PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
1, 2.5, 3, 5 L HDPE bottles and 10 L HDPE container
Carton/label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribamec Duo 50 mg/ml & 1 mg/ml Oral Suspension for Sheep

triclabendazole, ivermectin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 50 mg triclabendazole and 1 mg ivermectin..

Preservatives:

Methyl parahydroxybenzoate	1.2 mg/ml
Propyl parahydroxybenzoate	0.5 mg/ml
Benzyl alcohol	27.0 mg/ml

3. PHARMACEUTICAL FORM

Oral suspension

4. PACKAGE SIZE

1L, 2.5L, 3L, 5L and 10 L.

5. TARGET SPECIES

For sheep over 3 months of age.

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) 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.

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

Read the package leaflet before use.

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.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 1 year
Once opened, use by…..

11. SPECIAL STORAGE CONDITIONS

Do not store above 30ºC
Store in the original container in order to protect from light.
Protect from frost.

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

Disposal: read package leaflet

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

For animal treatment only.
To be supplied only on veterinary prescription.
POM-VPS

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

EU Pharmaceuticals Ltd.
37 Geraldine Road
London
SW18 2NR

16. MARKETING AUTHORISATION NUMBER

Vm 39787/4134

17. MANUFACTURER'S BATCH NUMBER

BN:

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Tribamec 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:

EU Pharmaceuticals Ltd.,
37 Geraldine Road
London
SW18 2NR
United Kingdom

Manufacturer responsible for the batch release:

Chanelle Pharmaceuticals Manufacturing Limited, Loughrea, Co. Galway, Ireland.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Tribamec 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 50 mg/ml triclabendazole and 1 mg/ml ivermectin.

Preservatives:

Methyl parahydroxybenzoate	1.2 mg/ml
Propyl parahydroxybenzoate	0.5 mg/ml
Benzyl alcohol	27.0 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
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

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. Protect from light and do not store above 30ºC.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after "*EXP*". The expiry date refers to the last day of the month. 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)

Special warnings for each target species
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* and *Haemonchus contortus* and increasing resistance to triclabendazole has been reported in *Fasciola* species in sheep in a number of countries including in Europe. Therefore, the use of this product should be based upon local (regional, farm) epidemiological information about susceptibility of the target parasites and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions for use in animals:
Animals must not be slaughtered for human consumption during treatment.

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.

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

- People with known hypersensitivity to active substances or parabens should avoid contact with the product.
- This product may cause skin and eye irritation.
- Avoid direct contact with the skin and eyes.
- 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 any exposed skin before meals and after work.

Other precautions
Ivermectin is highly toxic to aquatic organisms, and ivermectin and triclabendazole are highly toxic to dung flies and beetles. Long-term effects on dung insects caused by continuous or repeated use cannot be excluded.

The risk to aquatic ecosystems and dung fauna can be reduced by avoiding too frequent and repeated use of this product and other products of the same anthelmintic class in cattle, sheep and pigs. Therefore, the repetition of treatment in a pasture during a season should be performed only in the absence of alternative treatment and on veterinary advice.

Interaction with other medicinal products and other forms of interaction
In the absence of compatibility studies, this veterinary medicinal product should not be mixed with any other veterinary medicinal product.

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.

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

15. OTHER INFORMATION

Authorised pack sizes: 1L, 2.5L, 3L, 5L and 10 L.
Not all pack sizes may be marketed.
To be supplied only on veterinary prescription.
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Approved 16 November 2021