CONTRAINDICATIONS

5.1 Contraindications

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 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 possibility of primary pulmonary hypertension.

5.2 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 valvular pathologies 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.

5.3 Hypersensitivity

5.4 Allergic drug reactions, including angioedema, urticaria, or other manifestations of anaphylaxis, have been reported during treatment with phentermine. These have been characterized by symptoms of urticaria, angioedema, or anaphylaxis, such as dyspnea, angioedema, and/or hypotension. Phentermine should be withheld when such symptoms occur and, if necessary, treatment with an antihistamine and other appropriate means of therapy should be instituted. In patients with a history of drug allergy, caution should be exercised when prescribing phentermine.

5.6 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.

6. ADVERSE REACTIONS

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

6.1 Primary Pulmonary Hypertension

6.2 Valvular Heart Disease

6.3 Hypersensitivity

6.4 Allergic drug reactions, including angioedema, urticaria, or other manifestations of anaphylaxis, have been reported during treatment with phentermine. These have been characterized by symptoms of urticaria, angioedema, or anaphylaxis, such as dyspnea, angioedema, and/or hypotension. Phentermine should be withheld when such symptoms occur and, if necessary, treatment with an antihistamine and other appropriate means of therapy should be instituted. In patients with a history of drug allergy, caution should be exercised when prescribing phentermine.

6.5 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.
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.

Phentermine hydrochloride is a Schedule IV controlled substance.

Dosage and Administration

Phentermine should be used only by those who have an established need for the use of an anorectic drug and who can most likely benefit from the use of this drug. Phentermine should be taken with food or a carbohydrate-containing beverage in order to reduce the risk of feelings of hunger.

Phentermine should be used concurrently with a reduction in caloric intake and an increase in physical activity.

Phentermine should be used for a short period of time (2-3 months). If no weight loss occurs, the drug should be discontinued until the patient has been carefully evaluated.

If weight loss occurs, the dosage of phentermine should be increased at intervals of one or two weeks, depending on the patient's response.

Phentermine should be used cautiously in patients with a history of cardiac disease or psychosis.

Phentermine should be used with caution in patients with a history of hyperthyroidism.

Phentermine should be used with caution in patients with a history of peptic ulcer disease.

Phentermine should be used with caution in patients with a history of hypertension.

Phentermine should be used with caution in patients with a history of diabetes.

Phentermine should be used with caution in patients with a history of impaired renal function.

Phentermine should be used with caution in patients with a history of liver disease.

Phentermine should be used with caution in patients with a history of mental illness.

Phentermine should be used with caution in patients with a history of seizure disorders.

Phentermine should be used with caution in patients with a history of substance abuse.

Phentermine should be used with caution in patients with a history of anorexia nervosa.

Phentermine should be used with caution in patients with a history of obesity.

Phentermine should be used with caution in patients with a history of restless leg syndrome.

Phentermine should be used with caution in patients with a history of sleep apnea.

Phentermine should be used with caution in patients with a history of migraine headaches.

Phentermine should be used with caution in patients with a history of chronic pain.

Phentermine should be used with caution in patients with a history of Raynaud's disease.

Phentermine should be used with caution in patients with a history of dyspepsia.

Phentermine should be used with caution in patients with a history of diverticulitis.

Phentermine should be used with caution in patients with a history of peptic ulcer disease.

Phentermine should be used with caution in patients with a history of bleeding disorders.

Phentermine should be used with caution in patients with a history of ascites.

Phentermine should be used with caution in patients with a history of heart rate abnormalities.

Phentermine should be used with caution in patients with a history of palpitations.

Phentermine should be used with caution in patients with a history of angina.

Phentermine should be used with caution in patients with a history of chest pain.

Phentermine should be used with caution in patients with a history of shortness of breath.

Phentermine should be used with caution in patients with a history of syncope.

Phentermine should be used with caution in patients with a history of orthostatic hypotension.

Phentermine should be used with caution in patients with a history of urinary retention.

Phentermine should be used with caution in patients with a history of genitourinary pain.

Phentermine should be used with caution in patients with a history of urinary tract infections.

Phentermine should be used with caution in patients with a history of renal stones.

Phentermine should be used with caution in patients with a history of bladder neck obstruction.

Phentermine should be used with caution in patients with a history of prostate hypertrophy.

Phentermine should be used with caution in patients with a history of polyuria.

Phentermine should be used with caution in patients with a history of nocturia.

Phentermine should be used with caution in patients with a history of nocturnal enuresis.

Phentermine should be used with caution in patients with a history of general mental confusion.

Phentermine should be used with caution in patients with a history of amnesia.

Phentermine should be used with caution in patients with a history of drug therapy-induced seizures.

Phentermine should be used with caution in patients with a history of drug therapy-induced dyskinesia.

Phentermine should be used with caution in patients with a history of drug therapy-induced akathisia.

Phentermine should be used with caution in patients with a history of drug therapy-induced extrapyramidal symptoms.

Phentermine should be used with caution in patients with a history of drug therapy-induced tardive dyskinesia.

Phentermine should be used with caution in patients with a history of drug therapy-induced hyperprolactinemia.

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