

COBASWIFT NASAL SPRAY

To be sold by retail on the prescription of a RMP only.

Abbreviated Prescribing information for COBASWIFT (Methylcobalamin Nasal Spray)
[Please refer the complete prescribing information available at www.torrentpharma.com]

PHARMACOLOGICAL PROPERTIES:

Mechanism of action: Vitamin B12 can be converted to coenzyme B12 in tissues, and as such is essential for conversion of methylmalonate to succinate and synthesis of methionine from homocysteine, a reaction which also requires folate. In the absence of coenzyme B12, tetrahydrofolate cannot be regenerated from its inactive storage form, 5-methyltetrahydrofolate, and a functional folate deficiency occurs. Vitamin B also may be involved in maintaining sulfhydryl (SH) groups in the reduced form required by many SH activated enzyme systems. Through these reactions, vitamin B12 is associated with fat and carbohydrate metabolism and protein synthesis.

DOSAGE AND ADMINISTRATION:

Adults: Instill one spray in each nostril on day 0, 2 and 7. Thereafter, for maintenance instill one spray in each nostril once a week for 4 weeks. **Paediatric use:** As methylcobalamin nasal spray has not been studied in children, safety and effectiveness have not been established in paediatric patients.

CONTRAINDICATION: Sensitivity to cobalt and/or vitamin B12.

WARNINGS & PRECAUTIONS: Warnings: Patients with early Leber's disease who were treated with vitamin B12 suffered severe and swift optic atrophy, Hypokalemia and sudden death may occur in severe megaloblastic anemia which is treated intensely with vitamin B12, Folic acid is not a substitute for vitamin B12 although it may improve vitamin B12-deficient megaloblastic anemia, Exclusive use of folic acid in treating vitamin B12- deficient megaloblastic anemia could result in progressive and irreversible neurologic damage, Anaphylactic shock and death have been reported after parenteral vitamin B12 administration. **Precautions:** Doses of vitamin B12 exceeding 10 mcg daily may produce hematologic response in patients with folate deficiency. Indiscriminate administration may mask the true diagnosis, Vitamin B12 is not a substitute for folic acid and since it might improve folic acid deficient megaloblastic anemia, indiscriminate use of vitamin B12 could mask the true diagnosis, Hypokalemia and thrombocytosis could occur upon conversion of severe megaloblastic to normal erythropoiesis with vitamin B12 therapy. Therefore, serum potassium levels and the platelet count should be monitored carefully during therapy, Vitamin B12 deficiency may suppress the signs of polycythemia. Treatment with vitamin B12 may unmask this condition, if a patient is not properly maintained with Cobaswift NS, intramuscular vitamin B12 is necessary for adequate treatment of the patient, the effectiveness of Cobaswift NS in patients with nasal congestion, allergic rhinitis and upper respiratory infections has not been determined. Cobaswift NS should be deferred until symptoms have subsided.

DRUG INTERACTION:

Persons taking most antibiotics, methotrexate and pyrimethamine invalidate folic acid and vitamin B12 diagnostic blood assays.

ADVERSE REACTIONS: Blood and lymphatic system disorders: Leukopenia, Gastrointestinal disorders: Dyspepsia, General disorders and administration site conditions:

Fatigue, Pyrexia, Infections and infestations, Upper respiratory tract infection, Nervous system disorders: Headache, Respiratory, thoracic and mediastinal disorders: Cough, Nasal pruritus.

**MANUFACTURED BY:
TORRENT PHARMACEUTICALS LTD.**



IN/COBASWIFT NS 250mcg/Oct-21/01/ABPI
(Additional information is available on request)