients.

Patients with a history of drug abuse.

Patients taking other CNS stimulants, including monoamine oxidase inhibitors.

WARNINGS

Tolerance to the anorectic effect of phendimetrazine develops within a few weeks. When this occurs, its use should be discontinued; the maximum recommended dose should not be exceeded.

Use of phendimetrazine tartrate within 14 days following the administration of monoamine oxidase inhibitors may result in a hypertensive crisis.

Abrupt cessation of administration following prolonged high dosage results in extreme fatigue and depression. Because of the effect on the central nervous system, phendimetrazine 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.

PRECAUTIONS

Caution is to be exercised in prescribing phendimetrazine tartrate for patients with even mild hypertension.

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

Phendimetrazine 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.

The phendimetrazine tartrate pink and yellow tablets contain FD&C yellow No. 5 (tartrazine) which may cause allergic type reactions (including bronchial asthma) in certain susceptible individuals. Although the overall incidence of FD&C yellow No. 5 (tartrazine) sensitivity in the general population is low, it is frequently seen in patients who also have aspirin hypersensitivity.

Usage in Pregnancy

Safe use in pregnancy has not been established. Until more information is available, phendimetrazine tartrate should not be taken by women who are or who may become pregnant unless, in the opinion of the physician, the potential benefits outweigh the possible hazards.

Usage in Children

Phendimetrazine tartrate is not recommended for use in children under 12 years of age.

ADVERSE REACTIONS

Cardiovascular: Palpitation, tachycardia, elevated blood pressure.

Central Nervous System: Overstimulation, restlessness, insomnia, agitation, flushing, tremor, sweating, dizziness, headache, psychotic state, blurring of vision.

Gastrointestinal: Dryness of the mouth, nausea, diarrhea, constipation, stomach pain.

Genitourinary: Urinary frequency, dysuria, changes in libido.

DRUG ABUSE AND DEPENDENCE

Controlled Substance

Phendimetrazine tartrate tablets are defined by the Drug Enforcement Administration as a Schedule III controlled substance.

Dependence

Phendimetrazine tartrate is related chemically and pharmacologically to the amphetamines. Amphetamines and related stimulant drugs have been extensively abused and the possibility of abuse of phendimetrazine 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 intoxications is psychosis, often clinically indistinguishable from schizophrenia.

OVERDOSAGE

Acute overdosage with phendimetrazine tartrate may manifest itself by the following signs and symptoms: unusual restlessness, confusion, belligerence, hallucinations 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. Poisoning may result in convulsions, coma and death.

The management of overdosage is largely symptomatic. It includes sedation with a barbiturate. If hypertension is marked, the use of a nitrate or rapid-acting alpha receptor-blocking agent should be considered. Experience with hemodialysis or peritoneal dialysis is inadequate to permit

recommendations for its use.

DOSAGE AND ADMINISTRATION

Usual Adult Dose

1 tablet (35 mg) b.i.d. or t.i.d., one hour before meals.

Dosage should be individualized to obtain an adequate response with the lowest effective dosage. In some cases 1/2 tablet (17.5 mg) per dose may be adequate. Dosage should not exceed 2 tablets t.i.d.

HOW SUPPLIED

Phendimetrazine Tartrate Tablets 35 mg are available in bottles of 30 NDC 68071-3062-3

bottles of 60 NDC 68071-3062-6

bottles of 90 NDC 68071-3062-9

yellow, bisected, round tablet; imprinted *"E* 76"

Storage

Store at 20° to 25°C (68° to 77°F) [see USP Controlled Room Temperature]. Protect from moisture.

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

To report SUSPECTED ADVERSE REACTIONS, contact Sandoz Inc. at 1-800-525-8747 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Manufactured for

Sandoz Inc.

