1.3 Product Information

1.3.1 Summary of Product Characteristics (SmPC)

Structure of the Summary of Product Characteristics (SPC)

1. NAME OF THE FINISHED PHARMACEUTICAL PRODUCT

Multivitamin injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Composition	**Quantity**
Vitamin A	4,000IU
Vitamin D_3	800IU
Vitamin E	10mg
Thiamine Hydrochloride	10mg
Riboflavine Phosphate Sodium	2mg
Pyridoxine Hydrochloride	10mg
Folic acid	0.1mg
Nicotinamide	20mg
D-panthenol	10mg
Biotin	0.15mg
Vitamin K_3	1.0mg
Taurine	10mg
Choline Chloride	50mg
Water for injection	Add to 1ml

3. PHARMACEUTICAL FORM

Injection

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horse, goats and sheep.

4.2 Indications

It is used for the treatment and prevention of multiple vitamins deficiencies. These vitamin deficiencies can occur due to insufficient uptake of vitamins, in cases of illness or anorexia, insufficient absorption in case of diarrhea and malabsorption, and in conditions that result in physioligically increased requirements, like pregnancy, growth, high milk production, convalescence, disease, and stress. It is also used in the prevention and treatment of folate deficiency, promotes intestinal absorption of lipids, aids fat metabolism, energy balance, reproduction and overall animal productivity.

4.3 Contraindications

Not to be administered by Intravenous route.

4.4 Special warnings for each target species

Excessive dosage of vitamin A and D may lead to hypervitaminoses. Due allowance should always be made for intake of these vitamins from other sources.

Patients with rare hereditary problems of fructose intolerance, glucose-galactose malabsorption or sucrase-isomaltase insufficiency should not take this medicine.

The recommended dosage must not be exceeded. Very high doses of some ingredients, particularly vitamin D, iron and copper, can be harmful to health.

As calcium, ascorbic acid and Vitamin D may have an effect on stone formation, patients with nephrolithiasis or urolithiasis should use caution when using vitamin supplements.

4.5 Special precautions for use

Keep out of reach of children.

4.6 Side effects

Injection site reactions, which disappear with time.

4.7 Use during pregnancy, lactation or lay

Chronic overdose of vitamin D might be harmful to the foetus.

In animals, overdoses of vitamin D during pregnancy have been shown to have teratogenic effects. There is no evidence that vitamin D at the recommended dose is teratogenic in humans.

The vitamins and minerals in the product are excreted into breast milk. This must be taken into consideration if the cub is receiving any respective supplements.

4.8 Fertility

Fertility is not affected by administration of the product.

4.9 Interaction with other medicinal products and other forms of interaction

The dosage of drugs known to be influenced by folic acid and pyridoxine, for example phenytoin and phenobarbital, must be carefully monitored. Pyridoxine can reduce the effect of levodopa.

Folic acid has been reported to be unstable in the presence of calciumgluconate. Bisulfites have been reported to affect the stability of Vitamin A, thiamine, and ascorbic acid.

The pH of the parenteral nutrition admixture may affect the stability of Vitamin C and thiamine.

When used as recommended no specific interactions are expected. However, potential interactions for single ingredients are reported in the literature, thus patients receiving any other medication or those under medical care should consult a physician or health-care professional before taking the product.

The absorption of iron may be decreased by concurrent administration with antacids, gastric acid suppressive medications, fluoroquinolone, bisphosphonates, levodopa, levothyroxine, penicillamine, tetracycline antibiotics or trientine. If simultaneous use of one of these medications is necessary.

4.10 Amount(s) to be administration and administration route

Kattle Care Multivitamin Injection should be given by Intramuscular or Subcutaneous route.

Cattle, Horse, Sheep and Goat: 1ml/10-15kg body weight on alternate days.

4.11 Overdose

Overdose leads to hypervitaminosis.

4.12 Withdrawal period(s)

None.

5. Pharmacological properties

5.1 Pharmacodynamic properties

Vitamins are essential nutrients. They are indispensable for the normal development and growth of the foetus and the cub, for the metabolism and formation of carbohydrates, energy, lipids, nucleic acids and proteins, as well as for the synthesis of amino acids, collagen and neurotransmitters.

Multivitamins preparations are indicated to prevent and correct nutritional micronutrient deficiencies. Pregnancy and lactation represent periods with increased micronutrient requirements and, as a consequence, increased risks of micronutrient deficiencies for both the female mother and the cub. Especially during pregnancy, micronutrient deficiencies exhibit a more serious health risk, as they may also impair the normal development of the unborn cub. Supplementation with folic acid or folic acid-containing multivitamins is recommended to decrease the risk of congenital malformations including neural tube defects. Neural tube defects develop in the first weeks after conception, a period during which pregnancy may not have been diagnosed yet - thus, supplementation with folic acid is essential at the stage when is being planned.

Specifically, the product is recommended to prevent folic acid deficiency anaemia during pregnancy.

5.2 Pharmacokinetic properties

Absorption of vitamin C is through the oropharynx, stomach and the entire length of the small intestine. Absorption of vitamins B_2, B_3 and B_6 is primarily through the upper small intestine. Absorption of vitamins B1, D, E, folate, biotin and the minerals/trace elements copper, iron, magnesium, zinc and manganese are through the entire length of the small intestine. Absorption of calcium pantothenate, calcium and iodine is through the entire length of the small intestine and the colon.

Primarily all vitamins and minerals are required for cellular functions and are distributed throughout the body. Water soluble vitamins are stored only to a minor extent, while fat soluble vitamins can be stored in the liver and adipose tissue.

Folate is metabolised by the intestinal cells. The liver is the primary organ for metabolism/ biotransformation of vitamins B6, B12, C, D, E and calcium pantothenate. Copper and iron are incorporated into plasma proteins in the liver. Vitamin D is further metabolised by the kidney.

Folate enters enterohepatic circulation and is eliminated by the faeces and kidneys. The major route of elimination for iron is through tissue and blood loss. All other vitamins, minerals and trace elements are eliminated through the kidneys. In addition, vitamins D, E, B12, copper, zinc and manganese can be eliminated through faeces.

5.3 Environmental properties

Any unused product or waste material should be disposed of in accordance with national requirements.

Extremely dangerous to fish and aquatic life. Do not contaminate surface waters or ditches with the product or used containers.

6. Pharmaceutical particulars

6.1 List of excipients

Thiamine Hydrochloride

Riboflavine Phosphate Sodium

Pyridoxine Hydrochloride

Folic acid

Nicotinamide

D-panthenol

Biotin

Vitamin K_3

Taurine

Choline Chloride

Water for injection

6.2 Incompatibilities

None.

6.3 Special precautions for storage

Store in a cool, dry place, not exceeding 30℃.

6.4 Nature and composition of immediate packaging

Pack size: Glass vials of 100 ml provided with rubber stoppers of bromobutyl and metallic aluminium capsules with FLIP-OFF ring. Containers of 100 ml.

6.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such product

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed accordance to local requirements.

7. Marketing authorization holder

Company name: Hebei New Century Pharmaceutical Co., Ltd.

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8. Marketing authorization number(s)

GMP number: (2022) Veterinary drug GMP No.03034

9. Date of revision of the text

08.2024