1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Quinox 6 mg/g Oral powder for cattle and sheep

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each g contains:

Active substance:
Decoquinate…… 6 mg

Excipients:

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

White to off-white powder, fine, 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 prophylaxis of coccidiosis in lambs and calves.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.
Not to be used in pre-ruminating animals receiving only milk or milk-replacer.

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.

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.

To alter the course of an established clinical coccidial infection, in individual animals already showing signs of diarrhoea, additional supportive therapy may be required.
Maximum benefit will be seen if the veterinary medicinal product is administered to animals in the group before onset of clinical signs.
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 veterinary medicinal product should be in accordance with official, national and regional antimicrobial policies.
Repeated use for an extended period, particularly when using the same class of substances, increases the risk of resistance development.
If resistance to decoquinate is present, the use of an antiprotozoal from another class/with a different mechanism of action should be considered.

The veterinary medicinal product should not be used as part of herd health programmes.

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

Treatment should be initiated as early as possible.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Not for use for group treatment.
This veterinary medicinal product should only be used in individual animals or in a restricted number of animals.
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 hand-to-mouth contact. Avoid accidental ingestion.
Do not smoke, eat or drink while handling the veterinary medicinal product.
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 (lambs), cattle (calves):
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.

The veterinary medicinal product is to be administered only for individually fed animals or a small group of animals where the intake by individual animals can be effectively controlled.
To be mixed with a small quantity (20%) of the daily solid feed ration and administered prior to offering the remaining feed. The medicated feed must be prepared daily. Animals to be treated should be separated and treated individually.

Treatment of coccidiosis in lambs and calves, and prophylaxis of coccidiosis in lambs:
1 mg decoquinate / kg bodyweight / day (corresponding to 166.7 mg of the veterinary medicinal product / kg bodyweight /day).

Feed continuously for 28 days when coccidiosis is expected to be a hazard.

Prophylaxis of coccidiosis in calves:

0.5 mg decoquinate / kg bodyweight / day (corresponding to 83.3 mg of the veterinary medicinal product / kg bodyweight /day), for 28 days.
Feed continuously for 28 days to calves when coccidiosis is likely to occur.

To ensure a correct dosage, body weight should be determined as accurately as possible. 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. The use of suitably calibrated measuring equipment is recommended. Underdosing could result in ineffective use and may favour resistance development.

Partly-consumed feed must be disposed of with other waste feed and not given to other animals.

For infections with coccidia, the need for and frequency of re-treatment(s) 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 when administered in feed medication. In sheep at least four times, and in calves at least six times, the recommended use levels of veterinary medicinal products 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.

Not applicable.

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

Decoquinate 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.
Recovery of the administered material via excretion is essentially complete.

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: 3 years.
Shelf-life after a first opening:
- 1 kg bag: 28 days
- 5 kg bag: 2 months

Shelf-life after mixing into feed: 24 hours.

5.3 Special precautions for storage

Do not store above 25°C.

After first opening, store in a dry place and keep the bags tightly closed in order to protect from moisture.

5.4 Nature and composition of immediate packaging

Zipped 1 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)

VPA10782/051/001

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).