<table>
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<th>MIRROR PHARMACEUTICAL</th>
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<td>12/21/12</td>
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<tr>
<td>ITEM #:</td>
<td>5518 REV. 12/12</td>
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<tr>
<td>PRODUCT:</td>
<td>Phentermine Hydrochloride Tablets (RISING), USP 37.5 mg</td>
</tr>
<tr>
<td>FLAT:</td>
<td>11.25&quot; x 9.75&quot;</td>
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<tr>
<td>SUPPLIER:</td>
<td>Chesapeake - Fairfield, NJ</td>
</tr>
<tr>
<td>PHONE:</td>
<td>973-808-8000</td>
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<tr>
<td>MACOP:</td>
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**APPROVAL**

- □ APPROVED AS IS
- □ NOT APPROVED - REPROOF IS REQUIRED

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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 excessive 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. (1)

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### 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).**
- **Phentermine hydrochloride can be taken with or without food.** (12.3)

### DOSAGE FORMS AND STRENGTHS

- Tablets containing 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** (4.2)
- **Glucoma** (4)
- **Agitated states** (4)
- **History of drug abuse (4)**
- **Pregnancy (4, 8.1)**
- **Nursing (4, 8.3)**
- **Known hypersensitivity, or idiosyncrasy to the sympathetic amines** (4)

### WARNINGS AND PRECAUTIONS

- **Coadministration with other drugs for weight loss is not recommended (safety and efficacy of combination not established).** (5.1)

### FULL PRESCRIBING INFORMATION: CONTENTS*

#### 1 INDICATIONS AND USAGE
- Phentermine hydrochloride tablets are indicated only as short-term (a few weeks) monotherapy for the management of exogenous obesity. The safety and efficacy of combination therapy with phentermine and any other drug products for weight loss including phentermine, over-the-counter preparations, and herbal products, or serotonergic agents such as selective serotonin reuptake inhibitors (e.g., fluoxetine, fluvoxamine, paroxetine), have not been established. Therefore, coadministration of phentermine and these drug products is not recommended.

### 2 DOSAGE AND ADMINISTRATION
- **Adverse reactions have been reported in the cardiovascular, central nervous, gastrointestinal, allergic, and endocrine systems.** (6.2)
- **To report SUSPECTED ADVERSE REACTIONS, contact Rising Pharmaceuticals, at 1-800-961-9000 or FDA at 1-800-FDA-1088 or www.fda.gov/reportwhee.

### 3 DRUG INTERACTIONS
- **Monoamine oxidase inhibitors: Risk of hypertensive crisis.** (4, 7.1)
- **Alcohol: Consider potential interaction.** (7.2)
- **Insulin and oral hypoglycemic medications: Requirements may be altered.** (7.3)
- **Adrenergic neuron blocking drugs: Hypotensive effect may be decreased by phentermine.** (7.4)

### 4 ADVERSE REACTIONS

- **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)
- **Caution when administering phentermine to patients with renal impairment.** (8.6)

### 5 WARNINGS AND PRECAUTIONS

See 17 for PATIENT COUNSELING INFORMATION. Revised: [12/2012]

### 6 USE IN SPECIFIC POPULATIONS

- **Pediatric use**
- **Reproductive harm**

### 7 ADVERSE REACTIONS

- **Adverse reactions have been reported in the cardiovascular, central nervous, gastrointestinal, allergic, and endocrine systems.** (6.2)

### 8 DRUG ABUSE AND DEPENDENCE

### 9 OVERDOSAGE

### 10 CLINICAL PHARMACOLOGY

### 11 DESCRIPTION

### 12 NONCLINICAL TOXICOLOGY

### 13 CLINICAL STUDIES

### 14 HOW SUPPLIED/STORAGE AND HANDLING

### 15 PATIENT COUNSELING INFORMATION

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

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### 5 WARNINGS AND PRECAUTIONS

#### 5.1 Coadministration with Other Drug Products for Weight Loss

Phentermine hydrochloride tablets are indicated only as short-term (a few weeks) monotherapy for the management of exogenous obesity. The safety and efficacy of combination therapy with phentermine and any other drug products for weight loss including phentermine, over-the-counter preparations, and herbal products, or serotonergic agents such as selective serotonin reuptake inhibitors (e.g., fluoxetine, fluvoxamine, paroxetine), have not been established. Therefore, coadministration of phentermine and these drug products is not recommended.

