

333-33-100411

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use ADIPEX-P® safely and effectively. See full prescribing information for ADIPEX-P®, ADIPEX-P® (phentermine hydrochloride USP) CIV for oral use.

Initial U. S. Approval: 1959

--- INDICATIONS AND USAGE ---
ADIPEX-P® 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 (BMI) ≥ 30 kg/m², or ≥ 27 kg/m² in the presence of other risk factors (e.g., controlled hypertension, diastolic hypertension). The limited usefulness of agents of this class, including ADIPEX-P®, 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)

- ADIPEX-P® can be taken with or without food. (12.3)

- DOSAGE FORMS AND STRENGTHS -
Capsules containing 37.5 mg phentermine hydrochloride. (3)

- Tablets containing 37.5 mg phentermine hydrochloride. (3)

- CONTRAINDICATIONS -
History of cardiovascular disease (e.g., coronary artery disease, stroke, arrhythmias, congenital heart disease, failure (uncontrolled hypertension)) (4)

- During or within 14 days following the administration of monoamine oxidase inhibitors (4)

- Hyperthyroidism (4)

- Glaucoma (4)

- Agitated states (4)

- 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. Phenetermine should be discontinued in case of new, unexplained symptoms of dyspnea, angor pectoris, syncope or lower extremity edema. (5.2)

- Rare cases of serious reurgitant cardiac valve disease have been reported. (5.3)

- Tolerance to the anorectic effect usually develops within a few weeks. If this occurs, phenetermine should be discontinued. The recommended dose should not be exceeded. (5.4)

- Phentermine 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 use of alcohol 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 oral or hypoglycemic medication may be required in some patients. (5.9)

- ADVERSE REACTIONS -
Adverse effects have been reported in the cardiovascular, central nervous, gastrointestinal, allergic, and endocrine systems. (6)

To report SUSPECTED ADVERSE REACTIONS, contact TEVA USA, PHARMACOVIGILANCE at 1-888-638-2572, X6351 or drug.safety@tevapharm.com; 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: Interaction (7.2). (7.3)

Phentermine is related chemically and pharmacologically to amphetamine (d- and dl-amphetamine) and other related stimulant drugs have been extensively abused. The possibility of abuse of phenetermine should be kept in mind when evaluating the desirability of including a drug as a part of a weight reduction program. (7.4)

Dependence (9) The usual adult dose is one capsule (37.5 mg) daily, as prescribed by the physician, administered before breakfast or 1 to 2 hours after breakfast. Consider importance of possibility of overdosage. (9.1)

Withdrawal effects following prolonged high dosage administration (9.1)

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. (9.2)

5.6 Risk of Abuse and Dependence Phentermine is related chemically and pharmacologically to amphetamine (d- and dl-amphetamine) and other related stimulant drugs have been extensively abused. The possibility of abuse of phentermine should be kept in mind when evaluating the desirability of including a drug as a part of a weight reduction program. (9.3)

5.7 Usage With Alcohol Use caution in prescribing phentermine for patients with even mild hypertension (risk of increase in blood pressure). (9.3)

5.8 Use in Patients With Hypertension Use caution in prescribing phentermine for patients with even mild hypertension (risk of increase in blood pressure). (9.3)

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. (9.3)

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 phenetermine have been identified:

Cardiovascular

Primary pulmonary hypertension and/or regurgitant cardiac valvular disease, palpitation, tachycardia, elevation of blood pressure, ischemic events. (10.2)

Central Nervous System Overstimulation, restlessness, dizziness, insomnia, euphoria, dysphoria, tremor, headache, psychosis. (11.1)

Gastrointestinal Dysphoria of the mouth, unpleasant taste, diarrhea, constipation, other gastrointestinal disturbances. (11.2)

Allergic Urticaria.

Endocrine Impotence, changes in libido. (11.3)

Drug Interactions

- Monoamine Oxidase Inhibitors Use of phenetermine is contraindicated during or within 14 days following the administration of monoamine oxidase inhibitors because of the risk of hypertensive crisis. (12.2)

- Alcohol Concomitant use of alcohol with phentermine may result in an adverse drug reaction. (12.2)

- Insulin and Oral Hypoglycemic Medications Requirements may be altered [see Warnings and Precautions (5.9)]. (12.2)

- Adrenergic Neuron Blocking Drugs Phenetermine may decrease the hypertensive effect of adrenergic neuron blocking drugs. (12.2)

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15.2 Tolerance to the anorectic effect usually develops within a few weeks. If this occurs, phenetermine should be discontinued. The recommended dose should not be exceeded. (5.4)

15.4 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. (5.5)

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- Adrenergic Neuron Blocking Drugs Phenetermine may decrease the hypertensive effect of adrenergic neuron blocking drugs.
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.

ADIPEX-P® (Dimethylphenethylamine hydrochloride) is an anorectic agent for oral administration, available as a capsule or tablet containing 37.5 mg of phentermine hydrochloride (equivalent to 30 mg of phentermine base).

ADIPEX-P® Capsules contain the inactive ingredients Com Starch, Gelatin, Lactose Monohydrate, Magnesium Stearate, Titanium Dioxide, Black Iron Oxide, FD&C Blue #1, FD&C Red #40 and D&C Red #33.

ADIPEX-P® Tablets contain the inactive ingredients Com Starch, Lactose (Anhydrous), Magnesium Stearate, Microcrystalline Cellulose, Pregelatinized Starch, Sucrose, and FD&C Blue #1.

Phentermine hydrochloride is a stimulant used in the treatment of obesity. It acts by increasing the feeling of satiety and reducing appetite. It is not recommended as a weight loss drug for patients with untreated hypertension or those with a history of cardiovascular disease. It is not recommended for use in pregnancy or in nursing mothers.

Phentermine hydrochloride is available in the form of capsules and tablets, each containing 37.5 mg of phentermine hydrochloride. It is indicated for the management of exogenous obesity, and that coadministration of phentermine with other drugs for weight loss is not recommended.

Studies have shown that phentermine hydrochloride is effective in producing weight loss, with the greatest weight loss occurring in the first weeks of therapy. However, long-term use of phentermine may lead to the development of tolerance and dependence.

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 (5.3)]
- 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 (5.7, 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 reactions 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 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.

Regitine® is a registered trademark of CIBA PHARMACEUTICAL PRODUCTS, INC.

Manufactured for:

TEVA PHARMACEUTICALS USA
Sellersville, PA 18960
Division of Teva Pharmaceuticals USA

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