PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {0.8 L bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combinex 50 mg/ml + 37.5 mg/ml oral suspension for sheep

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substances:

Triclabendazole	50 mg
Levamisole hydrochloride	37.5 mg

3. PACKAGE SIZE

0.8 L

4. TARGET SPECIES

Sheep

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.

Do not mix with other veterinary medicinal products. The veterinary medicinal product is given as an oral liquid and is suitable for use through most types of automatic drenching gun.

7. WITHDRAWAL PERIODS

Withdrawal period:

Animals must not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 56 days from the last treatment.

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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 1 year.

Once opened, use by:

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C
Protect from frost.
Protect from light.

Store

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

14. MARKETING AUTHORISATION NUMBER

UK(NI): Vm 52127/3038

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET: 0.8 L bottles

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Combinex 50 mg/ml + 37.5 mg/ml oral suspension for sheep

2. Composition

Each ml contains:

Active substances:

Triclabendazole	50 mg
Levamisole hydrochloride	37.5 mg

Excipients:

Methyl hydroxybenzoate	0.95 mg
Propyl hydroxybenzoate	0.35 mg
Benzoic Acid	1 mg
Sodium metabisulphite	2.5 mg
Disodium edetate	1.3 mg

A cream coloured aqueous suspension.

3. Target species

Sheep

4. Indications for use

For the treatment and control of parasitic bronchitis, parasitic gastro-enteritis and fascioliasis in sheep. When used at the recommended dose rate, the veterinary medicinal product is effective against mature and developing immature stages of levamisole susceptible *Haemonchus, Ostertagia, Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Chabertia* and *Oesophagostomum* species in the gastro-intestinal tract, and *Dictyocaulus* spp in the lungs. It is also effective against all stages of Triclabendazole susceptible *Fasciola hepatica* from two day old early immature to adult fluke, and so is indicated against both acute and chronic fascioliasis.

5. Contraindications

None.

6. Special warnings

Special warnings:
Efficacy of this veterinary medicinal product against roundworms is reduced if levamisole resistant strains are present. Efficacy of this veterinary medicinal product against liver fluke is reduced if triclabendazole resistant strains are present.

Special precautions for safe use in the target species:
Assess bodyweight as accurately as possible before calculating the dosage.
Animals must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.
Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your Veterinary Adviser.
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 body weight, 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 levamisole has been reported in *Teladorsagia*, *Cooperia* and *Trichostrongylus* species in sheep in a number of countries, including ones in the EU. There are reports of resistance in *Haemonchus* in sheep outside the EU. Resistance to triclabendazole has been reported in *Fasciola* species in small ruminants in a number of countries including ones in the EU. Therefore the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
When using, do not eat, drink or smoke.
Wash splashes from eyes and skin immediately. Take off immediately any contaminated clothing.
Wash hands and exposed skin before meals and after work.
Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the veterinary medicinal product, or sore mouth/throat or fever occurs shortly afterwards, then medical advice should be sought immediately.

Special precautions for the protection of the environment:
None

Pregnancy and lactation
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose
At higher doses transient side effects due to levamisole may occur (i.e. salivation and dose dependent muscle tremors).

Major incompatibilities:
None known.

7. Adverse events

Target species: Sheep

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersalivation Muscle tremor

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes and method of administration

Recommended dose rate:

10mg/kg triclabendazole, 7.5mg/kg levamisole hydrochloride i.e. 1ml of this veterinary medicinal product per 5kg bodyweight.

<Pictogram of a Sheep>	<Pictogram of measuring device>	<0.8L>
Animal Weight	Dose of COMBINEX ORAL SUSPENSION FOR SHEEP	Number of doses per pack
Up to 10 kg	2 ml	400
11 – 15 kg	3 ml	266
16 – 20 kg	4 ml	200
21 – 30 kg	6 ml	133
31 – 40 kg	8 ml	100
41 – 50 kg	10 ml	80
51 – 60 kg	12 ml	66
61 – 70 kg	14 ml	57
71 – 80 kg	16 ml	50
81 – 90 kg	18 ml	44
91 – 100 kg	20 ml	40

For each additional 10kg bodyweight add 2ml to dose.

