

NASCOBAL

Nastech announces FDA approval of Nascobal (Cyanocobalamin) labeling supplement to include maintenance of hematologic status in patients with HIV infection, AIDS, multiple sclerosis and Crohn's disease

Nastech Pharmaceutical Company Inc. announced today that the U.S. Food and Drug Administration (FDA) has approved a labeling supplement to the Nascobal™ NDA that states that Nascobal can be used in patients with HIV, AIDS, multiple sclerosis, and Crohn's disease, conditions which can result in vitamin B12 deficiency, and for which Nascobal is indicated to maintain hematologic status. Nascobal (Cyanocobalamin, USP) Gel for Intranasal Administration safely and effectively maintains therapeutic serum levels of vitamin B12. Nascobal can be self administered through a simple non-injection delivery system. Compared to other methods of vitamin B12 maintenance therapy, patient convenience is enhanced, as fewer physician office visits are required for maintenance therapy. Significant peer-reviewed published clinical research supports the importance of the maintenance of proper vitamin B12 levels in this diverse group of patients. For example, in one study of over 200 consecutive multiple sclerosis (MS) patients over 20 percent had abnormally low serum vitamin B12 levels. Cerebral spinal fluid levels of vitamin B12 are also reduced in patients with MS and some investigators speculate that vitamin B12 associated transmethylation may be an important component in the demyelination that is characteristic of MS. Symptoms of vitamin B12 deficiency include fatigue, weakness, sore tongue, forgetfulness, weight loss, lack of coordination and difficulty walking. Vitamin B12 deficiency may lead to anemia, intestinal problems, and irreversible nerve damage.