SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:

Triclabendazole	50 mg
Levamisole hydrochloride	37.5 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl hydroxybenzoate	0.95 mg
Propyl hydroxybenzoate	0.35 mg
Benzoic Acid	1 mg
Sodium metabisulphite	2.5 mg
Disodium edetate	1.3 mg
Macrogol	
Sodium chloride	
Silica, Colloidal anhydrous	
Citric acid monohydrate	
Simeticone (based on dimethypolysiloxane, water and silica)	
Sodium hydroxide (for pH adjustment)	
Water, deionized	

A cream coloured aqueous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Sheep.

3.2 Indications for use for each target species

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.

3.3 Contraindications

None.

3.4 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.

3.5 Special precautions for use

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:

Not applicable.

3.6 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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy and lactation.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

Do not mix with other veterinary medicinal products.
Suitable for use through most types of automatic drenching gun.

Shake container thoroughly before use and use undiluted product from the original container.
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.

It can be safely administered to young or pregnant sheep.

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

Clean drenching equipment before and after use.

Recommended dose rate: 7.5 mg levamisole hydrochloride/kg and 10 mg triclabendazole/kg. This is equivalent to 1 ml of the product per 5 kg bodyweight.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

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

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QP52AE51

4.2 Pharmacodynamics

Levamisole is an anthelmintic acting by causing muscular paralysis and expulsion of the nematode. Triclabendazole is a flukicide, highly active against all life stages of Fasciola from 2 days.

4.3 Pharmacokinetics

Majority of triclabendazole oral dose in rats, sheep, goats and rabbits is eliminated in faeces after 6-10 days as unchanged drug or products of biliary excretion.
Urinary excretion is minimal. Sulphone, sulphoxide, ketone and 4-hydroxy triclabendazole derivatives are the main metabolites identified in plasma. Levamisole is rapidly absorbed after oral administration, is extensively metabolised and by 8 days after application excretion is virtually complete.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 1 year

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

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.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

The 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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH

7. MARKETING AUTHORISATION NUMBER

Vm 52127/5103

8. DATE OF FIRST AUTHORISATION

13 August 1991

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

July 2026

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

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

Gavin Hall

Approved: 13 August 2026