



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: Treximet™

Common Name: Sumatriptan and Naproxen sodium

PDL Category: MIGRAINE - SELECTIVE SEROTONIN AGONISTS (5HT) COMBINATIONS

<u>Comparable Products</u>	<u>Preferred Drug List/ Recommended Drug List Status</u>
Imitrex® (Sumatriptan)	Preferred with conditions
Naproxen Sodium	Preferred

Summary

Indications and Usage: Acute treatment of migraine headaches with or without aura

Mechanism of Action: Sumatriptan: Constricts blood vessels via activation of vascular serotonin 5-HT₁ receptors; Naproxen: Reduces prostaglandin synthesis by inhibiting cyclooxygenase and lipooxygenase.

Dosage Forms: Tablets; 119mg of sumatriptan succinate (equal to 85mg of sumatriptan) and 500mg of naproxen sodium

Recommended Dosage: Take 1 tablet; if second dose is needed, space doses by at least two hours. Efficacy of taking a second dose has not been established.

Common Adverse Drug Reactions: Dizziness, nausea/upset stomach (incidence similar to sumatriptan alone), somnolence, chest pain/discomfort, dry mouth, neck or jaw pain, numbness and tingling

Contraindications: Patients with a history of cardiac, cerebrovascular, or peripheral vascular disease, uncontrolled hypertension, concurrent use of MAO-Is, hepatic insufficiency, previous adverse reactions to sumatriptan or NSAIDs.

Manufacturer: GlaxoSmithKline

Analysis: Treximet™ is the first combination triptan/NSAID product introduced to the market. The combination was designed to treat the multiple symptoms often associated with migraine headaches. Sumatriptan has been widely studied since its initial approval in 1995. Treximet's™ approval was based on data from two double-blind, randomized, placebo-controlled, multicenter trials which had more than 2,900 patients were enrolled. These trials compared Treximet™ to sumatriptan, naproxen sodium, and placebo. Both studies showed Treximet™ superior to sumatriptan, naproxen, or placebo in relieving migraine symptoms within two hours. The percent of patients who reported relief of symptoms within 2 hours were as follows: Treximet™ 57-65%; sumatriptan 85mg 50-55%; naproxen 500mg 43-44%; placebo 28-29%. Treximet™ also showed superiority over the individual ingredients and placebo at maintaining relief from migraine symptoms for up to 24 hours after the initial dose. The percent of patients who reported sustained pain relief up to 24 hours were as follows: Treximet™ 23-25%; sumatriptan 85mg 14-16%; naproxen 500mg 10%; placebo 7-8%. It is currently more cost effective to use the preferred individual products, Imitrex® tablets and naproxen sodium tablets, as opposed to the combination product, Treximet™. Therefore, Treximet™ should be added to the Preferred Drug List as a non-preferred drug with the same clinical prior authorization criteria as the other serotonin 5-HT₁-receptor agonists.

IME Recommendation:

<input type="checkbox"/> Preferred Drug	<input type="checkbox"/> Recommended Drug
<input checked="" type="checkbox"/> Non-Preferred Drug	<input type="checkbox"/> Non-Recommended Drug
<input type="checkbox"/> Preferred Drug with Conditions	