SUMMARY OF PRODUCT CHARACTERISTICS

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasimec Duo 50 mg/ml + 1 mg/ml oral suspension for sheep.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

Ivermectin	1	mg/ml
Triclabendazole	50	mg/ml

Excipients:

Methyl parahydroxybenzoate (E218)	1.4	mg/ml
Propyl parahydroxybenzoate (E216)	0.5	mg/ml
Benzyl alcohol	5.0	mg/ml

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Oral suspension

Cream coloured aqueous oral suspension

4. CLINICAL PARTICULARS

4.1 Target Species

For sheep over 3 months of age.

4.2 Indications for use, specifying the target species

Treatment of mixed trematode (fluke) and nematode or arthropod infections due to gastrointestinal roundworms, lungworms, liver fluke and nasal bots.

Gastrointestinal nematodes (adult and immature):
Haemonchus contortus, Teladorsagia (Ostertagia) circumcincta, Trichostrongylus spp, Cooperia spp, Nematodirus spp including *N. battus*, *Strongyloides papillosus, Oesophagostomum spp*, and adult *Chabertia ovina.*
Inhibited larval stages and benzimidazole resistant strains of *Haemonchus contortus* and *Teladorsagia (Ostertagia) circumcincta* are also controlled.

Liver fluke (mature, immature and early immature stages down to less than 1 week of age):

Fasciola hepatica

Lungworms (adult and immature):
Dictyocaulus filaria
Nasal bots (all stages): *Oestrus ovis*

4.3 Contraindications

Do not use in animals with known hypersensitivity to the active ingredients or any of the excipients.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

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 (if any).

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 test(s) strongly suggest resistance to a particular anthelmintic, an anthelmintic belonging to another pharmacological class and having a different mode of action should be used.

Resistance to ivermectin has been reported in *Teladorsagia (Ostertagia) circumcincta* in sheep and increasing resistance to triclabendazole has been reported in *Fasciola* species in small ruminants in a number of countries including the EU. Therefore the use of this product should be based upon local (regional, farm) epidemiological information about susceptibility of the *Teladorsagia (Ostertagia) circumcincta* and trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Extra-label use in dogs should be avoided as severe adverse reactions may occur. In common with other avermectins, certain breeds of dogs, such as Collies are especially sensitive to ivermectin and particular care should be taken to avoid accidental consumption of the product.

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

People with known hypersensitivity to the active substances should avoid contact with the product. Protective gloves should be worn when handling the veterinary medicinal product.

In case of accidental spillage onto skin or into the eyes wash immediately with water. Take off any contaminated clothes.

Do not eat, drink or smoke whilst handling the product. Wash hands and exposed skin before meals and after work.

iii. Other precautions

Ivermectin is very toxic to aquatic organisms and dung insects.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

The safety of this combination of active ingredients has not been shown during pregnancy or lactation or in animals intended for breeding. No alteration of lactation has been reported for ivermectin and triclabendazole when used as monotherapy in sheep. Therefore it should be used in pregnant/lactating animals only according to a risk:benefit analysis by the responsible veterinarian.

4.8 Interaction with other medicinal products and other forms of interactions

No data available.

4.9 Amounts to be administered and administration route

For oral use.

The dose rate is 0.2 mg ivermectin and 10 mg triclabendazole per kg bodyweight equivalent to 2 ml/10 kg bodyweight.

Bodyweight should be assessed accurately before calculating the dose. The product is for oral administration using a suitably calibrated dosing gun. The container should be shaken thoroughly before use. Drenching equipment should be cleaned before and after use.

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.

The timing for treatment should be based on epidemiological factors and should be customised for each individual farm. 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 resistance developing.

Dosing Table:

Animal Weight	Dose of the product
20 – 25 kg	5 ml
26 – 30 kg	6 ml
31 – 35 kg	7 ml
36 – 40 kg	8 ml
41 – 50 kg	10 ml
51 – 60 kg	12 ml
61 – 70 kg	14 ml
71 – 80 kg	16 ml
81 – 90 kg	18 ml
91 – 100 kg	20 ml

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

No clinical signs were observed after overdosing 5 times. At 10 times overdosing liver and kidney function may be affected slightly. There is no antidote.

4.11 Withdrawal period(s)

Meat and offal: 27 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

Ivermectin is an endectocidal macrocyclic lactone.
Triclabendazole is an anthelmintic benzimidazole.

ATCvet Code: QP54AA51

5.1 Pharmacodynamic properties

Avermectins interact with glutamate-gated chloride ion channels, to increase membrane permeability to chloride ions, causing irreversible neuromuscular blockade in nematodes and arthropods, followed by paralysis and death.

Triclabendazole interferes with intracellular transport mechanisms and inhibits protein synthesis and is active against the liver fluke Fasciola.

5.2 Pharmacokinetic particulars

Ivermectin is readily absorbed and reaches peak plasma concentrations within 1 day. Afterwards plasma concentrations decrease with a half life of up to 5 days.

Triclabendazole is readily absorbed, oxidised to triclabendazole sulfoxide and to triclabendazole sulfone. Peak plasma concentrations are reached within 2 days. Afterwards plasma concentrations decrease with a half life of about 1.5 days. Both metabolites bind strongly to plasma proteins, particularly albumin. More than 90 % of the dose is excreted in the feces, about 2 % in the urine and less than 1 % in the milk within 10 days. The inter-individual variability of the kinetics of ivermectin and metabolites of triclabendazole in ovine species is high.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Methyl parahydroxybenzoate (E218)
Propyl parahydroxybenzoate (E216)
Benzyl alcohol

Microcrystalline cellulose and carmellose sodium
Povidone K30

Propylene glycol

Disodium phosphate dodecahydrate

Purified water

6.2 Major incompatibilities

None known.

6.3 Shelf-life

Shelf life of the 0.8 litre and 2.2 liter veterinary medicinal product as packaged for sale : 18 months
Shelf life of the 5.0 litre veterinary medicinal product as packaged for sale : 3 Years

Shelf-life after first opening the immediate packaging: 1 year.

6.4 Special precautions for storage

Store the product in closed original container.

6.5 Nature and composition of immediate packaging

The product is available in the following containers:

0.8, 2.2 and 5.0 litre white high density polyethylene (HDPE) bottles with blue polypropylene screw-on cap with flip-top; 12.0 litre white HDPE container with blue polyethylene screw-cap.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. Dangerous to fish and other aquatic life. Do not contaminate ponds, waterways or ditches with the product or used container.

7. MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
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Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 00879/4072

9. DATE OF FIRST AUTHORISATION

20 November 2007

10. DATE OF REVISION OF THE TEXT

December 2020

Approved 29 December 2020