PARTICULARS TO APPEAR ON THE OUTER PACKAGE – 0.8 litre bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240, 240 mg/ml Oral Suspension for Cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance: Triclabendazole 240 mg

3. PACKAGE SIZE

0.8 L

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral Suspension

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 52 days.
Milk: Milk for human consumption may only be taken from 48 hours after calving. Not intended for use within 48 days of calving. Should a cow calve earlier than 48 days after the last treatment, milk for human consumption may only be taken from 50 days after the last treatment.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within12 months.

Date of discard:

9. SPECIAL STORAGE PRECAUTIONS

Store in the original container.
Keep the container tightly closed.
Shake thoroughly before use.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco Europe Ltd.

14. MARKETING AUTHORISATION NUMBERS

Vm 00879/4006

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET 0.8 litre bottle:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fasinex 240, 240 mg/ml Oral Suspension for Cattle

2. Composition

Active substance:
Triclabendazole 240 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.1 mg
Propyl parahydroxybenzoate (E216)	0.4 mg
Benzyl alcohol (E1519)	5.0 mg

A cream coloured aqueous suspension for oral administration.

3. Target species

Cattle

4. Indications for use

For the treatment and control of liver fluke from 2 week old early immature to adult forms.
When used at the recommended dose rate the veterinary medicinal product 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.

5. Contraindications

None known.

6. Special warnings

Special warnings:
Not intended for use within 48 days of calving. 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product against liver fluke is reduced if triclabendazole resistant strains are present.

Special precautions for safe use in the target species:

None known.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Do not eat, drink, or smoke while handling the veterinary medicinal product. Wash hands and exposed skin after handling the veterinary medicinal product.
In case of accidental spillage onto skin or in eyes, wash immediately with water. Take off any contaminated clothes.

Pregnancy and lactation:

Can be used during pregnancy and lactation.
Concerning use during lactation refer to section '**Withdrawal periods'**.

Interaction with other medicinal products and other forms of interaction:
None known.

Overdose:
A single oral dose of 150-200 mg triclabendazole/kg of body weight was shown to lead to side effects such as stumbling gait, depression, and decreased appetite. These side effects are slight and last 1 to 3 days. An antidote is not known.

Major incompatibilities:

None known.

7. Adverse events

Target species: Cattle

None Known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

Recommended dose rate: 12 mg triclabendazole/kg bodyweight i.e. 5 ml of the veterinary medicinal product per 100 kg bodyweight.

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

<Pictogram of a cow> Animal weight	<Pictogram of measuring device> Dose of **FASINEX 240**	**<0.8L>** Number of doses per pack
Up to 50 kg	**2.5 ml**	320
>50-70 kg	**3.5 ml**	228
>70-100 kg	**5 ml**	160
>100-150 kg	**7.5 ml**	106
>150-200 kg	**10 ml**	80
>200-300 kg	**15 ml**	53
>300-400 kg	**20 ml**	40
>400-500 kg	**25 ml**	32

Add 5 ml **FASINEX 240** for additional 100 kg

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 the veterinary medical product 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.

Clean drenching equipment before and after use.

9. Advice on correct administration

To ensure administration of a correct dose, body weight 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. The veterinary medicinal product is given as an oral drench and is suitable for use through most types of automatic drenching guns. The veterinary medicinal product can safely be given to young, pregnant or stressed cattle, cattle not producing milk intended for human consumption or dry cattle. However, the veterinary medicinal product is not permitted for use in lactating animals producing milk for human consumption. For lactating dairy cattle see under **Withdrawal Periods**.

10. Withdrawal periods

Meat and offal : 52 days. Milk:

Milk for human consumption may only be taken from 48 hours after calving. Not intended for use within 48 days of calving. Should a cow calve earlier than 48 days after the last treatment, milk for human consumption may only be taken after 50 days after the last treatment.

11. Special storage precautions

Keep out of the sight and reach of children.

Store in the original container.
Keep the container tightly closed.
Shake thoroughly before use.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

The veterinary medicinal product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

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

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/4006

High density polyethylene bottles of 0.8, 2.2, 5.0 and 12.0 litres.

Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Elanco Europe Ltd
Form 2
Bartley Way
Bartley Wood Business Park
HookRG27 9XA

PV.GBR@elancoah.com
+443308221732

Manufacturer responsible for batch release:

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

17. Other information

POM-VPS

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, i.e. Combined label and package leaflet – 2.2, 5.0 and 12.0 litre bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240, 240 mg/ml Oral Suspension for Cattle

2. COMPOSITION

Active substance:
Triclabendazole 240 mg

Excipients:

Methyl parahydroxybenzoate (E218)	1.1 mg
Propyl parahydroxybenzoate (E216)	0.4 mg
Benzyl alcohol (E1519)	5.0 mg

A cream coloured aqueous suspension for oral administration.

