

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Flukanide 30 mg/ml oral suspension for sheep

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

Each ml contains:

**Active substance:**

Rafoxanide 30.00 mg

**Excipients:**

Tartrazine yellow (E102) 0.07 mg

Propyl parahydroxybenzoate (E216) 0.20 mg

Methyl parahydroxybenzoate (E218) 2.00 mg

For the full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Oral suspension.  
Yellow suspension.

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Sheep.

#### **4.2 Indications for use, specifying the target species**

For the treatment of mature liver fluke infections (*Fasciola hepatica*).

#### **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**

Unnecessary use of antiparasitics 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 product should be based on confirmation of the parasitic

species and burden, or of the risk of infection based on its epidemiological features, for each individual flock.

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of bodyweight, mis-administration of the product or lack of calibration of the dosing device.

Resistance to rafoxanide has been reported in immature 6-week-old *Fasciola hepatica* in artificially infected sheep in Australia (1989). In the study, two isolates of *Fasciola hepatica* that were resistant to rafoxanide were also resistant to closantel (another salicylanilide), indicating possible side resistance. However, the fluke isolates resistant to rafoxanide and closantel did not demonstrate side resistance to the salicylanilide oxyclozanide.

Suspected clinical cases of resistance to anthelmintics should be further investigated using appropriate tests (e.g. Faecal Egg Count Reduction Test). Where the results of the tests strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

#### **4.5 Special precautions for use**

##### Special precautions for use in animals

When a dosing gun is used to administer the product, care must be taken to avoid damage to the pharyngeal region.

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

This product may be irritating to skin and eyes or cause hypersensitivity. People with known hypersensitivity to rafoxanide or any of the listed excipients should avoid contact with the product. Wear nitrile rubber gloves when applying the product. Do not eat, drink, or smoke while handling the product. If accidental contact with the skin or eyes occurs, wash off any skin contamination with soap and water immediately. Rinse the affected eyes thoroughly with clean, fresh water. Remove and wash any contaminated clothing immediately. Wash hands after use.

##### Environmental precautions

Rafoxanide is very toxic to dung insects. Long term effects on dung insects caused by continuous or repeated use cannot be excluded. Therefore, the product must only be administered once per year to affected animals only.

#### **4.6 Adverse reactions (frequency and seriousness)**

None.

#### **4.7 Use during pregnancy, lactation or lay**

Can be used during pregnancy.  
(see section 4.11).

#### **4.8 Interaction with other medicinal products and other forms of interaction**

None known.

#### **4.9 Amounts to be administered and administration route**

For oral administration.

To be given orally at a dose of 11.25 mg rafoxanide per kg bodyweight equivalent to 3 ml of product per 8 kg bodyweight.

Accuracy of the dosing device should be checked.

Underdosing could result in ineffective use and may favour resistance development.

To ensure a correct dosage, body weight should be determined as accurately as possible. If animals are to be treated collectively, reasonably homogeneous groups should be set up, and all animals of a group should be dosed at the rate corresponding to the heaviest one.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. As with other anthelmintics, veterinary advice should be sought on appropriate dosing programmes and stock management to achieve adequate parasite control and reduce the likelihood of resistance developing.

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

No specific signs.

#### **4.11 Withdrawal period(s)**

Meat: 78 days

Milk: Not authorised for use in ewes producing milk for human consumption including during the dry period. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

### **5. PHARMACOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Anthelmintics, rafoxanide.  
ATC vet code: QP52AG05.

#### **5.1 Pharmacodynamic properties**

The product contains the active ingredient rafoxanide, a halogenated salicylanilide. Its principal use is as an adulticide for *F. hepatica*. The product acts by uncoupling oxidative phosphorylation. Liver flukes treated *in vivo* or *in vitro* with rafoxanide show

indirect evidence of uncoupling, including reduced ATP levels, decreased glycogen content and accumulation of succinate. This results in paralysis and death of the fluke. The product also binds strongly to plasma proteins and is inactive until ingested by the parasite and separated from the plasma albumin by digestion. For this reason, rafoxanide does not affect the host's mitochondria *in vivo*. Only flukes residing in the bile, through which salicylanilides are excreted from the host's body, are susceptible to rafoxanide.

## **5.2 Pharmacokinetic particulars**

Halogenated salicylanilides are strongly bound to plasma proteins. After oral administration of the product rafoxanide is slowly absorbed reaching peak plasma concentrations approximately 2 days post treatment and its elimination half-life is approximately 22 days.

## **5.3 Environmental properties**

Rafoxanide is very persistent in soils.

# **6. PHARMACEUTICAL PARTICULARS**

## **6.1 List of excipients**

Methyl parahydroxybenzoate (E218)  
Propyl parahydroxybenzoate (E216)  
Xanthan gum  
Tartrazine yellow (E102)  
Simethicone emulsion  
Polysorbate 20  
Propylene glycol  
Colloidal anhydrous silica  
Citric acid monohydrate  
Purified water

## **6.2 Major incompatibilities**

None known.

## **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 36 months. Following withdrawal of the first dose, use the product within 3 months.

## **6.4 Special precautions for storage**

Do not freeze.

## **6.5 Nature and composition of immediate packaging**

1, 2.5 and 5 litre high density polyethylene (HDPE) white containers with 38 mm white wadded polypropylene caps.

This product may be marketed with or without an outer carton.

Not all pack sizes may be marketed.

#### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Medicines should not be disposed of via wastewater. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

Rafoxanide should not enter water courses as this may be dangerous for fish and other aquatic organisms.

### **7. MARKETING AUTHORISATION HOLDER**

Univet Ltd  
Tullyvin  
Cootehill  
Co. Cavan  
Ireland

### **8. MARKETING AUTHORISATION NUMBER**

Vm 05150/4009

### **9. DATE OF FIRST AUTHORISATION**

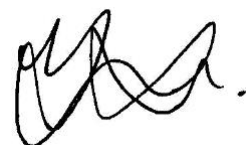
19 April 2023

### **10. DATE OF REVISION OF THE TEXT**

April 2023

### **PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.



Approved: 19 April 2023