

IONAMIN "15" & "30"

NDA 11613

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3. Kinard, S., L. C. Mills, J. Terrell, and J. H. Moyer. Use of d-amphetamine to curb the increased appetite and over-eating induced by reserpine therapy. J. Amer. Geriat. Soc. 4:1073-1077, 1956.
4. Thorn, G. W., and P. K. Bondy. Obesity, p. 398. In T. R. Harrison, R. D. Adams, I. L. Bennett, Jr., W. H. Resnik, G. W. Thorn, and M. M. Wintrobe, Eds. Principles of Internal Medicine. (5th ed.) New York: McGraw-Hill Book Co., 1966.

II. Ionamin effects: 10-14 hr of appetite appeasement.

EVALUATION: Possibly effective.

COMMENTS: Inadequate documentation regarding blood levels of the preparation following the use of the sustained-release capsule is available to the Panel; the Panel suggests that further studies be conducted to demonstrate the superiority of the sustained release form to the usual form of administration.

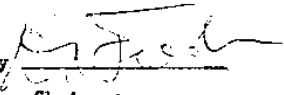
DOCUMENTATION: Clinical experience and judgment of the Panel.

GENERAL COMMENTS

The Panel suggests the deletion from the package insert of the following statement, because it refers to the possible consequences of weight loss, and not to a direct action of the drug:

Ionamin (phentermine resin) is useful and effective in weight control problems requiring safe and predictable appetite appeasement, including:

Arthritis:	Weight loss decreases the load on diseased joints.
Cardiovascular Disease:	Loss of weight relieves the work load on the heart.
Hypertension:	Loss of weight frequently is followed by decrease in blood pressure.
Obstetrics:	Weight control decreases risk at delivery.
Gynecology:	Weight loss improves surgical risk.
Diabetes:	Weight loss aids in controlling the disease. Dosage of insulin or oral diabetic therapy should be adjusted to cover decreased caloric intake.
Surgery:	Preoperative weight loss improves surgical risk.

Approved by 

Chairman