

ENCLOSURE
NDA 11355
LOG 1205

Panel on Drugs Used in Correction of Fluid and Electrolyte Balance

1. Nephrocalcinosis.

EVALUATION: Possibly effective.

COMMENTS: The only supporting documentation submitted by the manufacturer is a report of a single patient with extensive nephrocalcinosis who was given EDTA (5 g daily) for 2 weeks. The authors estimated a 50-65% decrease in renal calcification by radiologic criteria, but data on excreted calcium were not given. Obviously, this report and the literature known to the Panel do not adequately support the efficacy of EDTA in this situation. This claim should be considered inappropriate unless additional sound documentation is submitted by the manufacturer.

DOCUMENTATION:

1. Clarke, N. E., C. N. Clarke, and R. E. Mosher. "In vivo" dissolution of metastatic calcium; approach to atherosclerosis. Amer. J. Med. Sci. 229:142-149, 1955.

GENERAL COMMENTS

- I. The use of EDTA for heavy-metal poisoning or hypercalcemia is not mentioned in the brochure.
- II. Although nephrotoxicity may be reversible, as judged by animal studies, this is not necessarily so in clinical situations. Therefore, statements regarding reversibility of clinical renal disease should be more conservative.

Approved by

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Chairman