9. Advice on correct administration

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Do not mix with other products. The veterinary medicinal product is given as an oral liquid and is suitable for use through most types of automatic drenching gun.

Unscrew the blue cap from the container and replace it with the white spigot cap provided. If using an automatic drenching-gun, attach the tube from the application device to the white spigot cap. After use, remove the white spigot cap and close the container with the blue cap.

The veterinary medicinal product can safely be given to young or pregnant sheep. (For dairy sheep, see ‘Special precautions for safe use in the target species’).

Shake the container thoroughly before use.

Use undiluted product from the original container. Clean drenching equipment before and after use.

10. Withdrawal periods

Animals must not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 56 days from the last treatment.

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.

Do not store above 25 °C.
Protect from frost.
Protect from light

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.

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

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as it may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK(NI): Vm 52127/3038

1, 2.5 or 5 litre natural HDPE bottles. Heat sealed polyethylene closure. White HDPE screw cap.

0.8, 2.2 or 5 litre white HDPE bottles with blue induction seal cap.

12 or 21 litre white HDPE bottles with blue HDPE closure.

Not all pack sizes may be marketed.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

PV.XXI@elancoah.com
Tel: +443308221732

Manufacturer responsible for batch release:

Additional site for UK (NI):
Elanco France S.A.S.
26 Rue de la Chapelle
68330 Huningue
France

17. Other information

POM-VPS

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet: 2.2 L and 5 L bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combinex 50 mg/ml + 37.5 mg/ml oral suspension for Sheep

2. COMPOSITION

Each ml contains:

Active substances:

Triclabendazole	50 mg
Levamisole hydrochloride	37.5 mg

Excipients:

Methyl hydroxybenzoate	0.95 mg
Propyl hydroxybenzoate	0.35 mg
Benzoic Acid	1 mg
Sodium metabisulphite	2.5 mg
Disodium edetate	1.3 mg

A cream coloured aqueous suspension.

3. PACKAGE SIZE

2.2 L
5.0 L

4. TARGET SPECIES

Sheep

5. INDICATIONS FOR USE

Indications for use

For the treatment and control of parasitic bronchitis, parasitic gastro-enteritis and fascioliasis in sheep. When used at the recommended dose rate, the veterinary medicinal product is effective against mature and developing immature stages of levamisole susceptible *Haemonchus, Ostertagia, Trichostrongylus, Cooperia, Nematodirus, Bunostomum, Chabertia* and *Oesophagostomum* species in the gastro-intestinal tract, and *Dictyocaulus* spp in the lungs. It is also effective against all stages of Triclabendazole susceptible *Fasciola hepatica* from two day old early immature to adult fluke, and so is indicated against both acute and chronic fascioliasis.

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
Efficacy of this veterinary medicinal product against roundworms is reduced if levamisole resistant strains are present. Efficacy of this veterinary medicinal product against liver fluke is reduced if triclabendazole resistant strains are present.

Special precautions for safe use in the target species:
Assess bodyweight as accurately as possible before calculating the dosage.
Animals must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.
Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your Veterinary Adviser.
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 body weight, 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 levamisole has been reported in *Teladorsagia*, *Cooperia* and *Trichostrongylus* species in sheep in a number of countries, including ones in the EU. There are reports of resistance in *Haemonchus* in sheep outside the EU. Resistance to triclabendazole has been reported in *Fasciola* species in small ruminants in a number of countries including ones in the EU. Therefore the use of this veterinary medicinal product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and trematodes and recommendations on how to limit further selection for resistance to anthelmintics.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
When using, do not eat, drink or smoke.
Wash splashes from eyes and skin immediately. Take off immediately any contaminated clothing.

