

Only for Veterinary Use

COMPOVIT[®]

Solution for Injection

Veterinary Vitamin

COMPOSITION

Compovit Solution for Injection is a yellow, clear and sterile vitamin solution that it contains 5 mg Vitamin B₁, 2 mg Vitamin B₂, 20 mg Vitamin B₃, 10 mg Vitamin B₅, 2 mg Vitamin B₆ and 5 µg Vitamin B₁₂ per ml.

PHARMACOLOGICAL PROPERTIES

Compovit is sterile, apyrogenic multivitamin solution for injection which was developed for parenteral administration and formulated to contain B complex vitamins in order to meet miscellaneous vitamin needs of animals during the treatment of absorption disorders resulting from various gastrointestinal disorders, chronic diseases, metabolic diseases, recovery period and antibacterial therapies in pets. Group B vitamins play role in reactions regulating carbohydrate and protein metabolisms which are extremely important for survival and growth of cells and tissues. In addition to metabolic effects, B vitamins have antitoxic, antineuritic, lipotropic and anabolic effects. Clinical studies indicated that B complex vitamins have hepato-protective effect and they accelerate repair process of hepatic parenchyma.

Vitamin B1 (Thiamine) is water-soluble organic substance which is comprised of pyrimidine and thiazole cores and plays role in carbohydrate metabolism; it is found in form of thiamine hydrochloride and deficiency may lead to severe neuromuscular symptoms. It plays important roles as co-enzyme in intermediate metabolism. Absorption rapidly occurs in oral and intramuscular administrations. It is largely distributed to many body tissues. It is excreted in non-metabolized form or in the form of metabolites.

Vitamin B2 (Riboflavine) is a vitamin which has good water solubility as phosphate salt and is required in nicotinic acid and pyridoxine metabolism. It plays enzymatic role in oxy-reduction process of carbohydrate metabolism. Moreover, it forms a part of the enzyme oxidase which is effective in desamination of amino acids in protein metabolism. Absorption is good for both parenteral and oral administrations. It is distributed to whole body following absorption and only low amount is stored. It is excreted via urine.

Vitamin B3 (Nicotinamide) is a member of B complex vitamins and it is well absorbed from parenteral administration site and gastrointestinal tract and converted into nicotinamide adenine dinucleotide (NAD) and nicotinamide adenine dinucleotide phosphate (NADP); it is involved in structure of enzymes playing role in oxido-reduction processes of cells. It plays role in glucose, protein and lipid metabolisms; it is distributed to all body tissues and it is excreted at low amounts via urine.

Vitamin B5 (Pantothenic acid, dexpanthenol) forms the core of Co-enzyme A and the enzyme is found in the form of cysteine phosphorylated ester. The enzyme plays significant roles in intermediate metabolism of glucose and fats and it enables transportation of 2-carbon structures (acyl and acetyl

groups). Following oral administration, pantothenic acid is well absorbed in gastrointestinal tract. When it is administered in alcohol form via skin, it is absorbed at concentration enough to eliminate deficiency and fulfill the need. It is distributed to whole body and it is excreted in non-metabolized form via urine.

Vitamin B6 (Pyridoxine): among water-soluble vitamins, pyridoxine is a pyridine-derivative vitamin which has co-enzymatic effects in availability of unsaturated fatty acids and protein metabolism. Pyridoxine is rapidly absorbed and it is metabolized into the active form, namely pyridoxal phosphate and pyridoxamin phosphate. It is primarily oxidized to 4-pyridoxic acid and other inactive metabolites in liver and it is excreted via urine.

Vitamin B₁₂ (Cyanocobalamin), Vitamin B12 molecule is comprised of corine core, 5,6-dimethylbenzimidazol core, cobalt and various groups. The family of chemicals also involving Vitamin B12 is referred as corrinoids. Name of chemical is determined according to the group bond to cobalt. Cyanocobalamin is well absorbed in subcutaneous and intramuscular administrations. Vitamin B12 has significant roles in intermediate metabolism. It is required for synthesis of co-enzymes playing role in normal growth and nutrition, maturation of blood cells, growth, development and proliferation of cells, including epithelial cells and synthesis of myelin. Vitamin B12 has positive effects on rumination in ruminants resulting with maximum benefit from herbal proteins.

