Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Endex 8.75 % w/v Oral Suspension for Sheep

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substances		
Triclabendazole	5.0	% w/v
Levamisole hydrochloride	3.75	% w/v
Excipients		
Methyl parahydroxybenzoate (E218)	0.095	% w/v
Propyl parahydroxybenzoate (E216)	0.035	% 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

Sheep.

4.2 Indications for use, specifying the target species

For the simultaneous treatment and control of mature and immature infections, including inhibited stages of stomach worms (*Haemonchus, Ostertagia, Trichostrongylus axei*), gut worms (*Trichostrongylus, Cooperia, Nematodirus, Busonstomum, Gaigeria, Chabertia, 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* susceptible to triclabendazole).
For the treatment and control of nematodes resistant to benzimidazoles and probenzimidazoles, macrolide anthelmintics (e.g. ivermectin), salicylanides and tetrahydropyrimidines.

4.3 Contraindications

Do not administer to animals with known hypersensitivity to the active ingredients.
Do not administer to goats.

4.4 Special warnings for each target species

Special care should be taken when dosing early spring lambs to ensure that the appropriate meat withholding period is observed, ie. 55 days.
Not permitted for use in lactating sheep producing milk for human consumption.
Care must be taken in dosing sheep to avoid causing damage to the mouth and pharynx of treated animals.

4.5 Special precautions for use

Special precautions for use in animals
Parasite resistance to a particular class of anthelmintic may develop following frequent repeated use of an anthelmintic of that class.
Only use for liver fluke strains susceptible to Triclabendazole. If lack of efficacy is suspected seek veterinary advice.
Shake well before use.
Clean drenching equipment before and after use.

Special precautions to be taken by the person administering the veterinary medical product to animals
Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Endex can be given to animals at all stages of pregnancy. See section 4.11.

4.8 Interaction with other medicinal products and other forms of interactions

None known.

4.9 Amounts to be administered and administration route

Administer by oral drench.
Shake thoroughly before use.

Recommended dose rate is 10 mg/kg triclabendazole and 7.5 mg/kg levamisole ie. 1 ml Endex per 5 kg body weight.

BodyweightDose

10 kg 2 ml
15 kg 3 ml
20 kg 4 ml
30 kg 6 ml
40 kg 8 ml
50 kg 10 ml
60 kg 12 ml
for each additional 10 kg 2 ml

Dosing Programme

The adoption of a strategic dosing programme is the most effective way to control worms and liver fluke. Veterinary advice should be sought.
To avoid the production losses caused by the lower levels of infection, which otherwise can go undetected and those caused by immature stages of parasites, a whole-flock programme should be followed. Because Endex is active against mature and developing immature worms and the 3 stages of liver fluke, Endex can be effectively used in a strategic programme. Endex is also effective for emergency treatment should acute cases occur.

Season

Spring: Treat ewes immediately before or after lambing.

Summer: Dose lambs regularly (in cases of heavy infestation, particularly following mild winters). Dose ewes in mid-summer.

Autumn: Treat all stock in early autumn.

Bought-in Sheep
As the grazing pattern and previous worm and fluke treatment history for bought in sheep is often unknown, all bought in sheep should be dosed with Endex before entering the main flock.

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

Overdosing may cause transient side effects (muscle tremors, salivation).

4.11 Withdrawal period(s)

Foodstuffs must not be taken for human consumption during the treatment period.
Edible tissues: 55 days.
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 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. 15ppm) 20 hours after administration and the sulfone reaches peak concentrations (ca. 10ppm) 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 of triclabendazole 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 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 chloride
Citric acid monohydrate

Sodium metabisulphite
Disodium edetate
Antifoam AF emulsion
Macrogol 400
Colloidal anhydrous silica
Sodium hydroxide
Water for injections

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°C. 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 a white to off-white aqueous suspension.

Contents: Liquid 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)

VPA22020/036/001

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 2018