Wash hands and exposed skin before meals and after work.
Levamisole can cause idiosyncratic reactions and serious blood disorders in a very small number of people. If symptoms such as dizziness, nausea, vomiting or abdominal discomfort are experienced when using the veterinary medicinal product, or sore mouth/throat or fever occurs shortly afterwards, then medical advice should be sought immediately.

Special precautions for the protection of the environment:
None

Pregnancy and lactation
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose
At higher doses transient side effects due to levamisole may occur (i.e. salivation and dose dependent muscle tremors).

Major incompatibilities:
None known.

8. ADVERSE EVENTS

Adverse events

Target species: Sheep

Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersalivation Muscle tremor

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Recommended dose rate:

10mg/kg triclabendazole, 7.5mg/kg levamisole hydrochloride i.e. 1ml of this veterinary medicinal product per 5kg bodyweight.

<Pictogram of a Sheep>	<Pictogram of measuring device>	<2.2 L>
Animal Weight	Dose of COMBINEX ORAL SUPENSION FOR SHEEP	Number of doses per pack
Up to 10 kg	2 ml	1100
11 – 15 kg	3 ml	733
16 – 20 kg	4 ml	550
21 – 30 kg	6 ml	366
31 – 40 kg	8 ml	275
41 – 50 kg	10 ml	220
51 – 60 kg	12 ml	183
61 – 70 kg	14 ml	157
71 – 80 kg	16 ml	137
81 – 90 kg	18 ml	122
91 – 100 kg	20 ml	110

<Pictogram of a sheep> Animal Weight	<Pictogram of measuring device> Dose of COMBINEX ORAL SUSPENSION FOR SHEEP	<5.0 L> Number of doses per pack
Up to 10 kg	2 ml	2500
11 – 15 kg	3 ml	1666
16 – 20 kg	4 ml	1250
21 – 30 kg	6 ml	833
31 – 40 kg	8 ml	625
41 – 50 kg	10 ml	500
51 – 60 kg	12 ml	416
61 – 70 kg	14 ml	357
71 – 80 kg	16 ml	312
81 – 90 kg	18 ml	277
91 – 100 kg	20 ml	250

For each additional 10kg bodyweight add 2ml to dose.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

Do not mix with other products. The veterinary medicinal product is given as an oral liquid and is suitable for use through most types of automatic drenching gun.
Unscrew the blue cap from the container and replace it with the white spigot cap provided. If using an automatic drenching-gun, attach the tube from the application device to the white spigot cap. After use, remove the white spigot cap and close the container with the blue cap.

The veterinary medicinal product can safely be given to young or pregnant

sheep. (For dairy sheep, see 'Special precautions for safe use in the target species').

Shake the container thoroughly before use.

Use undiluted product from the original container. Clean drenching equipment before and after use.

11. WITHDRAWAL PERIODS

Withdrawal periods

Animals must not be slaughtered for human consumption during treatment. Sheep may be slaughtered for human consumption only after 56 days from the last treatment.

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.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C
Protect from frost.
Protect from light

Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

This veterinary medicinal product should not enter water courses as it may be dangerous for fish and other aquatic organisms.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK(NI): Vm 52127/3038

Pack sizes

1, 2.5 or 5 litre natural HDPE bottles. Heat sealed polyethylene closure. White HDPE screw cap.

0.8, 2.2 or 5 litre white HDPE bottles with blue induction seal cap.

12 or 21 litre white HDPE bottles with blue HDPE closure.

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco GmbH
Heinz-Lohmann Strasse 4
Groden
27472 Cuxhaven
Germany

PV.XXI@elancoah.com
Tel: +443308221732

Manufacturer responsible for batch release:
Additional site for UK (NI):
Elanco France S.A.S.
26 Rue de la Chapelle
68330 Huningue
France

18. OTHER INFORMATION

Other information

POM-VPS

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

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

Once opened, use by:

21. BATCH NUMBER

Lot {number}

Approved 06 October 2026
Gavin Hall