ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

LABEL - PACKAGE LEAFLET:
UK (Northern Ireland): DECCOX 6% w/w Premix for Medicated Feeding Stuff for Sheep and Cattle.
ES: DECCOX 60 mg/g Premix for Medicated Feeding Stuff for Sheep and Cattle

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:

To be completed nationally

Manufacturer responsible for batch release:

Zoetis Belgium SA
Rue Laid Burniat 1
1348 Louvain-la-Neuve
BELGIUM

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

UK (Northern Ireland): DECCOX 6% w/w Premix for Medicated Feeding Stuff for Sheep and Cattle.
ES: DECCOX 60 mg/g Premix for Medicated Feeding Stuff for Sheep and Cattle

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each gram contains:
Active substance:
Decoquinate 60 mg
Excipients: Wheat middlings

4. INDICATION(S)

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**.**
For the relief of pain associated with equine colic.

5. CONTRAINDICATIONS

Do not use in case of hypersensitivity to the active substance or to any of the excipients.
Do not mix with or into feeds containing any other anticoccidial.

6. ADVERSE REACTIONS

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Sheep and cattle.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 concentration of 100 mg decoquinate/kg of 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 concentration of DECCOX should be raised proportionally to achieve the target intake of approximately 1 mg decoquinate/kg bodyweight daily.

For example:

Daily feeding rate		DECCOX
Lambs (bodyweight)	Calves (bodyweight)	Inclusion rate
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 identified 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 concentration 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 concentration of DECCOX 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 a more severe challenge exists, double dosage should be used.

As an aid in the prevention of abortions and perinatal losses due to toxoplasmosis by medication of ewe feed:
For use during pregnancy. Administer medicated feed at a rate to provide the target intake of 2.0 mg decoquinate/kg bodyweight daily, according to the rate at which DECCOX has been incorporated in the ration. Two examples which achieve the recommended dosage of 2.0 mg decoquinate/kg are shown below:
1. Mid pregnancy Add 6.68 kg of premix per tonne, feed at 250 g/50 kg bodyweight daily.
2. Late pregnancy Add 3.34 kg of premix per tonne, feed at 500 g/50 kg bodyweight daily.

If ewes are to be fed at other rates, the level of DECCOX in the feed should be adjusted accordingly. Medicated feed should state the feeding rate required to achieve the target intake of decoquinate. Feed continuously for the last two-thirds of pregnancy (i.e. for the final 14 weeks prior to lambing).

9. ADVICE ON CORRECT ADMINISTRATION

To ensure thorough dispersion, 1 part of DECCOX should be mixed with 3 parts of the feed before incorporation in the final mix. The product can be incorporated into pelleted feed preconditioned for up to 10 minutes at temperatures up to 80°C.

10. WITHDRAWAL PERIOD(S)

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in a dry place. The product will remain stable in the finished feed for 3 months.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

For animal treatment only – to be supplied only on veterinary prescription.
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

Medication of ewe rations may not prevent coccidiosis occurring in lambs and should only be given in conjunction with lamb medication.
Incorporation in feedstuffs must be in accordance with the terms of the marketing authorisation. This product is only authorised for use in medicated feeding stuffs or premixtures. In both cases it must be thoroughly mixed with feeding stuffs materials to ensure it is evenly distributed throughout the mixture. Any premixture containing this product must

be thoroughly mixed with feeding stuffs materials to ensure that it is evenly distributed throughout the final feed.
Care should be taken to ensure that the daily dose rate of decoquinate is achieved.
DECCOX can be used during pregnancy and lactation.

User warnings
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.
These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Presentation: Coarse beige powder with the odour of wheat middlings.
Further information: 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.
The use of DECCOX will maintain normal growth under conditions of coccidial challenge, but does not improve the growth of healthy lambs or calves. Decoquinate dosages of 4 mg/kg in sheep and 6 mg/kg in calves have been found to be well tolerated and without observable side effects.
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.

Net weight: 10 kg
Licence number:
Expiry date:
Batch number: