PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Front and Back Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Combinex Cattle Oral Suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 12% w/v triclabendazole and 7.5% w/v levamisole hydrochloride

3. PHARMACEUTICAL FORM

Oral Suspension

4. PACKAGE SIZE

0.8 Litre
2.2 Litre

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Combined fluke and worm drench for cattle.

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and administration:

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

COMBINEX CATTLE can safely be given to young or pregnant cattle or cattle not producing milk for human consumption. (For dairy cattle see Contra-indications, Warnings, etc).

Recommended dose rate:12 mg/kg triclabendazole, 7.5 mg/kg levamisole hydrochloride i.e. 1 ml **COMBINEX**

CATTLE per 10kg 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 cow >		<Pictogram of measuring device>	<0.8L>
Weight (kg) (approx)	(cwt)	Dose of **COMBINEX CATTLE**	Number of doses per pack
100 kg	2	**10 ml**	80
150 kg	3	**15 ml**	53
200 kg	4	**20 ml**	40
250 kg	5	**25 ml**	32
300 kg	6	**30 ml**	26
350 kg	7	**35 ml**	22
400 kg	8	**40 ml**	20
450 kg	9	**45 ml**	17
500 kg	10	**50 ml**	16
550 kg	11	**55 ml**	14
600 kg	12	**60 ml**	13
650 kg	13	**65 ml**	12
700 kg	14	**70 ml**	11
750 kg	15	**75 ml**	10

For each additional 50 kg bodyweight add 5 ml to the dose.

<Pictogram of a cow >		<Pictogram of measuring device>	<2.2L>
Weight (kg) (approx)	(cwt)	Dose of **COMBINEX CATTLE**	Number of doses per pack
100 kg	2	**10 ml**	220
150 kg	3	**15 ml**	146
200 kg	4	**20 ml**	110
250 kg	5	**25 ml**	88
300 kg	6	**30 ml**	73
350 kg	7	**35 ml**	62

400 kg	8	**40 ml**	55
450 kg	9	**45 ml**	48
500 kg	10	**50 ml**	44
550 kg	11	**55 ml**	40
600 kg	12	**60 ml**	36
650 kg	13	**65 ml**	33
700 kg	14	**70 ml**	31
750 kg	15	**75 ml**	26

For each additional 50 kg bodyweight add 5 ml to the dose.

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

8. WITHDRAWAL PERIOD (S)

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

Not authorised for use in cattle producing milk for human consumption including during the dry period. Do not use during the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

9. CONTRA-INDICATIONS, WARNINGS ETC.:

Precautions:

Shake thoroughly before use.

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

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 dosages, transient side effects due to levamisole may occur (i.e. salivation and muscle tremors).
- Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 56 days from the last treatment.
- Not authorised for use in cattle producing milk for human consumption including during the dry period. Do not use during the last trimester of pregnancy in heifers which are 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.

Resistance to levamisole has been reported in **Teladorsagia** species in cattle in developed countries such as New Zealand. Therefore the use 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. 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

Efficacy of this product against roundworms is reduced if levamisole resistant strains are present. Efficacy of this product against liver fluke is reduced if triclabendazole resistant strains are present.

- Wash hands and exposed skin before meals and after work.
- When using do not eat, drink or smoke.
- Wash splashes from eyes and skin immediately.
- Take off immediately all 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:
Following withdrawal of the first dose, use the product within 1 year. Date of discard:

11. SPECIAL STORAGE CONDITIONS

Protect from freezing
Do not store above 25°C
Protect from light

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

A. Dangerous to aquatic life.
B. Do not contaminate ponds, waterways or ditches with the product or used

Dispose of any unused product and empty containers in accordance with guidance 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

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

Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4083

17. MANUFACTURER'S BATCH NUMBER

Bn.:

Approved 25 September 2020