PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
0.8, 2.2, 5.0 L HDPE bottles and 12 L HDPE container

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasimec Duo 50 mg/ml + 1 mg/ml Oral Suspension for Sheep

triclabendazole, ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml of Fasimec Duo contains 1 mg ivermectin and 50 mg triclabendazole.

Preservatives:

Methyl parahydroxybenzoate	1.4 mg/ml
Propyl parahydroxybenzoate	0.5 mg/ml
Benzyl alcohol	5.0 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension
Cream coloured aqueous oral suspension.

4. PACKAGE SIZE

0.8, 2.2, 5.0 and 12 litre

5. TARGET SPECIES

For sheep over 3 months of age.

6. INDICATION(S)

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*

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

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 over-dosing.

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

8. WITHDRAWAL PERIOD

Withdrawal period: 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

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.
- Under dosing which may be due to underestimation of bodyweight, misadministration of the product or lack of calibration of the dosing device (if any)

10. EXPIRY DATE

Use by end: *"EXP{month/year}"*
Once opened, use by __/__/__

11. SPECIAL STORAGE CONDITIONS

Store the product in closed original containers.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

UK, ES: To be supplied only on veterinary prescription.
IE: *LM*

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4072

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Fasimec Duo 50 mg/ml + 1 mg/ml Oral Suspension for Sheep

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
United Kingdom

Manufacturer for the batch release:
Argenta Dundee Limited
Kinnoull Road
Dunsinane Industrial Estate
Dundee
DD2 3XR
United Kingdom

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasimec Duo 50 mg/ml + 1 mg/ml Oral Suspension for Sheep

triclabendazole, ivermectin

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

A cream coloured aqueous suspension for oral administration containing 1 mg/ml ivermectin and 50 mg/ml triclabendazole.

Preservatives:	
Methyl parahydroxybenzoate	1.4 mg/ml
Propyl parahydroxybenzoate	0.5 mg/ml
Benzyl alcohol	5.0 mg/ml

4. INDICATION(S)

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*

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

None known. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

For sheep over 3 months of age.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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	Number of doses per pack
20 – 25 kg	5 ml	
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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	

9. ADVICE ON CORRECT ADMINISTRATION

Shake the container thoroughly before use.
Clean drenching equipment before and after use.

10. WITHDRAWAL PERIOD

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store the product in closed original container.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "*EXP*". Once opened, use within 1 year. After opening the container for the first time, calculate the discard date which is the opening date plus 1 year. This discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Animals must not be slaughtered for human consumption during treatment.

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.

Interaction with other medicinal products and other forms of interaction
No data available

Overdose
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.

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

Other precautions
Ivermectin is very toxic to aquatic organisms and dung insects.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

December 2020

15. OTHER INFORMATION

Authorised pack sizes: 0.8, 2.2, 5.0 L and 12 L. Not all pack sizes may be marketed.

Approved 29 December 2020