MAX-COC POWDER

(Amprolium HCl, Sulfaquinoxaline Base, Menadione Sodium Bisulphite)

SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

MAX-COC POWDER.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

3. PHARMACEUTICAL FORM

Oral Powder.

4. CLINICAL INFORMATION

4.1. Target species

Cattle, Poultry.

4.2. Indications for use specifying the target species

The combination of Amprolium and Sulfaquinoxaline maximizes the prevention of antibiotic resistance.

Treatment of Coccidiosis caused by Eimeria tenella and Eimeria necatrix, fresh bloody diarrhea, **faeces** mixed with mucus and blood, green **faeces**, white **faeces**. Reduces hemorrhage in the digestive tract.

Safe for poultry during the egg-laying preparation phase and egg-harvesting period.

4.3. Contraindications

Do not use in animals with known hypersensitivity to components of the product

4.4. Special warnings for each target species

None

4.5. Special precautions for use

Special precautions for safe use in the target species:

None.

Special precautions to be taken by the person administering the product to animals:

In case of hypersensitivity, avoid all contact with the product.

If a skin rash, facial, lip, or eye swelling, or breathing difficulties occur, seek immediate medical advice.

Avoid inhaling dust and avoid skin and eye contact when handling the product.

In case of accidental eye contact, rinse thoroughly with clean water.

Wash hands after using the product

Special precautions for environmental protection:

Not applicable.

4.6. Adverse reactions (frequency and seriousness)

Not Reported.

4.7. Use during pregnancy and lactation or lay

Not Reported.

4.8. Interaction with other veterinary medicinal products and other forms of interaction

Not Reported.

4.9. Dosage and administration route

Dissolve in drinking water or mix with feed.

Poultry: For treatment: 1 g per 5-8 kg body weight. For prevention: 1 g per 10-15 kg body weight.

Livestock: 1 g per 8-10 kg body weight.

Use continuously for 5-7 days

4.10. Overdose (symptoms, emergency procedures, antidotes), if necessary

Not known

4.11. Restrictions and special conditions of use, including restrictions on the use of antimicrobial and antiparasitic veterinary drugs, in order to reduce the risk of resistance development

Medication administered under the control or supervision of the veterinarian

4.12. Withdrawal period:

For meat: 7 days.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of Antiparasitic + Antibacterial+ Mineral supplements.

5.1. Pharmacodynamics properties

<u>Amprolium</u> is an antiprotozoal agent primarily used as a coccidiostat in poultry. Its pharmacodynamics are based on its structural similarity to thiamine (Vitamin B1). Amprolium acts as a competitive antagonist of thiamine, blocking the thiamine transporters of *Eimeria*

species, the protozoa that cause coccidiosis. Since coccidia require thiamine for carbohydrate metabolism, this competitive inhibition effectively starves the parasite and inhibits its growth and replication, particularly during the first-generation schizont stage of its life cycle.

<u>Sulfaquinoxaline</u> is a broad-spectrum sulfonamide antibiotic and a potent coccidiostat. Its pharmacodynamic action involves the inhibition of folic acid synthesis in susceptible bacteria and protozoa, including *Eimeria* species. It competitively inhibits the enzyme dihydropteroate synthase, which is essential for converting para-aminobenzoic acid (PABA) into dihydrofolic acid. Since folic acid is a crucial coenzyme for the synthesis of purines and nucleic acids, this inhibition prevents the growth and reproduction of the parasites. <u>Menadione Sodium Bisulphite</u> is a water-soluble form of Vitamin K3. Its pharmacodynamic role is to supplement the diet and prevent hemorrhagic conditions often associated with coccidiosis and certain drug treatments. Coccidial infections can damage the intestinal lining, impairing nutrient absorption, including fat-soluble vitamins like K1 and K2. Furthermore, some sulfonamide drugs, like sulfaquinoxaline, can interfere with the synthesis of Vitamin K in the gut flora. As a result, this can lead to a deficiency in Vitamin K, which is essential for the synthesis of blood clotting factors in the liver. Menadione Sodium Bisulphite provides a readily available source of Vitamin K activity to support proper blood coagulation and prevent bleeding.

5.2. Pharmacokinetic information

<u>Amprolium is</u> absorbed from the gastrointestinal tract following oral administration. It is a weak base, and its absorption is relatively limited, which allows it to remain in the gut where it exerts its anticoccidial effect. The drug is rapidly distributed and eliminated from the body, primarily through the kidneys, within a few hours. Due to its rapid elimination, there is a low risk of tissue residue accumulation.

<u>Sulfaquinoxaline</u> show that it is well-absorbed from the gastrointestinal tract and widely distributed throughout the body. It can reach therapeutic concentrations in various tissues. It is primarily metabolized in the liver and excreted through the kidneys, with a relatively long half-life, which allows for sustained therapeutic levels in the blood.

Menadione Sodium Bisulphite differ from the fat-soluble forms of Vitamin K. Because it is water-soluble, it does not require bile salts for absorption, making it particularly useful in cases where intestinal damage or disease may compromise fat absorption. It is absorbed from the gut, converted into the active Vitamin K form, and utilized by the liver for the synthesis of coagulation proteins. Excess is quickly metabolized and excreted from the body.

6. PHARMACEUTICAL INFORMATION

6.1. Incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.2. Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years. Shelf life after mixing into feed: use immediately after mixing

6.3. Special precautions for storage

Store below 25°C in a dry place. Do not store in the refrigerator or freezer. Protect from light and moisture.

Keep out of the reach of children.

To be used as directed by the registered veterinary practitioner only.

6.4. Nature and composition of primary conditioning

Metalized Aluminum Foil pouch for 200gm, 500gm, 1 Kg & 2.5 Kg

SPECIAL PRECAUTIONS FOR THE DISPOSAL OF WASTE MATERIALS UNUSED MEDICINAL PRODUCTS OR WASTE MATERIALS

Any unused veterinary medicinal products or waste materials derived from such medicinal products should be disposed of in accordance with local requirements and placed in appropriate collection and disposal systems for unused or expired medicinal products.

7. MARKETING AUTHORISATION HOLDER

Nawan Laboratories (Pvt.) Ltd. Plots No. 136-138, Sector-15, Korangi Industrial Area, Karachi-74900, Pakistan.

8. MARKETING AUTHORISATION NUMBER

Reg. No.: 063708

9. DATE OF FIRST AUTHORISATION

Date of Reg.: 16-08-2010

10. DATE OF REVISION OF THE TEXT

17-02-2025