Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex Super 19.5% w/v Oral Suspension

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains :

Active Substance

Triclabendazole	12.0	% w/v
Levamisole hydrochloride	7.5	% w/v

Excipients

Methyl Parahydroxybenzoate (E218)	0.08	% w/v
Propyl Parahydroxybenzoate (E216)	0.03	% w/v
Benzoic Acid (E210)	0.10	% w/v
Sodium metabisulphite (E223)	0.25	% w/v

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Oral suspension.
A white to off-white aqueous suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle.

4.2 Indications for use, specifying the target species

For the simultaneous treatment and control of mature and developing immature infections of stomach worms *(Haemonchus, Ostertagia, Trichostrongylus axei*), gut worms (*Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Oesophagostomum*) and lung worms (*Dictyocaulus)* as well as all forms of liver fluke infection (early immature, immature and adult stages of *Fasciola hepatica* and *Fasciola gigantica*) in cattle.

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients. Do not use for the control of inhibited Type II Ostertagia infestations.

4.4 Special warnings for each target species

Fasinex Super is not suitable for sheep.

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

The product is effective on the mature and developing immature stages of Ostertagia, but is not indicated for the control of inhibited larvae (i.e. Type II ostertagiasis).

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

Wash hands after use.

Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the product, or sore mouth/throat or fever occur shortly afterwards, then medical advice should be sought immediately.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The product is safe for use during pregnancy and lactation. However, the product is not permitted for use in animals producing milk for human consumption,including pregnant animals intended to produce milk for human consumption.

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.
Clean drenching equipment before and after use.
Shake thoroughly before use.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible. 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.
Use properly calibrated dosing equipment.
The recommended dose rate is 12 mg/kg triclabendazole and 7.5 mg/kg levamisole, i.e. 1 ml Fasinex Super per10 kg bodyweight.

Bodyweight	**Dose Volume**
100 kg	10 ml
150 kg	15 ml
200 kg	20 ml
250 kg	25 ml
300 kg	30 ml
350 kg	35 ml
400 kg	40 ml
450 kg	45 ml
For each additional 50 kg	5 ml

Dosing Programme
The adoption of a strategic dosing programme is the most effective way to control worms and liver fluke. To avoid the production losses caused by the lower levels of infection, which otherwise go undetected, and those caused by immature stages of parasites; a whole-herd programme should be followed. Because Fasinex Super is active against mature and developing immature worms and the 3 stages of liver fluke, Fasinex Super can be effective for emergency treatment should acute cases occur. Effective worm control is necessary in young stock throughout the summer grazing period. Fasinex Super may be used routinely during the season to control worms.

Bought-in Animals
As the grazing pattern and previous worm and fluke treatment history for bought-in cattle is often unknown, all bought-in animals should be dosed with Fasinex Super before entering the main herd.

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

Transient side effects (muscle tremors, salivation) may occur following overdosing.

4.11 Withdrawal period(s)

Foodstuffs must not be taken for human consumption during the treatment period.

Meat and offal: 46 daysMilk:Not permitted for use in animals producing milk for human consumption, including pregnant animals intended to produce milk for human consumption.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Triclabendazole is active primarily against fluke. Triclabendazole is an anthelmintic which belongs chemically to the benzimidazoles.

The mode of action of triclabendazole is not known but is probably different from that of other benzimidazoles as it does not exert its activity by association with tubulin. Triclabendazole and its sulfoxide metabolite are anthelmintically active.

About half of the orally administered dose of triclabendazole is absorbed from the gastrointestinal tract. Very rapidly, absorbed triclabendazole is almost completely oxidised to its sulfoxide and sulfone. Triclabendazole sulfoxide reaches peak concentrations (ca. 15 ppm) 20 hours after administration and the sulfone reaches peak concentrations (ca. 10 ppm) 30 to 32 hours after administration. Both metabolites bind strongly to plasma proteins, particularly albumin.
Metabolites are excreted via the bile mainly as conjugates. More than 90% of the total dose is excreted in the faeces, about 2% in the urine and less than 1% in the milk. The elimination is virtually complete by 10 days after administration.

Levamisole is active against stomach, gut and lung worms. Levamisole is an imidazothiazole and interferes with parasite neuromuscular transmission causing muscular paralysis and rapid expulsion. Levamisole is readily absorbed, reaching peak plasma concentrations of about 0.5 – 1 ppm 0.5 – 4.0 hours after oral administration. It is extensively metabolised with a plasma half life of 1 – 4 hours. Excretion via urine and faeces is nearly complete 1 week after administration.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate E218
Propyl parahydroxybenzoate E216
Benzoic acid E210
Sodium metabisulphite E223
Sodium chloride
Disodium edetate
Antifoam
Macrogol 6000
Colloidal anhydrous silica
Citric acid monohydrate
Povidone K30
Sodium hydroxide
Purified water

6.2 Major 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 ºC.
Protect from frost.

6.5 Nature and composition of immediate packaging

0.8, 2.2, 5.0 and 12 litre HDPE containers with screw cap lids containing white to off-white aqueous suspension.
Not all pack sizes may be marketed.

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

Do not contaminate ponds, waterways or ditches with the product or used container. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/005/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 6th August 2004
Date of last renewal: 5th August 2009

10 DATE OF REVISION OF THE TEXT

June 2018