#### 5.2 Primary Pulmonary Hypertension

Primary Pulmonary Hypertension (PPH) – a rare, frequently fatal disorder 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 phentermine 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 patients who have 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 phentermine 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 anorectic effect develops, the recommended dose should not be increased 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

Phentermine 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

Phentermine is related chemically and pharmacologically to amphetamine (d- and dl-amphetamine) and to other related stimulant drugs that have been extensively abused. The possibility of abuse of phentermine should be kept in mind when evaluating the desirability of continuing the drug as part of a weight reduction program. See Drug Abuse and Dependence (9) and Overdose (10).

The least amount feasible should be prescribed or dispensed at one time in order to minimize the possibility of overdose.

#### 5.7 Usage with Alcohol

Concomitant use of alcohol with phentermine may result in an adverse drug reaction.

#### 5.8 Use in Patients with Hypertension

Use caution in prescribing phentermine 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. (5.9)

(Continued on other side...)
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 phentermine is contraindicated during or within 14 days following the administration of monamine oxidase inhibitors because of the risk of hypertensive crisis.

7.2 Alcohol
Concomitant use of alcohol with phentermine 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
Phentermine may decrease the hypotensive effect of adrenergic neuron blocking drugs.

8 USE IN SPECIFIC POPULATIONS
8.1 Pregnancy
Pregnancy Category X
Phentermine 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 3-amphetamine) [see Clinical Pharmacology (12.4)].

Phentermine is known to be substantially excreted by the kidney, and exposure increases can be expected in patients with renal impairment. Use caution when administering phentermine to patients with renal impairment [see Clinical Pharmacology (12.3)].

8.2 Lactation
It is not known if phentermine is excreted in human milk; however, other amphetamines are present in human milk. It is not known if phentermine is excreted in human milk; however, other amphetamines are present in human milk. It is not known if phentermine is excreted in human milk; however, other amphetamines are present in human milk. It is not known if phentermine is excreted in human milk; however, other amphetamines are present in human milk. It is not known if phentermine is excreted in human milk; however, other amphetamines are present in human milk.

8.3 Nursing Mothers
It is not known if phentermine 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
Phentermine 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 phentermine 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.

Phentermine is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, amphetamine (d- and 3-amphetamine). Drugs of this class used in obesity are commonly known as "anorectics" or "anorexigens." It has not been established that the primary action of such drugs is suppression of appetite and when in the presence of central nervous system actions, or metabolic effects, may also be involved.

12 CLINICAL PHARMACOLOGY
12.1 Mechanism of Action
Phentermine is a sympathomimetic amine with pharmacologic activity similar to the prototype drugs of this class used in obesity, amphetamine (d- and 3-amphetamine). Drugs of this class used in obesity are commonly known as “anorectics” or “anorexigens.” There is evidence that phentermine may be effective in weight loss in patients with obesity, but the exact mechanism of action is not known.

12.2 Pharmacokinetics
Typical 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
Following the administration of phentermine, phentermine reaches peak concentrations (C_max) after 3 to 4.4 hours.

Specific Populations
Renal Impairment
Phentermine 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 phentermine to patients with renal impairment.

Drug Interactions
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.

13 NONCLINICAL TOXICOLOGY
13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility
Studies have not been performed with phentermine to determine the potential for carcinogenesis, mutagenesis or impairment of fertility.

14 CLINICAL STUDIES
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 magnitude 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' administration; 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 tablets containing 37.5 mg of phentermine hydrochloride (equivalent to 30 mg phentermine base). Phentermine hydrochloride tablets USP, 37.5 mg are packaged in bottles of 30 (NDC 64980-190-03), bottles of 100 (NDC 64980-190-01) and bottles of 1000 (NDC 64980-190-10). 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 reach of children.

17 PATIENT COUNSELING INFORMATION
Patients must be informed that phentermine hydrochloride is a short-term (a few weeks) adjunct in a regimen of weight reduction based on exercise, behavioral modification and dietary 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 (5.1)]. Patients must be instructed on how much phentermine to take, and when and how to take it [see Dosage and Administration (3)].

Advise pregnant women and nursing mothers not to use phentermine [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 to take other actions. 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 (5.5)]
- The risk of an increased blood pressure [see Warnings and Precautions (5.5)]
- The risk of dependence and the potential consequences of abuse [see Warnings and Precautions (5.6, 5.9) 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, 5.9) and Drug Interactions (7)].

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

Manufactured for:
Rising Pharmaceuticals, Inc.
Allendale, NJ 07401

Manufactured by:
Mirror Pharmaceuticals, LLC
Fairfield, NJ 07004

5518
Rev. 12/12