Vitamin B12 deficiency results in megaloblastic anemia, GI lesions, and neurologic damage that begins with an inability to produce myelin and is followed by gradual degeneration of the myelin sheath.

Nascobal Nasal Spray contains 1.3 mL of a 500 mcg/0.1 mL solution of cyanocobalamin with sodium citrate, citric acid, glycerin and benzalkonium chloride in purified water. The spray solution has a pH between 4.5 and 5.5. The spray pump and unit must be fully primed (see Dosage and Administration) prior to initial use. After initial priming, each spray delivers an average of 200 mcg of cyanocobalamin and the 1.3 mL of spray solution contained in the bottle will deliver 4 doses of Nascobal Nasal Spray. The unit must be reprimed before each use. (see Dosage and Administration).

Vitamin B12 is essential to growth, cell reproduction, hematopoiesis, and nucleoprotein and myelin synthesis. Cells characterized by rapid division (e.g., epithelial cells, bone marrow, myeloid cells) appear to have the greatest requirement for vitamin B12. Vitamin B12 can be converted to cyanocobalamin in tissues, and as such is essential for conversion of methionine to sphthalic acid and from methionine to homocysteine, a reaction which also requires folate. In the absence of cyanocobalamin, B12, methionine cannot be converted to homocysteine, which in turn cannot be converted to cysteine, a reaction which also requires folate. In the absence of cyanocobalamin, B12, methionine cannot be converted to homocysteine, which in turn cannot be converted to cysteine, a reaction which also requires folate.

Vitamin B12 deficiency results in megaloblastic anemia, GI lesions, and neurologic damage that begins with an inability to produce myelin and is followed by gradual degeneration of the myelin sheath.

Vitamin B12 is quantitatively and rapidly absorbed from intramuscular and subcutaneous sites of injection. It is bound to plasma proteins and stored in the liver. Vitamin B12 is excreted in the bile and undergoes some enterohepatic recycling. Absorbed vitamin B12 is transported via specific B12 binding proteins, transcobalamin I and II, to the various tissues. The liver is the main organ for vitamin B12 storage.

Vitamin B12 is necessary for DNA synthesis and cell reproduction. It is also necessary for the production of red blood cells (erythropoiesis), which is essential for the transport of oxygen to body tissues. In addition, vitamin B12 is necessary for the production of white blood cells (lymphopoiesis), which are important for the immune system. It is also necessary for the production of platelets, which are essential for blood clotting.

Vitamin B12 is also important for the production of myelin, which is the protective covering of nerve fibers. It is necessary for the proper functioning of the nervous system, and deficiencies can lead to numbness, tingling, and weakness in the limbs. Vitamin B12 is also necessary for the production of the neurotransmitter acetylcholine, which is important for the proper functioning of the nervous system.

Vitamin B12 is absorbed from the intestinal tract, primarily in the jejunum and ileum. It is bound to specific plasma proteins, called transcobalamin I and II, which transport it to the tissues where it is needed. The liver is the main storage site for vitamin B12, and it is also stored in other tissues such as the bone marrow and the stomach.

Vitamin B12 is destroyed in the body if it is not absorbed. If vitamin B12 is not absorbed, it can be excreted in the feces. However, if only a small amount of vitamin B12 is absorbed, it can be stored in the liver and other tissues. The amount of vitamin B12 stored in the liver can vary, but it is typically enough to supply the needs of the body for several months.

Vitamin B12 is not readily excreted from the body. If a person takes too much vitamin B12, it can accumulate in the tissues and cause toxicity. Symptoms of vitamin B12 toxicity include numbness, tingling, and weakness in the limbs, as well as anemia, fatigue, and confusion. In severe cases, vitamin B12 toxicity can cause irreversible damage to the nervous system.

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In the blood, B12 is bound to transcobalamin II, a specific B-globulin carrier protein, and is distributed and stored primarily in the liver and bone marrow.

Absorption
About 3-8 mcg of B12 is secreted into the GI tract daily via the bile; in normal subjects with sufficient intrinsic factor, all but about 1 mcg is reabsorbed. When B12 is administered in doses which saturate the binding capacity of plasma proteins and the liver, unbound B12 is rapidly eliminated in the urine.

Retention of B12 in the body is dose-dependent. About 80-90% of an intramuscular dose up to 50 mcg is retained in the liver. The percentage of B12 absorbed in the GI tract decreases with increasing dose.

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ADVERSE REACTIONS

A summary of adverse experiences described in the Table below are based on data from a short-term clinical trial in vitamin B12-deficient patients in hemato logic remission receiving Nascobal (Cyanocobalamin, USP) Gel for Intranasal Administration and intramuscular vitamin B12 were generally mild. One patient reported severe headache following intramuscular dosing. Similarly, a trend toward increased severity of adverse events was observed following intranasal dosing (two headaches and one episode of facial flushing).

The following adverse reactions have been reported with parenteral vitamin B12: Anaphylactic shock and death (See Warnings and Precautions).

Cardiovascular: Pulmonary edema and congestive heart failure early in treatment; peripheral vascular thrombosis.

Dermatological: Itching; transitory exanthema.

Neurological: Convulsion, tremor, and occasionally convulsion and tremor in a patient with myasthenia gravis, the patient responded to intranasal vitamin B12 administration.

Pregnancy Category C: Animal reproduction studies have not been conducted with vitamin B12. It is also not known whether vitamin B12 can cause fetal harm when administered to a pregnant woman or can affect reproductive capacity. Adequate and well-controlled studies have not been done in pregnant women. However, vitamin B12 is an essential nutrient and requirements are increased during pregnancy. Amounts of vitamin B12 that are recommended by the Food and Nutrition Board, National Academy of Science - National Research Council for pregnant women should be consumed during pregnancy.

6. PREGNANCY

Deficiency has been recognized in infants of vegetarian mothers who were breast fed, even though the mothers had no symptoms of deficiency at the time. Since the time of nursing mothers is associated with an increased incidence of caries of the stomach, this is believed to be related to the underlying pathology and not to treatment with vitamin B12.

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