1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Deccox 60.6 g/kg Premix for Medicated Feeding Stuff

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each kg contains:
Active Substance
Decoquinate 60.6 g

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Premix for medicated feeding stuff.

4 CLINICAL PARTICULARS

4.1 Target Species

Sheep, cattle.

4.2 Indications for use, specifying the target species

For the treatment and prophylaxis of coccidiosis in lambs and calves during coccidial challenge, by medication of the feed.
As an aid in the control of coccidiosis in lambs, by medication of ewe feed.

4.3 Contraindications

None known.

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.

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

4.5 Special precautions for use

Special precautions for use in animals
None

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.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

May be used in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

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

4.9 Amounts to be administered and administration route

Treatment of coccidiosis in lambs and calves, and prevention of coccidiosis in lambs:

Add 1.67 kg of premix per tonne of feed, to provide the recommended level of 100 mg decoquinate/kg feed (100 ppm).

If creep feed is administered to lambs on a restricted basis (e.g. less than 100 g/10 kg bodyweight daily) or calves are fed at less than the recommended feeding rate of 500 g/50 kg bodyweight daily, the level of the product should be raised proportionally to achieve the target intake of approximately 1 mg decoquinate/kg bodyweight daily. For example:

Daily feeding rate		Deccox Inclusion rate
Lambs	Calves	
(bodyweight)	(bodyweight)	
100 g/10 kg	500 g/50 kg	1.67 kg/tonne
75 g/10 kg	375 g/50 kg	2.22 kg/tonne
50 g/10 kg	250 g/50 kg	3.34 kg/tonne

Feed continuously for 28 days when coccidiosis is expected to be a hazard. Medication may be continued if there is further risk beyond this period.

Prevention of coccidiosis in calves, and as an aid in prevention of coccidiosis in lambs by medication of the ewe's feed:

Add 833 g of premix per tonne of feed, to provide the recommended level of 50 mg decoquinate/kg of feed (50 ppm).

If ewe or calf feed is administered on a restricted basis (e.g. less than 500 g/50 kg bodyweight daily), the level of the product should be raised proportionally, to achieve the target intake of approximately 0.5 mg decoquinate/kg bodyweight daily.

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 more severe challenge exists, double dosage should be used.

If the product is given in feed blocks, there could be a degree of variation in intake by individual animals. Care should be taken to ensure that the daily dose rate of decoquinate is achieved.

To help obtain even distribution in the final feed, it is recommended to first thoroughly mix 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 70^{o}C for 10 minutes 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/tonne of final feed.

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

Overdosage is unlikely with in-feed medication. In sheep at least four times, and in calves at least six times, the recommended use levels of the product have been found to be well tolerated and without observable side effects.

4.11 Withdrawal period(s)

Cattle and sheep meat: zero days. Milk: Not permitted for use in lactating animals producing milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Antiprotozoals
ATCvet code: QP51AX14

5.1 Pharmacodynamic properties

Decoquinate has an anti-coccidial action. It belongs to the quinolone group of coccidiostats.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Soya-bean oil, refined
Wheat middlings

6.2 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 feed: 3 months

6.4 Special precautions for storage

Store in a dry place. Store below 25°C.

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

7 MARKETING AUTHORISATION HOLDER

Zoetis Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/018/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1989
Date of last renewal: 30th September 2009

10 DATE OF REVISION OF THE TEXT

August 2017