1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orafluke 100 mg/ml oral suspension for cattle.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Fenbendazole	100 mg
Rafoxanide	100 mg

Excipients

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Quinoline Yellow (E104)	0.09 mg
Propyl parahydroxybenzoate (E216)	0.10 mg
Methyl parahydroxybenzoate (E218)	1.00 mg
Xanthan gum (E415)	
Simeticone	
Polysorbate 80	
Sodium citrate (E331)	
Sodium metabisulphite (E223)	
Citric acid monohydrate	
Purified water	

A pale lemon, free flowing suspension.

3. CLINICAL INFORMATION

3.1 Target Species

Cattle.

3.2 Indications for use for each target species

The veterinary medicinal product permits a three-way activity against fluke, lungworms and stomach worms in cattle. It is a broad spectrum anthelmintic for the treatment of benzimidazole-susceptible mature and immature stages of nematodes and cestodes of the gastrointestinal and respiratory tracts of cattle.

Cattle:
Haemonchus spp.
Ostertagia spp.
Trichostrongylus spp.
Cooperia spp.
Nematodirus spp.
Bunostomum spp.
Trichuris spp.

Strongyloides spp.
Oesophagostomum spp.
Dictyocaulus spp.
Moniezia spp.
Rafoxanide is active against immature and mature *Fasciola* spp. over 8 weeks of age.

The veterinary medicinal product has a good therapeutic effect against type II Ostertagiasis.

3.3 Contraindications

None.

3.4 Special warnings

Where a dosing gun is used to administer the veterinary medicinal product, care should be taken to avoid causing injury to the mouth and pharynx of animals.

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 anthelmintic resistance developing. If the veterinary medicinal product does not achieve the desired clinical effect, other diseases, nutritional disturbances or anthelmintic resistance may be involved.

3.5 Special precautions for use

Special precautions for safe use in the target species:

To ensure a correct dosage, body weight should be determined as accurately as possible. The use of suitably calibrated measuring equipment is recommended.

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

Wash hands after use.
In case of accidental eye contact, rinse immediately with water.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

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 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 and lactation:

Can be used during pregnancy.

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

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.
The recommended therapeutic dose is 11.25 mg fenbendazole and 11.25mg rafoxanide per kilogram bodyweight.
Shake well before use. Practical dosage recommendations are as follows:

Cattle	
Bodyweight (kg)	**Dose (ml)**
50 kg	5.60
100 kg	11.25
300 kg	33.75
500 kg	56.25

3.10 Symptoms Overdose (and where applicable emergency procedures and antidotes)

The veterinary medicinal product is well tolerated in cattle at three times the recommended dosage.

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

Meat and offal: 60 days.
Milk:
Not authorised for use in animals 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code :

QP52AC13, QP52AG05

4.2 Pharmacodynamics

Fenbendazole, like many benzimidazoles, blocks fumarate reductase, which results in the inhibition of the formation of adenosine triphosphate (involved in mitochondrial energy). There is also evidence that it inhibits glucose uptake and therefore increases glycogen utilization and depletes the worm's glycogen reserves. The overall effect of this action is to effectively starve the parasite to death. Furthermore, this action results in the detachment of the parasites, but in the case of intestinal helminths, this detachment does not result in loss of contact with the drug, whereas in the case of the liver fluke, such detachment

would reduce such contact. This probably explains its limited effect on the liver fluke and the good effect on intestinal helminths.

*In vitr*o experiments indicate that salicylanilides, including the commercially used flukicides, oxyclozanide and rafoxanide, uncouple oxidative phosphorylation in *Fasciola hepatica* and other parasites

4.3 Pharmacokinetics

Fenbendazole

Fenbendazole is absorbed poorly from the gastro-intestinal tract leading to low plasma levels of fenbendazole, oxfendazole and sulphone. It is mainly excreted in the faeces though some of the metabolites that have been identified are excreted in the urine and bile. The active and its metabolites are mainly found in the plasma.

Rafoxanide

Kinetic studies of rafoxanide in cattle have shown that it is absorbed into the blood with a mean peak concentration of circa 23 µg/ml achieved in 2 to 3 days. Plasma levels are considerably higher than those in tissues. Only one metabolite has been identified (3,5-di-iodosalicylic acid) and this was found in blood tissues and milk. There is little known or reported on the excretion of rafoxanide though it is apparently excreted in the bile.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf-life

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

5.3 Special precautions for storage

Do not store above 25 °C.
Protect from frost.
Protect from light.

5.4 Nature and composition of immediate packaging

1 L (jerrican and backpack), 2.5 L (jerrican and backpack) or 5 L (jerrican and backpack) HDPE white rigid containers closed with a 38 mm polypropylene screw cap with an induction heat seal liner.

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

Interchem (Ireland) Ltd.,

7. MARKETING AUTHORISATION NUMBER(S)

VPA10555/003/002

8. DATE OF THE FIRST AUTHORISATION

05/06/2006

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

06/08/2026

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).