

ADIPEX-P[®] Important Safety Information

ADIPEX-P[®] (phentermine hydrochloride 37.5 mg, CIV) 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 ≥ 30 kg/m², or ≥ 27 kg/m² in the presence of other risk factors (e.g., hypertension, diabetes, hyperlipidemia).

Safety Information

ADIPEX-P[®] is contraindicated in advanced arteriosclerosis, cardiovascular disease, hyperthyroidism, glaucoma, moderate to severe hypertension, known hypersensitivity or idiosyncrasy to the sympathomimetic amines, agitation, drug abuse history, and during or within 14 days use of monoamine oxidase inhibitors (MAOIs). Adverse events include cardiovascular and central nervous system effects, gastrointestinal disturbances, and changes in libido. Exercise caution when prescribing phentermine for patients with even mild hypertension.

The safety and efficacy of combination therapy with phentermine and any other drug products for weight loss, including selective serotonin reuptake inhibitors (e.g., fluoxetine, sertraline, fluvoxamine, paroxetine), have not been established. Therefore, coadministration of these drug products for weight loss is not recommended. Primary pulmonary hypertension (PPH) has been reported in patients receiving a combination of phentermine and fenfluramine or dexfenfluramine. The possibility of an association between PPH or valvular heart disease and the use of phentermine alone cannot be ruled out.

Patient Fair Balance (as of 02/07/06)
(For use in Patient materials)

ADIPEX-P[®] (phentermine hydrochloride USP, 37.5 mg CIV) is used to treat obesity for a short period of time (a few weeks), as part of a treatment plan that includes exercise, behavioral changes, and a low-calorie diet, for people with a body mass index ≥ 30 kg/m² or a body mass index ≥ 27 kg/m² with other risk factors (e.g., high blood pressure, diabetes, elevated cholesterol).

Safety Information

People with the following medical conditions should not take ADIPEX-P[®]: advanced arteriosclerosis (hardening of the arteries), heart disease, overactive thyroid, moderate to severe high blood pressure, glaucoma (increased pressure in the eyes), hypersensitivity to stimulants, agitation, drug abuse history, or use within 14 days of taking a monoamine oxidase inhibitor drug (MAOI). Some side effects of ADIPEX-P[®] include elevated blood pressure, insomnia, restlessness, dry mouth, diarrhea, or changes in sexual drive. Primary pulmonary hypertension (PPH), a rare fatal lung disease, has been reported in patients taking both phentermine and fenfluramine or dexfenfluramine. The possible association between phentermine use alone and PPH or valvular heart disease cannot be ruled out. There have been rare cases of PPH or valvular heart disease in patients who reportedly have taken phentermine alone. The safety and benefit of taking other drugs with ADIPEX-P[®] for weight loss have not been established.