HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use Suprenza safely and effectively. See full prescribing information for Suprenza

Suprenza™ (phentermine hydrochloride) orally disintegrating tablet C IV
Initial U.S. Approval: 1959

INDICATIONS AND USAGE

Suprenza 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 greater than or equal to 30 kg/m^2, or greater than or equal to 27 kg/m^2 in the presence of other risk factors (e.g., controlled hypertension, diabetes, hyperlipidemia). (1)
The limited usefulness of agents of this class, including Suprenza, should be measured against possible risk factors inherent in their use. (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)
- Suprenza can be taken with or without food (12.3)

DOSAGE FORMS AND STRENGTHS

- Orally disintegrating tablets containing 15 mg, 30 mg, or 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 (4, 8.1)
- Nursing (4, 8.3)
- 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. Suprenza 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, Suprenza should be discontinued. The recommended dose should not be exceeded. (5.4)
- Suprenza 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)
- Contains FD&C Yellow No. 5 (tartrazine) as color additive. (5.10)

ADVERSE REACTIONS

Adverse events have been reported in the cardiovascular, central nervous, gastrointestinal, allergic, and endocrine systems. (6)
To report SUSPECTED ADVERSE REACTIONS, contact Akrimax Pharmaceuticals, LLC at 1-888-383-1733 or FDA at 1-800-FDA-1088 or *www.fda.gov/medwatch*.

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

DRUG INTERACTIONS

- Monoamine oxidase inhibitors: Risk of hypertensive crisis. (4, 7.1)
- 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 Suprenza. (7.4)

USE IN SPECIFIC POPULATIONS

- Nursing mothers: Discontinue drug or nursing taking into consideration importance of drug to mother. (4, 8.3)
- 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 Suprenza to patients with renal impairment (8.6)

See 17 for PATIENT COUNSELING INFORMATION

Revised: 12/2012

FULL PRESCRIBING INFORMATION: CONTENTS *

1 INDICATIONS AND USAGE
2 DOSAGE AND ADMINISTRATION
3 DOSAGE FORMS AND STRENGTHS
4 CONTRAINDICATIONS
5 WARNINGS AND PRECAUTIONS
5.1 Coadministration with Other Drug Products for Weight Loss
5.2 Primary Pulmonary Hypertension
5.3 Valvular Heart Disease
5.4 Development of Tolerance, Discontinuation in Case of Tolerance
5.5 Effect on the Ability to Engage in Potentially Hazardous Tasks
5.6 Risk of Abuse and Dependence
5.7 Usage with Alcohol
5.8 Use in Patients with Hypertension
5.9 Use in Patients on Insulin or Oral Hypoglycemic Medications for Diabetes Mellitus
5.10 Also contains FD&C Yellow No. 5 (tartrazine) as a color additive
6 ADVERSE REACTIONS
7 DRUG INTERACTIONS
7.1 Monoamine Oxidase Inhibitors
7.2 Alcohol
7.3 Insulin and Oral Hypoglycemic Medications
7.4 Adrenergic Neuron Blocking Drugs
8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
8.3 Nursing Mothers
8.4 Pediatric Use
8.5 Geriatric Use
8.6 Renal Impairment
9 DRUG ABUSE AND DEPENDENCE
9.1 Controlled Substance
9.2 Abuse
9.3 Dependence
10 OVERDOSAGE
10.1 Acute Overdosage
10.2 Chronic Intoxication
11 DESCRIPTION
12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
12.2 Pharmacodynamics
12.3 Pharmacokinetics
13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
14 CLINICAL STUDIES
16 HOW SUPPLIED/STORAGE AND HANDLING
17 PATIENT COUNSELING INFORMATION

*** Sections or subsections omitted from the full prescribing information are not listed**

FULL PRESCRIBING INFORMATION
Suprenza (phentermine hydrochloride) orally disintegrating tablet

1 INDICATIONS AND USAGE

Suprenza is 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^2, or greater than or equal to 27 kg/m^2 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

The limited usefulness of agents of this class, including Suprenza, [see *Clinical Pharmacology (12.1, 12.2)*] should be measured against possible risk factors inherent in their use such as those described below.

