PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Front and Back Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combinex Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 5% w/v triclabendazole and 3.75% w/v levamisole hydrochloride.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

0.8 litre white natural HDPE bottles
5.0 litre white natural HDPE bottles
2.2 litre white natural HDPE bottles

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Combined fluke and worm drench for sheep.

For the treatment and control of gastrointestinal worms, lungworm and liver fluke from
2 day old early immature to adult forms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and administration:
Do not mix with other products. COMBINEX SHEEP is given as an oral liquid and is suitable for use through most types of automatic drenching gun. COMBINEX SHEEP can safely be given to young or pregnant sheep. (For dairy sheep, see Contra-indications, warnings etc.)

Recommended dose rate:
10mg/kg triclabendazole, 7.5mg/kg levamisole hydrochloride i.e. 1ml COMBINEX SHEEP per 5kg bodyweight. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

<Pictogram of a Sheep> <Pictogram of measuring device> <0.8L> Animal Weight	Dose of COMBINEX SHEEP	Number of does 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

<Pictogram of a Sheep> <Pictogram of measuring device> <5.0L> Animal Weight	Dose of COMBINEX SHEEP	Number of does 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
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

<Pictogram of a Sheep> <Pictogram of measuring device> <2.2L>

Animal Weight	Dose of COMBINEX SHEEP	Number of does 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

For each additional 10kg bodyweight add 2ml to dose

Precautions
Shake the container thoroughly before use.

Use undiluted product from the original container.

Clean drenching equipment before and after use.

8. WITHDRAWAL PERIOD (S)

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.

9. CONTRA-INDICATIONS, WARNINGS ETC

When the product is used at the recommended dose rate and animals are not overly stressed, side effects are rare. At higher doses, transient side effects due to levamisole may occur (i.e. salivation and muscle tremors).

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. Assess bodyweight as accurately as possible before calculating the dosage.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with your Veterinary Advisor.

Animals must not be treated within a period of 14 days before or after treatment with organophosphorus compounds.

Anthelmintics are agents that destroy or result in the expulsion of susceptible parasitic worms. Parasite resistance to a particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.

Combinex contains the anthelmintic Triclabendazole.

Fluke (Fasciola hepatica) resistance to triclabendazole has been identified and losses associated with resistant strains of fluke in sheep flocks treated with triclabendazole can be significant.

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 triclabendazole has been reported in Fasciola, species in small ruminants. Therefore theuse of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

If signs of fascioliasis continue after treatment with COMBINEX SHEEP, DO NOT REPEAT THE DOSE and do not dose with other products containing triclabendazole.
Seek veterinary advice. If resistance is suspected or confirmed, you should change active ingredient on veterinary advice.
• Efficacy of this product against liver fluke is reduced if triclabendazole-resistant strains are present.
• Efficacy of this product against roundworms is reduced if levamisole-resistant strains are present.
• When using do not eat, drink or smoke.
• Wash hands and exposed skin before meals and after work.
• Wash splashes from eyes and skin immediately.
• Take off immediately any contaminated clothing.
• Dangerous to aquatic life.
• Do not contaminate ponds, waterways or ditches with the product or used container.

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 administering the product, or sore mouth/throat or fever occur shortly afterward, then medical advice should be sought immediately.

10. EXPIRY DATE

Exp:

Date of discard:

Following withdrawal of the first dose, use the product within 1 year.

11. SPECIAL STORAGE CONDITIONS

Protect from freezing

Do not store above 25˚C

Protect from light

STORE 

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

Dispose of any unused product and empty containers in accordance with guidelines from your local waste regulation authority.

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

For animal treatment only

To be supplied only on veterinary prescription.

POM-VPS products may only be supplied in accordance with a prescription from a Registered Qualified Person (RQP) as follows: (i) a registered veterinary surgeon; (ii) a registered pharmacist, or (iii) a registered suitably qualified person (SQP).

POM-VPS

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
UK

Tel: 01256 353131

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4084

17. MANUFACTURER'S BATCH NUMBER

Bn:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combinex Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 5% w/v triclabendazole and 3.75% w/v levamisole hydrochloride.

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

This value multi-pack contains:
2 x 5L Combinex Sheep
1 x 2.2L Combinex Sheep
1 x Applicator Gun

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Combined fluke and worm drench for sheep.

