

In rats (Sprague-Dawley) chlorphentermine (50 mg/kg, i.p. for 6 weeks) induced pulmonary hypertension. This was similar to the effects produced by aminorex and phenmetrazine but contrary to the effects of amphetamine, ephedrine and phentermine. Chlorphentermine was the only drug, which evoked morphological alterations: the alveoli contained a great abundance of macrophages resembling foam cells. No alterations could be detected in the vessels.

The excessive formation of foam cells was accompanied by a significant accumulation of chlorphentermine in the lungs. The foam cells contain a considerable amount of phospholipids (mainly lecithine), which are responsible for the increased binding capacity of chlorphentermine in the lungs.

In their opinion, the cellular alterations, which are also found in other organs (adrenals, spleen heart, etc.) as well as in different species (mice, g. pigs, rabbits) are to be considered as a chlorphentermine-induced phospholipidosis.

c. Munro, J. F.: Management of obesity. Brit. J. Hosp. Med. 8-14, July 1973. The sheet-anchor of the medical management of obesity is dietary restriction and re-education in eating habit. The success of dietary control depends upon the ability of the patient to adhere to the prescribed regime. Medical management cannot be separated from the psychological support that many obese patients need.

Summary of Study 10-6 by H. Gershberg, M.D. on 22 obese (at least 15% overweight) maturity-onset diabetics: 11 received Ionamin 30 and 11 placebo, for 16 weeks. All were placed on a 1000 calorie diet. Results cannot be evaluated for the 2 groups were not comparable. Ionamin group consisted of 7 males and 4 females, whereas 10 females and only 1 male received placebo. Also, no information is available on concomitant medication, except that none of the patients received insulin.

Comments: A 34 year old RN reported an adverse reaction on 3-15-75 to NDA-17-352 (Fastin). For 7 days in 3/75, she took one 30 mg capsule of Fastin (phentermine HCl) daily. She noticed palpitation, restlessness, insomnia, euphoria while on Fastin (3/8 - 3-14-75). On 3-15 she developed severe withdrawal Sx: tremor, confusion, restlessness and severe depression. This RN has been a "sober alcoholic" for 1 1/2 years.

Recommendation: as suggested by this RN, the labeling should be revised as follows, under: Contraindication: third sentence should read: "Patients with a history of drug abuse "or alcoholism."

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cc:
Orig. NDA
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HFD-120
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