Princeton, NJ 08540

Manufactured by

Epic Pharma, LLC

Laurelton, NY 11413

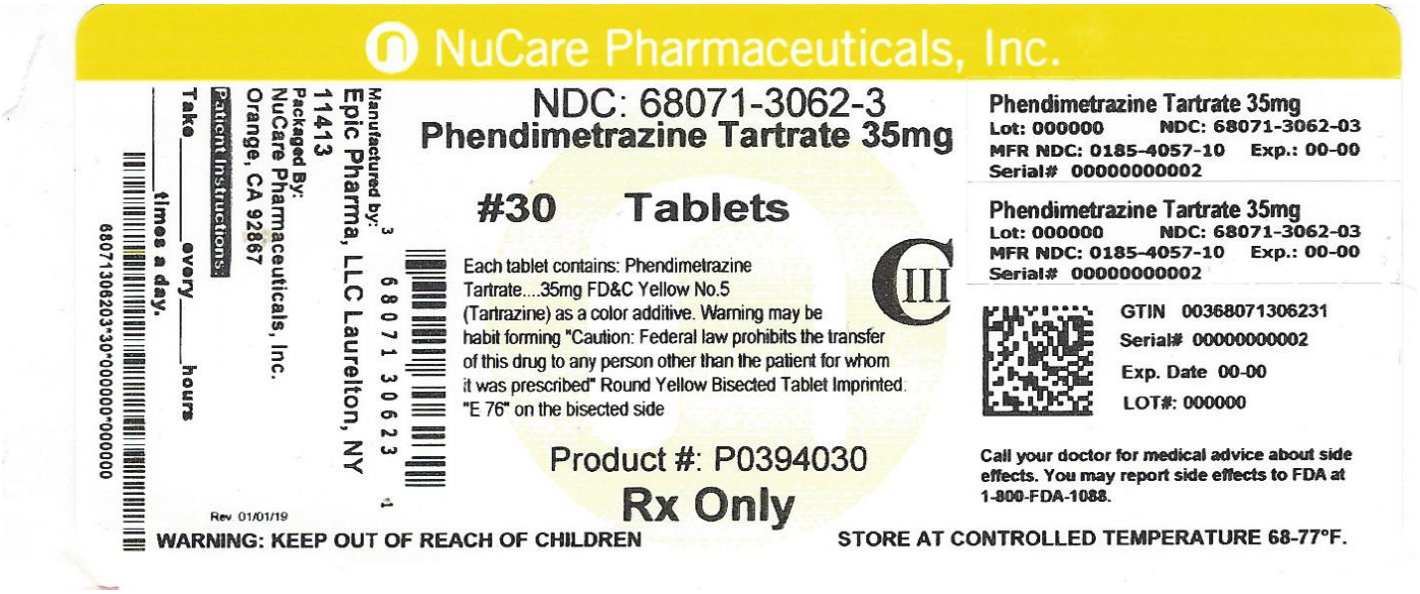
Rev. 10/08

MF4055REV10/08

OS7316

MG #16859

Phendimetrazine Tartrate Tablets USP



PHENDIMETRAZINE TARTRATE

phendimetrazine tartrate tablet

Product Information			
Product Type	HUMAN PRESCRIPTION DRUG	**Item Code (Source)**	NDC:68071-3062(NDC:0185-4057)
Route of Administration	ORAL	**DEA Schedule**	CIII

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
PHENDIMETRAZINE TARTRATE (UNII: 6985IP0T80) (PHENDIMETRAZINE - UNII:AB2794W8KV)	PHENDIMETRAZINE TARTRATE	35 mg

Inactive Ingredients	
Ingredient Name	**Strength**
STARCH, CORN (UNII: O8232NY3SJ)	
FD&C YELLOW NO. 5 (UNII: I753WB2F1M)	
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)	
POVIDONE, UNSPECIFIED (UNII: FZ989GH94E)	
SILICON DIOXIDE (UNII: ETJ7Z6XBU4)	
STEARIC ACID (UNII: 4ELV7Z65AP)	
SUCROSE (UNII: C151H8M554)	

Product Characteristics			
Color	yellow	**Score**	2 pieces
Shape	ROUND	**Size**	7mm
Flavor		**Imprint Code**	E;76
Contains			

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:68071-3062-3	30 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2017	
2	NDC:68071-3062-6	60 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2017	
3	NDC:68071-3062-9	90 in 1 BOTTLE; Type 0: Not a Combination Product	03/10/2017	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
ANDA	ANDA085588	08/19/1997	

Labeler - NuCare Pharmaceuticals, Inc. (010632300)

Establishment

Name	Address	ID/FEI	Business Operations
NuCare Pharmaceuticals, Inc.		010632300	repack(68071-3062)

Revised: 2/2021 NuCare Pharmaceuticals, Inc.