SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Brand Name: Amprolium 20

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains: Active substance: Amprolium 200 mg(equivalent to Amprolium Hydrochloride)
For the full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Water-soluble powder for use in drinking water. Off-white powder

4. CLINICAL PARTICULARS

4.1 Target species

Poultry, calves, lambs, young goats and sheep

4.2 Therapeutic indications

Amprolium 200 wsp is a concentrated powder of Amprolium HCl, water-soluble for use in drinking water of poultry, calves, lambs, young goats, cattle and sheep. It is used as a preventive or therapeutic agent against Eimeria infections in poultry, especially E. tenella, E. necatrix, E. acervulina and E. praecox. It is effective against other protozoal infections like Histomoniasis (Blackhead) in turkeys and poultry; against coccidiosis in calves, sheep and goats; against amaebiasis in various species.

4.3 Contraindications

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

4.5 Special warnings and precautions for use

As with any antiparasiticide, frequent and repeated use of antiprotozoals from the same class may lead to the development of resistance. In case of detection a lack of efficacy during treatment, communicate it to the national competent authorities.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

This product is acidic and may cause irritation to, or corrosion of, the skin, eyes, throat and airways.

Avoid all physical contact with the product, including any vapours.

Do not eat, drink or smoke whilst handling this product.

Wear impervious gloves and protective glasses when handling the product.

In the case of contact with skin or eyes, wash the affected area with clean running water immediately and remove any contaminated clothes. If irritation persists, seek medical advice and show the label to the physician.

In case of accidental ingestion, rinse the mouth with fresh water, seek medical advice immediately and show the label to the physician.

Those with known hypersensitivity to Amprolium or to any of the excipients should avoid contact with the product. Wash hands and exposed skin after use.

4.6 Adverse reactions (frequency and seriousness)

None known

4.7 Use during Pregnancy, Lactation or laying

Studies in laboratory animals have not produced any evidence of teratogenic effects. Use only according to the risk/benefit assessment by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interaction

Amprolium is a thiamine analogue. Therefore, the efficacy of amprolium may be reduced during a simultaneous administration of products containing vitamin B-complex.

4.9 Posology (dosage) and method of administration

For oral administration via feed or drinking water.

- Poultry: 100 – 150 g per 100 litres of drinking water during 5 – 7 days, followed by 25 g per 100 litres of drinking water during 1 or 2 weeks. During treatment, medicated drinking water should be the only source of drinking water.

- Calves, lambs, kids: 3 g per 20 kg bodyweight as drench during 1 – 2 days, followed by 7.5 kg per 1,000 kg of feed during 3 weeks.

- Cattle, sheep: 3 g per 20 kg bodyweight during 5 days (via drinking water). Mixed with feed, the product should be used immediately. Medicated drinking water should be used within 24 hours.

If no improvement is noted within 3 days, evaluate the symptoms to determine the presence of other diseases. Follow the instructions of your veterinarian or poultry pathologist.

Sufficient access to the system of water supply should be available for the animals to be treated to ensure adequate water consumption. No other source of drinking water should be available during the medication period. Medicated drinking water should be replaced every 24 hours.

After the end of the medication period, the water supply system should be cleaned appropriately to avoid intake of sub-therapeutic amounts of the active substance.

4.10 Overdose

Prolonged uses can produce thiamine deficiencies In cases of deficiency, thiamine must be administered to compensate for this

4.9 Withdrawal Periods

Chickens and turkeys:

- Meat and offal: 10 days

- Eggs: 3 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: antiprotozoals; agents against protozoal disease, amprolium ATCvet code: QP51AX09

5.1 Pharmacodynamic properties

Amprolium is an anticoccidial agent that acts as competitive inhibitor of thiamine in the parasite metabolism, and interferes with the metabolism of glucides necessaries for coccidian multiplication and survival. In in-vitro studies it was shown that the uptake of thiamine by schizonts of Eimeria tenella and by host intestinal cells can occur through passive diffusion or by an active, energy-and ph-dependent process. Amprolium competitively inhibited both systems, however, the parasite was shown to be more sensitive to amprolium than the host. As shown with Eimeria maxima inoculated chicken, the administration of Amprolium resulted in a proportion of morphologically abnormal macrogametes and oocysts which may be considered the reason for a reduced sporulation rate.

5.2 Pharmacokinetic particulars

After oral administration absorption is low, reaching the maximum concentration 4 hours later. It is excreted mainly through faeces

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium benzoate BP

Bentonite Hydrophilic F

umed Silica (Aerosil200)

Butylated Hydroxytoluene BP(White)

Dextrose Monohydrate BP

6.2 Incompatibilities

In absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal produc**t.**

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

Shelf life after first opening the immediate packaging: 6 months

Shelf life after dilution or reconstitution according to directions: 24 hours

6.4. Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

Sachet of 100 g. Jar of 500 / 1,000 g Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements

7. MARKETING AUTHORIZATION HOLDER AND MANUFACTURING SITE ADDRESSES

7.1 Marketing authorization holder

VETCARE KENYA LTD

Address: P.O Box 63405 – 00619 Nairobi

Country: Kenya

7.2 Manufacturing site addresses

VETCARE KENYA LTD

Winsford Park, BabaDogo Road

P.O. BOX 63405 00619 Nairobi, Kenya

7.3 Marketing Authorization Number

Rwanda FDA-VMP-MA-0002

7.4 Date of first Authorization/renewal of the Authorization

Date of first Authorization in Rwanda: 9th August 2021

7.5 Date of revision of the text

11th April 2022