1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quinox 60.6 mg/g Premix for Medicated Feeding Stuff for Cattle and Sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains

Active substance:
Decoquinate……..… 60.6 mg

Excipient:

Qualitative composition of excipients and other constituents
Soya-bean oil, refined
Silica colloidal hydrated
Wheat flour

White to off-white fine powder without agglomerates.

3. CLINICAL INFORMATION

3.1 Target species

Sheep (lambs), cattle (calves).

3.2 Indications for use for each target species

For the treatment and metaphylaxis of coccidiosis in lambs and calves during coccidial challenge.

The presence of the disease in the group/flock must be established before the product is used.

3.3 Contraindications

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

3.4 Special warnings

The use of the veterinary medicinal product will maintain normal growth under conditions of coccidial challenge but does not improve growth of healthy lambs or calves.
Coccidiosis is an indicator of insufficient hygiene in the flock/pen. It is recommended to improve hygiene and to treat all calves in a pen and all lambs in a group. This will contribute to reduce the infection pressure and assure a better epidemiological control of the coccidiosis infection.
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.
If resistance to decoquinate is present, the use of an antiprotozoal from another class/with a different mechanism of action should be considered.

Unnecessary use of antiprotozoals or use deviating from the instructions given in the SPC may increase the resistance selection pressure and lead to reduced efficacy. The decision to use the veterinary medicinal product should be based on confirmation of the coccidian species and burden, or of the risk of infection based on its epidemiological features, for each individual animal/herd. Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development.
To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.

This veterinary medicinal product should not be used together with feed additives or other veterinary medicinal products containing coccidiostats or histomonostats.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Animals to be treated should be separated and moved to dry and clean areas.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This veterinary medicinal product may be harmful in case of dermal contact including hand-to-mouth contact.
Avoid skin contact and accidental ingestion.
Do not smoke, eat or drink while handling the veterinary medicinal product.
Personal protective equipment consisting of protective gloves should be worn when handling the veterinary medicinal product.
In the case of skin contact rinse immediately with a large amount of water. Wash hands after use.
In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment
Not applicable.

3.6 Adverse events

Sheep, cattle:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy:
Can be used during pregnancy

3.8 Interaction with other medicinal products and other forms of interaction

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

3.9 Administration routes and dosage

In-feed use.

Treatment of coccidiosis in lambs and calves, and metaphylaxis of coccidiosis in lambs:
The recommended dosage is 1 mg decoquinate/kg bodyweight/day (i.e. 16.7 mg of the veterinary medicinal product/kg of bodyweight/day) for 28 days if coccidiosis is expected to be a hazard
For a feed intake of 100 g/10 kg, add 1.67 kg of premix per ton of feed this dose regimen corresponds to 100 ppm in medicated feed.

Metaphylaxis of coccidiosis in calves:
The recommended dosage is 0.5 mg decoquinate/kg bodyweight/day (i.e. 8.3 mg of the veterinary medicinal product/kg of bodyweight/day) for 28 days to calves when coccidiosis is likely to occur.
For a feed intake of 100 g/10 kg, add 833 g of premix per ton of feed this dose regimen corresponds to 50 ppm in medicated feed.

The intake of medicated feed depends on the clinical condition of the animals. In order to obtain the correct dosage, the concentration of decoquinate may need to be adjusted accordingly.
To ensure a correct dosage, body weight should be determined as accurately as possible.
The use of suitably calibrated measuring equipment is recommended.
Partly-consumed feed must be disposed of with other waste feed and not given to other animals.

In the preparation of pelleted feed, preconditioning temperatures of up to 70ºC for a short time have been used and shown to have no effect on the veterinary medicinal 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.

For infections with parasites, the need for and frequency of re-treatments should be based on professional advice and should take into account the local epidemiological situation and the animal's lifestyle.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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 veterinary medicinal product containing decoquinate have been found to be well tolerated and without observable side effects.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Do not use for prophylaxis.
This veterinary medicinal product is intended to be used for the preparation of medicated feed.

3.12 Withdrawal periods

Cattle (calves) and sheep (lambs):
Meat and offal: zero days.

Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code

QP51BX04

4.2 Pharmacodynamics

Decoquinate belongs to the quinolone group of coccidiostats. It has an anti-coccidial action, interfering with the electron transport in the mitochondrial cytochrome system. Decoquinate acts early in the life cycle of Eimeria on sporozoites, released form ingested oocysts and on first-generation meronts, arresting development and release of merozoites and thus preventing further damage to the intestines.

4.3 Pharmacokinetics

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.

Environmental properties
Decoquinate is very persistent in soil.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after first opening the immediate packaging:
- 0.833 kg bag: 3 months
- 5 kg bag: 6 months

Shelf-life after incorporation into feed: 6 months

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Zipped 0.833 kg heat-sealed bag made of low-density polyethylene/polyamide/aluminium/polyester
5 kg heat-sealed bag made of low-density polyethylene/aluminium/polyamide

Not all pack sizes may be marketed

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

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

HUVEPHARMA NV

7. MARKETING AUTHORISATION NUMBER(S)

VPA10782/052/001

8. DATE OF FIRST AUTHORISATION

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).