

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Ridafluke 30 mg/ml Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance

Rafoxanide 30.0 mg/ml

Excipients

Nipasept Sodium 2.0 mg/ml

Tartrazine (E102) 0.07 mg/ml

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, Sheep.

4.2 Indications for use, specifying the target species

Ridafluke is a flukacide drench containing Rafoxanide which is effective in the treatment and control of fluke infections in sheep and cattle.

In sheep, Ridafluke is effective against mature liverfluke and 83% effective against 4 week-old immature fluke.

In cattle, Ridafluke is effective against mature fluke.

4.3 Contraindications

Do not administer to animals with known hypersensitivity to the active ingredient.

4.4 Special warnings for each target species

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, misadministration of the product, or lack of calibration of the dosing device.

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. Careful estimate of liveweight must be made before dosing.

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

When using do not eat, drink or smoke. Wash hands and exposed skin before meals and after work. Remove immediately any contaminated clothing. Wash splashes from eyes and skin immediately.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Ridafluke is safe for use 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 use only at a dose rate, for cattle and sheep, of 11.25 mg radoxanide per kg bodyweight equivalent to:

Cattle 15 ml Ridafluke per 40 kg bodyweight.

Sheep 3 ml Ridafluke per 8 kg bodyweight.

If animals are to be treated collectively rather than individually, they should be grouped according to their bodyweight and dosed accordingly, in order to avoid under- or overdosing.

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

No specific signs.

4.11 Withdrawal Period(s)

Meat: Withdrawal time for cattle and sheep is 60 days.

Cattle:

Not authorised for use in cattle producing milk for human consumption including during the dry period.

Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

Sheep:

Not authorized 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 or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anthelmintcs, rafoxanide.

ATCvet code: QP52AG05

5.1 Pharmacodynamic properties

Ridafluke contains the active ingredient, Rafoxanide, a halogenated salicylanilide, which was developed in 1969. Its principal use is as an adulticide for both *F. hepatica* and *F. gigantica*, but it also has the advantage of having respectable efficacy for immature flukes. Rafoxanide 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. Rafoxanide 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 blood-sucking nematodes and flukes residing in the bile, through which salicylanilides are excreted from the host's body, are susceptible to rafoxanide.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric Acid Monohydrate
Colloidal Anhydrous Silica
Polysorbate 20
Propylene Glycol
Silica in Dimeticone Suspension
Nipasept Sodium
Xanthan Gum
Tartrazine (E102)

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

High density polyethylene containers and closures.

1, 2.5 & 5 litre packs.

Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Chanelle Pharmaceuticals Manufacturing Ltd.,

Loughrea,

Co. Galway.

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10987/013/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2009

10 DATE OF REVISION OF THE TEXT

June 2013