Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Endex 19.5 % w/v Oral Suspension for Cattle

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

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	0.1	% 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

Endex 19.5% is not suitable for sheep.

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.

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 interactions

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.

The recommended dose rate is 12 mg/kg triclabendazole and 7.5 mg/kg levamisole, i.e. 1 ml Endex per10 kg bodyweight.

BodyweightDose 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 Endex is active against mature and developing immature worms and the 3 stages of liver fluke, Endex can be effective for emergency treatment should acute cases occur.
Effective worm control is necessary in young stock throughout the summer grazing period. Endex 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 Endex 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.

Edible tissues: 46 days
Milk: 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 licenced 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 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. 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

Elanco GmbH
Heinz-Lohmann-Strasse 4
27472 Cuxhaven
Germany

8 MARKETING AUTHORISATION NUMBER(S)

VPA22020/035/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 8th April 2001
Date of last renewal: 7th April 2006

10 DATE OF REVISION OF THE TEXT

July 2017