

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - Bottle – Front
and Back Label**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FASINEX 100 10% (w/v) Oral suspension for cattle & sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

contains 10% w/v triclabendazole

3. PHARMACEUTICAL FORM

Cream coloured aqueous suspension

4. PACKAGE SIZE

5L

5. TARGET SPECIES

Sheep and Cattle

For animal treatment only

6. INDICATION(S)

<Front Label>

For the treatment and control of liver fluke in sheep from 2 days old early immature to adult forms, and in cattle from 2 week old early immature to adult forms.

<Back Label>

Fasinex® 100 is for the control of liver fluke infection in cattle and sheep caused by all stages of triclabendazole susceptible *Fasciola hepatica*.

In Sheep from 2 days old early immature to adult forms. In Cattle from 2 week old early immature to adult forms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

<Dosage and Administration heading>

Fasinex® 100 is given orally after thorough shaking of the suspension and is suitable for use through most types of automatic drenching guns. Read the label before use.

- Routine herd/flock treatment (high risk fluke areas):

As a guide, dose all animals exposed to fluke infested pastures preventatively at regular intervals of 10 weeks from March/April through to October/November. In situations where animals are outwintered, a dose in January may also be required. All animals grazing the pasture should be treated at these times. Any bought-in animals should be dosed before joining the main herd/flock. Veterinary advice should be sought with regards to specific preventative dosing regimes.

- Routine herd/flock treatment (moderate risk fluke areas):

Dose all animals exposed to fluke infested pastures at regular intervals of 10 weeks throughout the fluke season, usually from September to January/February. An additional preventative treatment in the spring will assist in reducing the amount of new infection on pasture in the following autumn. Animals bought-in from fluke risk areas should be treated before joining the main herd/flock.

- Recommended dose rate:

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

To reduce the risk of parasite resistance, dosing programmes should be discussed with a veterinary surgeon.

Cattle

12 mg triclabendazole/kg bodyweight i.e. 6 ml Fasinex® 100 per 50 kg bodyweight.

In wintering:

Where cattle are in wintered, a single dose of Fasinex® 100 should be given 2 weeks 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.

- Use during pregnancy and lactation:

Fasinex® 100 is neither embryotoxic nor teratogenic, and can be used in all stages of pregnancy and lactation in animals not producing milk for human consumption.

Not authorised for use in lactating animals producing milk for human consumption including during the dry period.

Sheep

10 mg triclabendazole/kg bodyweight i.e.1 ml Fasinex® 100 per 10 kg bodyweight.

Always dose to the heaviest member of the group.

Treatment of acute outbreaks:

The flock should be treated immediately after diagnosis is reached. Veterinary advice should be sought for subsequent dosing intervals.

<Dosing Table with pictograms of **cow**/measuring cylinder/5L bottle>

Animal Weight (kg)	Dose of FASINEX 100	Number of doses per pack
Up to 50 kg	6 ml	833
100 kg	12 ml	416
150 kg	18 ml	277
200 kg	24 ml	208
250 kg	30 ml	166
300 kg	36 ml	138
350 kg	42 ml	119
400 kg	48 ml	104

For each additional 50 kg add 6 ml

<Dosing Table with pictograms of **Sheep**/measuring cylinder/5L bottle>

Animal Weight (kg)	Dose of FASINEX 100	Number of doses per pack
Up to 10 kg	1 ml	5000
11 – 15 kg	1.5 ml	3333
16 - 20 kg	2 ml	2500
21 – 30 kg	3 ml	1666

31 – 40 kg	4 ml	1250
41 - 50 kg	5 ml	1000
51 – 60 kg	6 ml	833

For each additional 10 kg add 1 ml

8. WITHDRAWAL PERIOD

Cattle (meat and offal) – 56 days

Sheep (meat and offal) – 35 days

Animals must not be slaughtered for human consumption during treatment.

Not authorised for use in cattle and ewes 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. Do not use within 1 year prior to the first lambing in ewes intended to produce milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

<Back Label – towards bottle neck, Diagram of bottle closure>

FOR A PROPER CLOSURE, PRESS IN THE CENTRE OF THE LID

Shake thoroughly before use

<Heading – User Warnings:>

Do not eat, drink, or smoke while handling the product. Wash hands and exposed skin before meals and after work. In case of accidental spillage onto skin or in eyes, wash immediately with water. Take off any contaminated clothes immediately. Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements. The product or empty containers should not enter water courses as this may be dangerous for fish and other aquatic organisms. Use unaltered product from original container. Clean drenching equipment before and after use. Once opened, use within 12 months. Do not use after the expiry date.

<Heading – contraindications>

None Known

<Heading – Adverse reactions>

If you notice any serious effects or other effects not mentioned on this label, please inform your veterinary surgeon.

Fasinex® 100 contains triclabendazole. Resistance to triclabendazole has been reported in liver fluke (*Fasciola hepatica*) in cattle and sheep in a number of countries, including the 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.

If signs of fasciolosis continue after treatment with Fasinex® 100, 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.

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.

Under dosing, 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.

<Heading – Interactions>

None known.

Overdosage: Slight stumbling, depression and decreased appetite may be observed for 1 to 3 days after 15 to 20 times overdosing in sheep and after 12 times overdosing in cattle. There is no antidote.

10. EXPIRY DATE

end:

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

<Box with heading>

Date of discard

Protect from frost Store in tightly closed original container Protect from light.



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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE [Distribution category]

POM-
VPS

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 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

Manufacturer for the batch release:

Argenta Dundee Limited
Kinnoull Road
Dunsinane Industrial Estate
Dundee
DD2 3XR

MA Holder:
Elanco Europe Ltd.,
Lilly House
Priestley Road,
Basingstoke,
Hampshire,
RG24 9NL,
UK.
Tel: 01256 353131

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4005

17. MANUFACTURER'S BATCH NUMBER

Bn:

A handwritten signature in black ink, consisting of several vertical strokes followed by a long, sweeping horizontal stroke that curves upwards at the end.

Approved 06 July 2017