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APPLICATION NUMBER:

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MEDICAL REVIEW(S)

CLINICAL REVIEW

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Division / Office Division of Gastroenterology

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Review Completion Date April 2, 2010

Established Name Naproxen/Esomeprazole
Magnesium
Trade Name Vimovo
Therapeutic Class Combination NSAID and Proton
Pump Inhibitor
Applicant Pozen Inc
Formulation(s) Oral tablet
Dosing Regimen Naproxen (500 or 375mg) and
Esomeprazole (20mg) twice daily
Indication(s) Treatment of signs and symptoms
of osteoarthritis, rheumatoid
arthritis, and ankylosing
spondylitis in participants are risk
for developing NSAID-associated
gastric ulcers.
Intended Population(s) Adults 18 years and above

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