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 as prescribed by the physician, administered in the morning, with or without food. Suprenza is not recommended for use in pediatric patients less than or equal to 16 years of age.

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

With dry hands, gently remove the Suprenza (phentermine hydrochloride ODT) tablet from the bottle. Immediately place the Suprenza tablet on top of the tongue where it will dissolve, then swallow with or without water.

3 DOSAGE FORMS AND STRENGTHS

Orally disintegrating tablets (ODT) containing 15 mg, 30 mg, or 37.5 mg phentermine hydrochloride (equivalent to 12 mg, 24 mg, or 30 mg phentermine base, respectively). The tablets are not scored. The 15 mg ODT is a yellow with blue spots round tablet embossed with AX4 on one side. The 30 mg ODT is a yellow round tablet embossed with AX7 on one side. The 37.5 mg ODT is a white with blue spots round tablet embossed with AX8 on one 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

Suprenza is indicated only as short-term (a few weeks) monotherapy for the management of exogenous obesity. The safety and efficacy of combination therapy with Suprenza 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 Suprenza and these drug products is not recommended.

5.2 Primary 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 Suprenza alone cannot be ruled out; there have been rare cases of PPH in patients who reportedly have taken phentermine alone. 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.

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 Suprenza 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

Suprenza 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

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

5.8 Use in Patients with Hypertension

Use caution in prescribing Suprenza 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.

5.10 Also contains FD&C Yellow No. 5 (tartrazine) as a color additive

This product contains 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.

6 ADVERSE REACTIONS

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

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

The following adverse reactions to phentermine have been identified:

Cardiovascular

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

Central Nervous System

Overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache, psychosis.

Gastrointestinal

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

Allergic

Urticaria.

Endocrine

Impotence, changes in libido.

7 DRUG INTERACTIONS

7.1 Monoamine Oxidase Inhibitors

Use of Suprenza 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 Suprenza 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

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

8 USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Pregnancy Category X

Suprenza 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 *Clinical Pharmacology (12.1)*]. 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.

8.3 Nursing Mothers

It is not known if Suprenza 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
Suprenza 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 Suprenza 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.

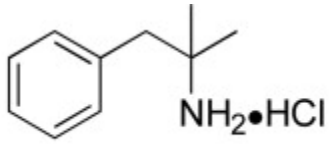
9.3 Dependence
Abuse of amphetamines and related drugs may be associated with intense psychological dependence and severe social dysfunction. There are reports of patients who have increased the dosage of these drugs to many times that recommended. Abrupt cessation following prolonged high dosage administration 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. 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 tachycardia, 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. 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
Suprenza is an orally disintegrating tablet (ODT) of phentermine hydrochloride, USP. Phentermine hydrochloride is a sympathomimetic amine anorectic. Its chemical name is α,α,-dimethylphenethylamine hydrochloride. The structural formula is as follows:



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

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.
Suprenza is available as an orally disintegrating tablet (ODT) containing 15 mg, 30 mg, or 37.5 mg of phentermine hydrochloride (equivalent to 12 mg, 24 mg, or 30 mg of phentermine base).

Suprenza contains the inactive ingredients mannitol powder, citric acid powder, Povidone CL, Povidone K 30, sucralose, magnesium stearate, peppermint flavor, talc, sodium lauryl sulfate, and mannitol pregranulated. Suprenza 15 mg ODT also contains FD&C Blue # 1 lake and FD&C Yellow # 5 lake. Suprenza 30 mg ODT also contains FD&C Yellow # 5 lake. Suprenza 37.5 mg ODT also contains FD&C Blue # 1 lake.

12 CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Suprenza is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, amphetamine (d- and d*l*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.

12.2 Pharmacodynamics

Typical actions 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

In terms of rate and extent of exposure, phentermine orally disintegrating tablets are equivalent to phentermine capsules and tablets administered under fasting conditions.

