PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

FRONT AND BACK LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 10% Oral Suspension for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Containing 10% w/v triclabendazole.

3. PHARMACEUTICAL FORM

Oral Suspension
A cream coloured aqueous suspension for oral administration.

4. PACKAGE SIZE

0.8 Litre
2.2 Litre
5.0 Litre

5. TARGET SPECIES

Cattle

6. INDICATION(S)

Indication
When used at the recommended dose rate **FASINEX 10%** is effective for the treatment and control of liver fluke (*Fasciola hepatica)* infection in cattle caused by all stages of triclabendazole susceptible F. hepatica from 2 week old early immature to adult forms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and Administration
FASINEX 10% is given as an oral drench and is suitable for use through most types of automatic drenching guns.
FASINEX 10% can safely be given to young, pregnant or stressed cattle, cattle not producing milk intended for human consumption or dry cattle. For lactating dairy cattle see under **Contra-Indications, warnings etc..**

Recommended dose rate:
12mg triclabendazole/kg bodyweight i.e. 6ml **FASINEX 10%** per 50kg bodyweight.

<Pictogram of a cow >	<Pictogram of measuring device>	**<0.8L>**
Animal weight	Dose of **FASINEX 10%**	Number of doses per pack
Up to 100 kg	**12 ml**	66
150 kg	**18 ml**	44
200 kg	**24 ml**	33
250 kg	**30 ml**	26
300 kg	**36 ml**	22
350 kg	**42 ml**	19
400 kg	**48ml**	16
450 kg	**54 ml**	14
500 kg	**60 ml**	13
550 kg	**66 ml**	12
600 kg	**72 ml**	11
650 kg	**78ml**	10
700 kg	**84 ml**	9
750 kg	**90 ml**	8

<Pictogram of a cow >	<Pictogram of measuring device>	**<2.2L>**
Animal weight per pack	Dose of **FASINEX 10%**	Number of doses
Up to 100 kg	**12 ml**	183
150 kg	**18 ml**	122
200 kg	**24 ml**	91
250 kg	**30 ml**	73
300 kg	**36 ml**	61
350 kg	**42 ml**	52
400 kg	**48 ml**	45
450 kg	**54 ml**	40
500 kg	**60 ml**	36

550 kg	**66 ml**	33
600 kg	**72 ml**	30
650 kg	**78ml**	28
700 kg	**84 ml**	26
750 kg	**90 ml**	24

<Pictogram of a cow > <Pictogram of measuring **<5.0L>**

Animal weight per pack	Dose of **FASINEX 10%**	Number of doses
Up to 100 kg	**12 ml**	416
150 kg	**18 ml**	227
200 kg	**24 ml**	208
250 kg	**30 ml**	166
300 kg	**36 ml**	138
350 kg	**42 ml**	119
400 kg	**48ml**	104
450 kg	**54 ml**	92
500 kg	**60 ml**	83
550 kg	**66 ml**	75
600 kg	**72 ml**	69
650 kg	**78ml**	64
700 kg	**84 ml**	59
750 kg	**90 ml**	55

Dosing Programme

Routine herd treatment (high risk fluke areas):

As a guide, dose all cattle exposed to fluke infected pastures preventatively at regular intervals of 10 weeks from March/April through to October/November. In situations where stock are outwintered, a dose in January may also be required. All animals grazing the pasture should be treated at these times. Veterinary

advice should be sought with regard to specific preventative dosing regimes.

Routine herd treatment (moderate risk fluke areas):
Dose all cattle exposed to fluke infected pastures at regular intervals of 10 weeks throughout the fluke season, usually from September to January/February. Milking cows should be dosed at drying off. An additional preventative treatment in the spring will assist in reducing the amount of new infection on pasture in the following autumn.

Bought in cattle:
Cattle bought in from fluke risk areas should be treated before joining the main herd.

In wintering: Where cattle are in wintered, a single dose of **FASINEX 10%** should be given at or shortly after housing.

Treatment of sub-acute and acute outbreaks:
Affected cattle, usually young animals, should be treated immediately after diagnosis is reached.
Veterinary advice should be sought for subsequent dosing intervals.

8. WITHDRAWAL PERIOD (S)

Withdrawal Periods
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 in the last trimester of pregnancy in heifers which are intended to produce milk for human consumption.

9. CONTRAINDICATIONS, WARNING(S), IF NECESSARY

Contra-indications, warnings etc.
To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked. 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 over-dosing. 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 triclabendazole has been reported in *Fasciola hepatica* in cattle in a number of countries including ones in the EU. Therefore the use of this product should be based on local epidemiological information about susceptibility of F. hepatica and recommendations on how to limit further selection for resistance to anthelmintics. Dosing programmes should be discussed with your Veterinary Adviser. Efficacy of this product against liver fluke is reduced if triclabendazole resistant strains are present. Not authorised for use in cattle producing milk for human consumption including during the dry period.

Operator Warnings
Do not eat, drink or smoke whilst handling the product.

Wash hands and exposed skin before meals and after work. In case of accidental spillage onto skin or eyes, wash immediately with water. Take off any contaminated clothing immediately.

Do not contaminate ponds, waterways or ditches with the product or used

container. Clean drenching equipment before and after use.

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

For full details of Dosing Programmes, Contraindications, warnings etc. & User Warnings, please read the full label.

Protect from freezing.

Protect from light.

Shake thoroughly before use.

10. EXPIRY DATE

EXP {month/year}

Date of discard:

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original

container. Do not store above 25°C.

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 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

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"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.,
Lilly House,
Priestley Road,
Basingstoke,
Hampshire,
RG24 9NL,
UK.

Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4004

17. MANUFACTURER'S BATCH NUMBER

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

Approved 06 July 2017