INDICATIONS

I. It has also been employed in variety of conditions associated with calcinosis.

EVALUATION: Effective, but . . .

COMMENTS: This material should remain restricted to short-term use for emergencies, "where it is necessary to reduce calcium levels in hypercalcemia," with the precautions provided.

One concern that arises in connection with this agent relates to the effect that it may have on ions other than calcium, such as potassium and magnesium. If information is available on this point, it is essential that it be incorporated into the insert. If such information is not available, then studies should be undertaken by the manufacturer to establish the effect of sodium versenate on such ions. For example, Batchelor (1) found that sodium versenate produced a 2- to 6-fold increase in urinary potassium excretion following administration of 3 g.

DOCUMENTATION:

GENERAL COMMENTS

I. In view of potential nephrotoxicity, a daily urinalysis is considered advisable. Furthermore, the drug should not be used where renal failure exists. The use of the EKG to evaluate cardiac conduction disorders resulting from electrolyte imbalance is recommended as a precautionary measure. There should also be a warning about the danger of removing calcium from sources other than the serum.

II. The Panel agrees with the statement that "edetate is a chelating agent, a substance which unites with cations to form chelates." It probably combines with all the cations mentioned in the insert.

III. Under "Miscellaneous Conditions Involving Calcinosis," the following conditions have been suggested for the possible use of edetate: conditions associated with calcinosis -- calcified mitral stenosis, nephrocalcinosis, peripheral vascular disorders, severe angina pectoris, indolent ulcer with extensive calcium metastasis in the neck, and cataracts.
The Panel would agree to its use in such conditions only when there is a state of hypercalcemia that requires specific treatment (see Indication 1). The Panel also finds that its unnecessary, inasmuch as most of the reports are testimony...