

Pharmacological references by author, title, journal and date are submitted on 46 items published 1966-1968. From the titles none deal with reproductive studies or teratology. Most of these involve amphetamine studies. Copies of 10 of these references are submitted. They are of dubious clinical significance.

Distribution:

January - December 1968: Ionamin '15': 290,000 Rx's averaging 27 capsules for a total of 7,830,000 capsules.

Ionamin '30': 545,000 Rx's averaging 30 capsules for a total of 16,350,000 capsules.

Adverse Reactions:

1. May 1, 1968, Dr. R. Grossman, Douglas, Arizona reported experiencing convulsions while taking Ionamin personally. He was also taking Lasix. He has not since responded to inquiries. Without additional information, this reaction would not be attributed to the taking of phentermine resin.
2. September 15 and 30, 1969, Dr. A. Guest, London, Ontario reports a 30 year old man developing an inferior myocardial infarction after taking Ionamin for 3 weeks. The Drug Experience Report indicates prior minimal angina pectoris for which he was being treated with Vitamin E. Since the label states that the drug "may be used with caution in hypertension and cardiovascular disease", it is possible that the reaction in this angina patient resulted from use of the drug. Comment: This case gives evidence for a need for labeling revision.

EVALUATION:

M.O. reviews of 10/17/66 and 7/17/68 recommend labeling revisions. These have not been acted upon.

Dr. J. K. Lamar reviewed the pharmacology of phentermine HCl, November 28, 1966, and reports "Studies are inadequate to support safe use in pregnant woman by our 1966 guidelines". He suggests that pregnancy warning should be included and that the manufacturer be asked to supply reproduction studies according to the 1966 guidelines for teratological effects.