3. PACKAGE SIZE

2.2 litres
5.0 litres
12.0 litres

4. TARGET SPECIES

Cattle

5. INDICATIONS FOR USE

Indications for use

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

When used at the recommended dose rate the veterinary medicinal product 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.

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

Special warnings:

Not intended for use within 48 days of calving. 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 veterinary medicinal 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 veterinary medicinal 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 veterinary medicinal product against liver fluke is reduced if triclabendazole resistant strains are present.

Special precautions for safe use in the target species:

None known.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Do not eat, drink, or smoke while handling the veterinary medicinal product. Wash hands and exposed skin after handling the veterinary medicinal product.

In case of accidental spillage onto skin or in eyes, wash immediately with water.
Take off any con-taminated clothes.

Pregnancy and lactation:

Can be used during pregnancy and lactation.
Concerning use during lactation refer to section **‘Withdrawal periods’.**

Interactions with other medicinal products and other forms of interaction:

None known.

Overdose:

A single oral dose of 150-200 mg triclabendazole/kg of body weight was shown to lead to side effects such as stumbling gait, depression, and decreased appetite. These side effects are slight and last 1 to 3 days. An antidote is not known.

Major incompatibilities:

None known.

8. ADVERSE EVENTS

Adverse events

Target species: Cattle

None known

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system at:

Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

e-mail: adverse.events@vmd.gov.uk

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Recommended dose rate: 12 mg triclabendazole/kg bodyweight i.e. 5 ml of the veterinary medicinal product per 100 kg bodyweight.

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

<Pictogram of a cow> Animal weight	<Pictogram of measuring device> Dose of **FASINEX 240**	**<2.2 L>** Number of doses per pack
Up to 50 kg	**2.5 ml**	880
>50-70 kg	**3.5 ml**	628
>70-100 kg	**5 ml**	440
>100-150 kg	**7.5 ml**	293
>150-200 kg	**10 ml**	220
>200-300 kg	**15 ml**	146
>300-400 kg	**20 ml**	110
>400-500 kg	**25 ml**	88

<Pictogram of a cow> Animal weight	<Pictogram of measuring device> Dose of **FASINEX 240**	**<5.0 L>** Number of doses per pack
Up to 50 kg	**2.5 ml**	2000
>50-70 kg	**3.5 ml**	1428
>70-100 kg	**5 ml**	1000
>100-150 kg	**7.5 ml**	666
>150-200 kg	**10 ml**	500
>200-300 kg	**15 ml**	333
>300-400 kg	**20 ml**	250
>400-500 kg	**25 ml**	200

<Pictogram of a cow> Animal weight	<Pictogram of measuring device> Dose of **FASINEX 240**	**<12.0 L>** Number of doses per pack
Up to 50 kg	**2.5 ml**	4800
>50-70 kg	**3.5 ml**	3428
>70-100 kg	**5 ml**	2400
>100-150 kg	**7.5 ml**	1600
>150-200 kg	**10 ml**	1200
>200-300 kg	**15 ml**	800
>300-400 kg	**20 ml**	600
>400-500 kg	**25 ml**	480

Add 5 ml **FASINEX 240** for additional 100 kg

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 **t**he veterinary medicinal product 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.

Clean drenching equipment before and after use.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure administration of a correct dose, body weight 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.The veterinary medicinal product is given as an oral drench and is suitable for use through most types of automatic drenching guns. The veterinary medicinal product can safely be given to young, pregnant or stressed cattle, cattle not producing milk intended for human consumption or dry cattle. However, the veterinary medicinal product is not permitted for use in lactating animals producing milk for human consumption. For lactating dairy cattle see under **Withdrawal Periods**.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal : 52 days.

Milk: Milk for human consumption may only be taken from 48 hours after calving. Not intended for use within 48 days of calving. Should a cow calve earlier than 48 days after the last treatment, milk for human consumption may only be taken after 50 days after the last treatment.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Store in the original container.
Keep the container tightly closed.
Shake thoroughly before use.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater.

The veterinary medicinal product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

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 applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

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

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 00879/4006

Pack sizes

High density polyethylene bottles of 0.8, 2.2, 5.0 and 12.0 litres.

Not all pack sizes may be marketed.

16. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

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

PV.GBR@elancoah.com
+443308221732

Manufacturer responsible for batch release:

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

18. OTHER INFORMATION

Other information

POM-VPS

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 12 months.

Date of discard:

21. BATCH NUMBER

Lot {number}

Gavin Hall

Approved 08 May 2025