Following the administration of the oral disintegrating tablet (ODT), phentermine reaches peak concentrations (C_{max}) after 3.0 to 4.4 hours. Swallowing the ODT after disintegration with or without water did not affect the extent (AUC) of phentermine exposure. Administration of the ODT after a high fat/high calorie breakfast decreased the C_{max} of phentermine by approximately 5% and the AUC by approximately 12%. Despite the decrease in Cmax and AUC, phentermine ODT can be administered with or without food. Swallowing the ODT without prior disintegration decreased the C_{max} of phentermine by approximately 7% and the AUC by approximately 8% compared to swallowing the ODT after disintegration.

<u>Drug Interactions</u>

In a single-dose study comparing the exposures after oral administration of a combination capsule of 15 mg phentermine and 92 mg topiramate to the exposures after oral administration of a 15 mg phentermine capsule or a 92 mg topiramate capsule, there is no significant topiramate exposure change in the presence of phentermine. However in the presence of topiramate, phentermine C_{max} and AUC increase 13% and 42%, respectively.

<u>Specific Populations</u>

Renal Impairment

Suprenza 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 Suprenza to patients with renal impairment.

13 NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

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

14 CLINICAL STUDIES

No clinical studies have been conducted with Suprenza.

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.

16 HOW SUPPLIED/STORAGE AND HANDLING

Available as orally disintegrating tablets (ODT) containing 15 mg, 30 mg, or 37.5 mg of phentermine hydrochloride (equivalent to 12 mg, 24 mg, or 30 mg phentermine base, respectively). The tablets are not scored. The 15 mg ODT is a yellow with blue spots round tablet embossed with AX4 on one side. The 30 mg ODT is a yellow round tablet embossed with AX7 on one side. The 37.5 mg ODT is a white with blue spots round tablet embossed with AX8 on one side.

Suprenza is available as described in Table 2.

Table 2. Suprenza Orally Disintegrating Tablet Presentations

Tablet Strength	Tablet Color/Shape	Tablet Markings	NDC Code
15 mg	Round, embossed tablets Yellow with blue spots	AX4 on one side	NDC: 24090 720 85
30 mg	Round, embossed tablets Yellow	AX7 on one side	NDC: 24090 721 85
37.5 mg	Round, embossed tablets White with blue spots	AX8 on one side	NDC: 24090 722 85

Suprenza 15 mg, 30 mg, and 37.5 mg ODT are packaged in bottles of 30.

Store at 20° to 25°C (68° to 77°F) [See USP Controlled Room Temperature].

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

Keep out of the reach of children.

17 PATIENT COUNSELING INFORMATION

Patients must be informed that Suprenza is 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, and that coadministration of phentermine with other drugs for weight loss is not recommended [see *Indications and Usage (1)* and *Warnings and Precautions (5)*].

Patients must be instructed on how much Suprenza to take, and when and how to take it [see *Dosage and Administration (2)*].

Advise pregnant women and nursing mothers not to use Suprenza *(see Use in Specific Populations (8.1, 8.3)]*.

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 *Warnings and Precautions (5.8)* and *Adverse Reactions (6)*]
- The risk of interactions [see *Contraindications (4), Warnings and Precautions (5)* and *Drug Interactions (7)*]

See also, for example, *Adverse Reactions (6)* and *Use 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 *Warnings and Precautions (5.4)*] and
- the risk of dependence and the potential consequences of abuse [see *Warnings and Precautions (5.6), Drug Abuse and Dependence (9),* and *Overdosage (10)*].

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

Manufactured for
Akrimax Pharmaceuticals, LLC
Cranford, NJ 07016
by: Alpex Pharma SA
Lugano, Switzerland
Marketed and Distributed by:
Akrimax Pharmaceuticals, LLC
Cranford, NJ 07016
372F004
Principal Display Panel – 15 mg Bottle Label
NDC 24090-720-85

Suprenza™
(Phentermine Hydrochloride)
Orally Disintegrating Tablets
15 mg
Rx Only
30 Tablets CIV

Principal Display Panel – 30 mg Bottle Label
NDC 24090-721-85
Suprenza™
(Phentermine Hydrochloride)
Orally Disintegrating Tablets
30 mg
Rx Only
30 Tablets CIV

Principal Display Panel – 37.5 mg Bottle Label
NDC 24090-722-85
Suprenza™
(Phentermine Hydrochloride)
Orally Disintegrating Tablets
37.5 mg
Rx Only
30 Tablets CIV