For the treatment and control of gastrointestinal worms, lungworm and liver fluke from 2 day old early immature to adult forms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and administration:
Do not mix with other products.

COMBINEX SHEEP is given as an oral liquid and is suitable for use through most types of automatic drenching gun.

COMBINEX SHEEP can safely be given to young or pregnant sheep. (For dairy sheep, see Contra-indications, warnings etc.)

Recommended dose rate:
10mg/kg triclabendazole, 7.5mg/kg levamisole hydrochloride i.e. 1ml COMBINEX

SHEEP per 5kg bodyweight. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

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

<Pictogram of a sheep> <Pictogram of measuring device> <Pictogram of bottles 5.0L, 5.0L, 2.2L> Animal Weight	Dose of COMBINEX SHEEP	Number of does per multi pack
Up to 10 kg	2 ml	6100
11 – 15 kg	3 ml	4066
16 – 20 kg	4 ml	3050
21 – 30 kg	6 ml	2033
31 – 40 kg	8 ml	1525
41 – 50 kg	10 ml	1220
51 – 60 kg	12 ml	1016
61 – 70 kg	14 ml	871
71 – 80 kg	16 ml	762
81 – 90 kg	18 ml	677
91 – 100 kg	20 ml	610

For each additional 10kg bodyweight add 2ml to dose

Precautions
Shake the container thoroughly before use.

Use undiluted product from the original container.

Clean drenching equipment before and after use.

8. WITHDRAWAL PERIOD (S)

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.

9. CONTRA-INDICATIONS, WARNINGS ETC

When the product is used at the recommended dose rate and animals are not overly
stressed, side effects are rare. At higher doses, transient side effects due to levamisole
may occur (i.e. salivation and muscle tremors).

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. Assess bodyweight as accurately as possible before
calculating the dosage.

Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk,
dosing programmes should be discussed with your Veterinary Advisor.

Animals must not be treated within a period of 14 days before or after treatment with
organophosphorus compounds.

Anthelmintics are agents that destroy or result in the expulsion of susceptible parasitic worms. Parasite resistance to a particular class of anthelmintic may develop following frequent, repeated use of an anthelmintic of that class. To reduce this risk, dosing programmes should be discussed with a veterinary surgeon.
Combinex contains the anthelmintic Triclabendazole.
Fluke (Fasciola hepatica) resistance to triclabendazole has been identified and losses
associated with resistant strains of fluke in sheep flocks treated with triclabendazole can
be significant.

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 triclabendazole has been reported in Fasciola, species in small ruminants. Therefore theuse of this product should be based on local (regional, farm) epidemiological information about susceptibility of nematodes and recommendations on how to limit further selection for resistance to anthelmintics.

If signs of fascioliasis continue after treatment with COMBINEX SHEEP, DO NOT REPEAT THE DOSE and do not dose with other products containing triclabendazole.
Seek veterinary advice. If resistance is suspected or confirmed, you should change active ingredient on veterinary advice.
• Efficacy of this product against liver fluke is reduced if triclabendazole-resistant strains are present.
• Efficacy of this product against roundworms is reduced if levamisole-resistant strains are present.
• When using do not eat, drink or smoke.
• Wash hands and exposed skin before meals and after work.
• Wash splashes from eyes and skin immediately.
• Take off immediately any contaminated clothing.
• Dangerous to aquatic life.
• Do not contaminate ponds, waterways or ditches with the product or used container.

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 administering the product, or sore mouth/throat or fever occur shortly afterward, then medical advice should be sought immediately.

10. EXPIRY DATE

Exp:

Date of discard:

Following withdrawal of the first dose, use the product within 1 year.

11. SPECIAL STORAGE CONDITIONS

Protect from freezing

Do not store above 25˚C

Protect from light

STORE 

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

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

For animal treatment only

To be supplied only on veterinary prescription.

POM-VPS products may only be supplied in accordance with a prescription from a Registered Qualified Person (RQP) as follows: (i) a registered veterinary surgeon; (ii) a registered pharmacist, or (iii) a registered suitably qualified person (SQP).

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

Keep out of the reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MA Holder:
Elanco Europe Ltd.
Form 2, Bartley Way
Bartley Wood Business Park
Hook
RG27 9XA
UK

Tel: 01256 353131

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4084

17. MANUFACTURER'S BATCH NUMBER

Bn:

Approved 18 December 2020