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

Generic name: Multivitamin Soluble Powder

Brand name: KATTLE CARE MULTIVITAMIN POWDER

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per g contains

Composition	**Quantity**	**Composition**	**Quantity**
Vitamin A	15,000IU	Potassium Chloride	87mg
Vitamin D_3	4,400IU	Sodium Sulphate	629mg
Vitamin E	2.5mg	Sodium Chloride	50mg
Vitamin K3	4.35mg	Manganese Sulphate	12mg
Vitamin B2	4.35mg	Copper Sulphate	12mg
Vitamin B3	16.7mg	Zinc Sulphate	12mg
Vitamin B6	2.35mg	Magnesium Sulphate	12mg
Vitamin B12	11.35mcg	Lysine HCl	15mg
Vitamin C	1mg	DL-methionine	10mg
Calcium Pantothenate	5.35mg	Anhydrous glucose	Add to 1g

3. PHARMACEUTICAL FORM

Soluble Powder

4. CLINICAL PARTICULARS

4.1 Target species

Poultry, cattle, sheep, goats, camels and horses

4.2 Indications for use, specifying the target species

A combination of vitamins, electrolytes and amino-acids for administration to poultry, cattle, sheep, goats, camels and horses to aid growth and performance, ideal for use at times of stress and to combat dehydration. Also a valuable and effective aid in recovery from disease.

4.3 Contraindications

This product is contraindicated in animals with known hypersensitivity to any of the ingredients, and existing hypervitaminosis D, severe impaired renal function, iron and/or copper metabolism disorders, hypercalcaemia, severe hypercalciuria and so on.

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.

Folic acid alone is improper therapy in the treatment of pernicious anemia and other meagloblastic anemias where vitamin B12 is deficient. Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that heamtologic remission can occur while neurological manifestations progress. Allergic sensitization has been reported following both oral and parentral administration of folic acid.

4.5 Special precautions for use

Keep out of reach of children.

4.6 Adverse effects

Gastrointestinal Disorders

Gastrointestinal and abdominal pain, constipation, diarrhoea, nausea and vomiting may occur.

Immune System Disorders

In isolated cases it may cause allergic reaction. Symptoms may include facial swelling, wheezing, skin reddening, blisters and shock. If an allergic reaction occurs, treatment must be stopped and a health care professional consulted.

A slight yellow discoloration of urine may be noticed. This effect is harmless and is due to the Vitamin B2 contained.

The product contains iron, which may lead to a black colouring of the stool. This effect is harmless and does not have any clinical relevance.

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

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

For poultry add 30g per 40-80 litres of drinking water for 5-6 consecutive days.

For cattle, sheep, goats, camels and horses: use 1g per 10kg body weight. Administer as a drench.

4.11 Overdose

There is no evidence that the product can lead to an overdose when used as recommended.

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 B2, B3 and B6 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

Anhydrous glucose

6.2 Incompatibilities

None.

6.3 Special precautions for storage

In a cool dry place under 30℃, away from light.

6.4 Nature and composition of immediate packaging

Pack size:.

15g/sachet: Plastic barrel with inner aluminum foil bag, 20bags per box; 50 boxes per carton.

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

09.2023