SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK: DECCOX 6% w/w Premix for Medicated Feeding Stuff for Sheep and Cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each gram contains:

Active substance
Decoquinate 60 mg

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Premix for medicated feeding stuffs.
Coarse beige powder with the odour of wheat middlings.

4. CLINICAL PARTICULARS

4.1 Target species

Sheep and cattle.

4.2 Indications for use, specifying the target species

For the treatment and prevention of coccidiosis in lambs and calves.

As an aid in the control of coccidiosis in lambs, by medication of ewe feed.

As an aid in the prevention of abortions and perinatal losses due to toxoplasmosis by medication of ewe feed.

4.3 Contraindications

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

4.4 Special warnings for each target species

The use of the product will maintain normal growth under conditions of coccidial challenge but does not improve growth of healthy lambs or calves.

4.5 Special precautions for use

To help obtain even distribution in the final feed, it is recommended first to mix thoroughly at the rate of 1 part of the product to 3 parts of feed before blending into the final mix. In the preparation of pelleted feed, preconditioning temperatures of up to 80°C for short periods have been used and shown to have no effect on the product.

A manufacturer authorised to incorporate at levels below 2 kg per tonne must be responsible for mixing when incorporation is less than 2 kg per tonne of final feed.

Special precautions for use in animals

Medication of ewe rations may not prevent coccidiosis occurring in lambs and should only be given in conjunction with lamb medication.

Do not mix with or into feeds containing any other anticoccidial.

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

When handling the product, prevent direct contact with the skin, avoid inhaling dust and wash hands after use.

Do not eat, drink or smoke when handling the product. Only handle in a well ventilated area.

Other precautions

This product is only authorised for use in medicated feedingstuffs or premixtures.

In both cases it must be thoroughly mixed with feedingstuffs materials to ensure it is evenly distributed throughout the mixture.

Any premixture containing this product must be thoroughly mixed with feedingstuffs materials to ensure that is evenly distributed throughout the final feed.

4.6 Adverse reactions (frequency and seriousness)

None known.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports.

4.7 Use during pregnancy, lactation or lay

Pregnancy
Can be used during pregnancy.

Lactation
Can be used during lactation.

4.8 Interaction with other medicinal products and other forms of interaction

Do not mix with or into feeds containing any other anti-coccidial product.

4.9 Amounts to be administered and administration route

Species and indication	Method of administration	Recommended dose level	Recommended duration of treatment
Treatment of coccidiosis in lambs and calves and prevention of coccidiosis in lambs	In lamb and calf feed	1 mg decoquinate/kg bodyweight daily	At least 28 days
Prevention of coccidiosis in calves and as an aid in prevention of coccidiosis in lambs	In calf and ewe feed	0.5 mg decoquinate/kg bodyweight daily	At least 28 days
As an aid in the prevention of abortions and perinatal losses due to toxoplasmosis	In ewe feed	2 mg decoquinate/kg bodyweight daily	Continuously for 14 weeks prior to lambing

Feed intake will depend on the clinical situation of the animal and on the season of the year. To ensure a correct dose, the concentration of active ingredient in the feed must be adjusted according daily feed intake. The following formula is recommended:

Kg Deccox 6% Premix/T feed = Dose (mg active ingredient/kg body weight) x Total weight of the animals to be treated (kg) / Daily feed intake (kg) x 60

1. **Treatment of coccidiosis in lambs and calves and prevention of coccidiosis in lambs:**
   Feed continuously for 28 days when coccidiosis is expected to be a hazard. Medication may be continued if there is further identified risk beyond this period.

2. **Prevention of coccidiosis in calves and as an aid in prevention of coccidiosis in lambs by medication of the ewe's feed:**
   Feed continuously for at least 28 days to ewes when oocyst shedding is likely to be a hazard to lambs (i.e. before, during or after lambing) or to calves when coccidiosis is likely to occur.
   The above provides good control of oocyst shedding from ewes under most conditions. In cases where a more severe challenge exists, double dosage should be used.

3. **As an aid in the prevention of abortions and perinatal losses due to toxoplasmosis by medication of ewe feed:**
   Feed continuously for the last two-thirds of pregnancy (i.e. for the final 14 weeks prior to lambing).
   On farms with a history of toxoplasmosis abortions, it may be economically beneficial to segregate susceptible ewes (e.g. bought in ewe-lambs) and administer medicated feed only to these animals, as the majority of older ewes will have been previously exposed to toxoplasma infection and will therefore be immune.

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

Overdosage is unlikely with in-feed medication. Decoquinate dosages of 4 mg/kg bodyweight in sheep and lambs and 6 mg/kg bodyweight in calves have been found to be well tolerated and without observable side effects.

4.11 Withdrawal period(s)

Cattle and sheep:
Meat and offal: zero days.
Milk: Not authorised for use in animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Other antiprotozoal agents
ATCVet code: QP51AX14

5.1 Pharmacodynamic properties

Decoquinate is a 4-hydroxyquinoline antiprotozoal compound active against *Eimeria* spp. and *Toxoplasma* spp.
Decoquinate inhibits the development of coccidia in the small intestine in the early part of the infective cycle, resulting in lower morbidity and mortality. The exact mode of action is unknown.

5.2 Pharmacokinetic particulars

The drug is administered by the oral route, the main site of action being within the gastro-intestinal tract. It is poorly absorbed by the target species and is largely eliminated in faeces unchanged. Consequently, tissue residues are low and deplete rapidly with time. Recovery of the administered material via excretion is essentially complete.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Wheat Middlings.
Anhydrous colloidal silica.
Soya bean oil.

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after incorporation into final feed: 3 months.

6.4. Special precautions for storage

Store in a dry place.

6.5 Nature and composition of immediate packaging

Three ply paper sack, with spray coated polyethylene interior face, closed with stitching, containing 10 kg of product.

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 AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4032

9. DATE OF FIRST AUTHORISATION

28 July 2004

10. DATE OF REVISION OF THE TEXT

November 2019

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