PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {Back/Front Bottles}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 5% w/v Oral Suspension
<Back and Front label – after product name>
for sheep

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains 5% w/v triclabendazole

3. PHARMACEUTICAL FORM

Oral suspension for sheep
A cream coloured aqueous suspension for oral administration containing 5% w/v Triclabendazole.

4. PACKAGE SIZE

5L

5. TARGET SPECIES

Sheep

6. INDICATION(S)

Front Label
For the treatment and control of liver fluke from 2 day old early immature to adult forms.
<Pictograms>
Showing the stages of Fluke life cycle.

Back Label
When used at the recommended dose rate
FASINEX 5% is effective for the treatment and control of liver fluke (Fasciola hepatica) infection in sheep caused by all stages of triclabendazole susceptible F. hepatica from 2 days old early immature to adult forms.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage and Administration
Do not mix with other products. FASINEX 5% is given as an oral drench and is suitable for use through most types of automatic drenching guns.
FASINEX 5% can safely be given to young, pregnant or stressed sheep. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
Recommended dose rate:

10 mg triclabendazole/kg bodyweight i.e. 1 ml FASINEX 5% per 5 kg bodyweight. For each additional 5 kg add 1 ml to the dose.
Dosing Programme
Routine flock treatment (high risk areas): As a guide, dose all sheep exposed to fluke infected pastures preventatively at regular intervals of 10 weeks from March/April through to October/November. A dose in January may also be required. All animals grazing the pasture should be treated at these times. Any bought-in sheep should be dosed before joining the main flock. Veterinary advice should be sought with regard to specific preventative dosing regimes.
Routine flock treatment (moderate risk fluke areas):
As a guide, dose all sheep exposed to fluke infected pasture 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. Any bought-in sheep should be dosed before joining the main flock.
Treatment of acute outbreaks: The flock should be treated immediately after diagnosis is reached. Veterinary advice should be sought for subsequent dosing intervals.
<Back Label – Dosae table with pictograms of Sheep, Measuring Cyclinder and Bottle>

Animal weight	Dose of FASINEX 5%	Number of doses per pack
10 kg	2 ml	2500
11 – 15 kg	3ml	1666
16 – 20 kg	4 ml	1250
21 – 25 kg	5 ml	1000
26 – 30 kg	6 ml	833
31 – 40 kg	8 ml	625
41 – 50 kg	10 ml	500
51 – 60 kg	12 ml	416

SHAKE THE COTAINER THOROUGHLY BEFORE USE

8. WITHDRAWAL PERIOD

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.

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

Operator Warnings
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.
Do not contaminate ponds, waterways or ditches with the product or used container.
Use unaltered from original container. Clean drenching equipment before and after use.

Contra-indications, Warnings etc.
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. FASINEX 5% 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 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 species in small ruminants in a number of countries including the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about the susceptibility of the Fasciola species and recommendations on how to limit further selection for resistance to anthelmintics.
If signs of fascioliasis continue after treatment with FASINEX 5%, 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.

The product can be used in pregnant ewes not producing milk for human consumption. Not authorised for use in ewes producing milk for human consumption including during the dry period.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Protect from freezing. Do not store above 25˚C. Store in tightly closed original container. Protect from light.
For animal treatment only.

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 IF APPLICABLE *[Distribution category]*

To be supplied only on veterinary prescript

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"

Keep out of reach and sight of children Shake thoroughly before use

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
United Kingdom

Elanco France S.A.S.
26 rue de la Chapelle,
68330 Huningue,
France

MA Holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook, RG27 9XA, UK
Tel: 01256 353131

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4007

17. MANUFACTURER'S BATCH NUMBER

Bn.:

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. Front and Back Bottle.

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Elanco France S.A.S.
26 rue de la Chapelle,
68330 Huningue,
France

MA Holder:
Elanco Europe Ltd
Form 2, Bartley Way
Bartley Wood Business Park
Hook, RG27 9XA, UK
Tel: 01256 353131

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 5% w/v Oral Suspension
<Back and Front label – after product name>
for sheep

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Contains 5% w/v triclabendazole

4. PHARMACEUTICAL FORM

Oral suspension for sheep
A cream coloured aqueous suspension for oral administration containing 5% w/v Triclabendazole.

5. PACKAGE SIZE

2.2L

6. INDICATION(S)

Front Label
For the treatment and control of liver fluke from 2 day old early immature to adult forms.
<Pictograms>
Showing the stages of Fluke life cycle.

Back Label
When used at the recommended dose rate
FASINEX 5% is effective for the treatment and control of liver fluke (Fasciola hepatica) infection in sheep caused by all stages of triclabendazole susceptible F. hepatica from 2 days old early immature to adult forms.

7. CONTRAINDICATIONS

Contra-indications, Warnings etc.
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. FASINEX 5% 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.
For full details of Dosing Programmes, Contraindications, warnings etc. & User Warnings, please read the full label.

<Heading>
Contra-indications (continued from page 1).
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 species in small ruminants in a number of countries including the EU. Therefore the use of this product should be based on local (regional, farm) epidemiological information about the susceptibility of the Fasciola species and recommendations on how to limit further selection for resistance to anthelmintics.
If signs of fascioliasis continue after treatment with FASINEX 5%, 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.

The product can be used in pregnant ewes not producing milk for human consumption. Not authorised for use in ewes producing milk for human consumption including during the dry period.

8. ADVERSE REACTIONS

9. TARGET SPECIES

Sheep

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dosage and Administration
Do not mix with other products. FASINEX 5% is given as an oral drench and is suitable for use through most types of automatic drenching guns.
FASINEX 5% can safely be given to young, pregnant or stressed sheep. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.
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Routine flock treatment (moderate risk fluke areas):
As a guide, dose all sheep exposed to fluke infected pasture 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. Any bought-in sheep should be dosed before joining the main flock.
Treatment of acute outbreaks: The flock should be treated immediately after diagnosis is reached. Veterinary advice should be sought for subsequent dosing intervals.
<Back Label – Dosae table with pictograms of Sheep, Measuring Cyclinder and Bottle>

Animal weight	Dose of FASINEX 5%	Number of doses per pack
10 kg	2 ml	1100
11 – 15 kg	3ml	733
16 – 20 kg	4 ml	550
21 – 25 kg	5 ml	440
26 – 30 kg	6 ml	366
31 – 40 kg	8 ml	275
41 – 50 kg	10 ml	220
51 – 60 kg	12 ml	183

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

Store

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

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.

13. SPECIAL STORAGE PRECAUTIONS

<Back Label – towards bottle neck, Diagram of bottle closure>
FOR A PROPER CLOSURE, PRESS IN THE CENTRE OF THE LID

Protect from freezing. Do not store above 25˚C. Store in tightly closed original container. Protect from light.
For animal treatment only.

[Pharmaceuticals ONLY - *The following statement should be included if there is an in-use shelf life (example: solution for injection)]*
<When the container is broached/opened for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.>

14. SPECIAL WARNING(S)<User Warnings>

Operator Warnings
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.
Do not contaminate ponds, waterways or ditches with the product or used container.
Use unaltered from original container. Clean drenching equipment before and after use.

15. EXPIRY DATE

EXP:

16. SPECIAL 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.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

September 2020

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

[Distribution category]

To be supplied only on veterinary prescript

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).

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

Keep out of reach and sight of children Shake thoroughly before use

20. MARKETING AUTHORISATION NUMBER

Vm 00879/4007

21. MANUFACTURER'S BATCH NUMBER

Bn.:

Approved 09 September 2020