AREA OF USE/INDICATIONS

Compovit is used for therapeutic purposes in deficiencies of B complex vitamins and resultant cases as well as supportive therapy in absorption disorders secondary to various disorders of gastrointestinal system, sub-clinical diseases, acute and chronic diseases as well as recovery periods, period of antibacterial therapies, parasitic infestations, metabolic diseases, various diseases of skin, muscle and nerve disorders, pregnancy, neonatal septicemias, pneumonia, diarrhea, anemia and miscellaneous yield losses secondary to stress factors in pets.

AMOUNTS TO BE ADMINISTERED AND ADMINISTRATION ROUTE

Compovit is administered via intramuscular (IM) or subcutaneous (SC) routes. Unless otherwise advised by veterinary surgeon:

Practical dose is administered at dose of 1 ml/10 kg live body weight for cattle,
1 ml / 5 kg live body weight for sheep and goats.

Administration is made once or twice a week as long as treatment is required.

Practical dose:

Cattle, Buffalo, Horse	: 15 - 30 ml.	Sheep, Goat	: 5 - 10 ml.
Calf, Heifer	: 10 - 15 ml.	Lamb, Goat Kid	: 3- 5 ml
Kid, Colt	: 5 - 10 ml.	Dog	: 1 - 5 ml.
Cat – Rabbit	: 1 ml.		

SPECIFIC CLINICAL INFORMATION AND WARNINGS FOR TARGET SPECIES

It is not administered via intravenous route.

ADVERSE / SIDE EFFECTS

Not reported.

DRUG INTERACTIONS

It should not be administered, due to incompatibility, concomitantly with alkaline substances, heavy metal salts, oxidants and reducers, mercury, iodine and iron salts, sodium bicarbonate infusion and ascorbic acid.

It should not be drawn into same injector, due to chemical incompatibility, with ampicillin, cloxacillin, clindamycin, chloramphenicol, carbenicillin, lincomycin, nafcillin, novobiocin, oxacillin, tetracyclines, cephalothin, streptomycin, vancomycin and Vitamin B complex.

SYMPTOMS, PRECAUTIONS AND ANTIDOTE IN OVERDOSE

Overdose is not observed if practical doses are administered. However, anaphylactic shock may develop if it is intramuscularly administered to horses. In such cases, treatment should be made with adrenaline and antihistaminic preparations.

WARNINGS FOR THE DRUG RESIDUES IN THE NUTRIENTS

Withholding Period (WHP): It is "0" day for meat and milk following last dose.

CONTRAINDICATIONS

It is not administered via intravenous route.

GENERAL WARNINGS

Do not use before veterinary surgeon is consulted.

Please read instructions for use before administering the drug.

Please refer to the veterinary surgeon before use and in case of an unexpected effect.

Keep out of reach of the children.

PRECAUTIONS TO BE TAKEN BY ADMINISTRATOR AND WARNING FOR VETERINARY SURGEON

Vitamin B1 may lead to anaphylactic shock if it is intravenously administered to horses, the administration should be avoided. Under compulsory situations, it should be diluted with water for injection and administration should be very slow.

STORAGE CONDITIONS AND SHELF LIFE

It should be stored in original package at room temperature (5-25 °C) away from exposure to sun light.

Shelf life is 2 years from the date of production.

FORM OF COMMERCIAL SUPPLY

It is commercially available in 20, 50 and 100 ml amber glass vials packed into cardboard boxes as well as 250 ml amber glass vials packed into plastic box.

SALE PLACE AND CONDITIONS

It is sold in the veterinary offices and the pharmacies with prescription written by veterinary surgeon (VP).

PROSPECTUS APPROVAL DATE: 11.05.2010

DATE AND NUMBER OF LICENSE AWARDED BY THE MINISTRY OF AGRICULTURE AND RURAL AFFAIRS: 11.05.2010-22/080

NAME AND ADDRESS OF MARKETING AUTHORIZATION OWNER:

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