



Preferred Drug List

NEW DRUG REVIEW

Proprietary Name: CaloMist™ Nasal Spray

Common Name: Cyanocobalamin

PDL Category: Vitamins

| <u>Comparable Products</u> | <u>Preferred Drug List/ Recommended Drug List Status</u> |
|----------------------------|--|
| Cyanocobalamin Inj | Preferred w/ conditions |
| Nascobal® (cyanocobalamin) | Non-Preferred |

Summary

Indications and Usage: Maintenance of vitamin B₁₂ concentrations

Mechanism of Action: Vitamin B₁₂ is converted to coenzyme B₁₂ in tissues which is required for the conversion of methylmalonate to succinate and synthesis of homocysteine to methionine.

Dosage Forms: Nasal Spray; 25mcg/0.1mL

Recommended Dosage: 1 spray in each nostril once daily

Common Adverse Drug Reactions: GI upset, bronchitis, nasopharyngitis, oral candidiasis, sinusitis, arthralgia, dizziness, headache, nasal discomfort, rhinorrhoea, rash.

Contraindications: Hypersensitivity to cobalt or any component of the compound, hereditary optic atrophy

Manufacturer: Fleming & Company, Pharmaceuticals

Analysis: CaloMist™ Nasal Spray is the first intranasal form of vitamin B₁₂ that is approved for once-a-day dosing. Once patients achieve a normalized vitamin B₁₂ with intramuscular cyanocobalamin, patients may be switched over to Calomist™ for maintenance therapy provided there is no nervous system involvement. An open-label study including 25 patients was submitted for initial approval. This study compared vitamin B₁₂ levels to patients who were switched over to CaloMist™ from IM cyanocobalamin. The results of the study suggest that when compared to pre-treatment vitamin B₁₂ levels, CaloMist™ is equivalent to IM injections of cyanocobalamin at maintaining vitamin B₁₂ levels. Other studies which have compared IM and oral vitamin B₁₂ supplementation found that for both routes of administration, serum vitamin B₁₂ levels increase rapidly and symptoms resolve comparably in patients who received oral and parenteral therapy (Adachi et al, 2000). Therefore, the main difference between the nasal spray and the IM injection/oral tablet is patient satisfaction. Since IM and PO cyanocobalamin are equally effective at maintaining vitamin B₁₂ concentrations, and costs pennies per day to dose compared to CaloMist™, it is recommended it be added to the Preferred Drug List as a non-preferred drug.

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 | |