1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240 mg/ml oral suspension for cattle

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance:
Triclabendazole 240 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Methyl parahydroxybenzoate (E218)	1.1 mg
Propyl parahydroxybenzoate (E216)	0.4 mg
Benzyl alcohol (E1519)	5.0 mg
Microcrystalline cellulose and carmellose sodium	
Povidone	
Simethicone Emulsion	
Propylene Glycol	
Purified Water	

White to cream-coloured aqueous suspension.

3. CLINICAL INFORMATION

3.1 Target species

Cattle.

3.2 Indications for use for each target species

For the treatment of acute, subacute and chronic infection due to early immature, immature, and mature stages of *Fasciola hepatica*. If infected animals are treated before disease has developed, fasciolosis can be prevented.

3.3 Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

3.4 Special warnings

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 bodyweight, 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 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Only for use for liver fluke strains susceptible to triclabendazole. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce the risk, dosing programs should be discussed with your veterinary practitioner. Efficacy of this veterinary medicinal product against liver fluke is reduced if triclabendazole resistant strains are present. Where a dosing gun is used to administer the veterinary medicinal product, care must be taken to avoid the occurrence of dosing gun pharyngitis.
Not intended for use within 35 days of calving.

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.

Special precautions for the protection of the environment:

Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

Other precautions

None known.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:

Can be used during pregnancy.
Laboratory studies have not produced any evidence of teratogenic or foetotoxic effects.
However, the product is not permitted for use in lactating animals producing milk for human consumption.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Oral use.

0.8 L, 2.2 L and 5.0 L pack sizes only:
Unscrew the cap from the container and replace it with the white spigot cap provided. If using an automatic drenching-gun, attach the tube from the application device to the white spigot cap. After use, remove the white spigot cap and close the container with the cap.

All pack sizes:
To ensure a correct dosage, 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.
Administer 5 ml/100 kg body weight, equivalent to 12 mg triclabendazole per kg of body weight. The veterinary medicinal product is administered orally after thorough shaking of the suspension. Most types of automatic drenching guns are suitable.
Clean drenching gun before and after use. The veterinary medicinal product can safely be given to young, pregnant or stressed cattle. However, the veterinary medicinal product is not permitted for use in lactating animals producing milk for human consumption.
The veterinary medicinal product is given once. The administration may be repeated several weeks or months after the first treatment depending on the epidemiological situation. In case of sub-acute and acute fasciolosis, affected cattle, usually young animals, should be treated immediately after diagnosis is reached. Advice from your prescriber or veterinary surgeon should be sought for subsequent dosing intervals.

Shake container well before use.

Dosing Table

Body Weight (kg)	Volume to Administer (ml)
Up to 50 kg	2.5
>50-70	3.5
>70-100	5
>100-150	7.5
>150-200	10
>200-300	15
>300-400	20
>400-500	25

Add 5 ml for each additional 100 kg

Dosing recommendations:

On land where sheep are being treated according to a preventative programme and where cattle are also grazing these areas, the veterinary medicinal product should be administered to the cattle on the same treatment dates as the sheep. Fasinex 5% should be used in sheep.

Treatment times should be customised under veterinary advice for each individual farm.

Bought in animals:
All bought in animals should be dosed before joining the main herd unless there is evidence of triclabendazole resistance in those cattle.

Housed cattle:
Dose cattle, which have grazed fluke infected pasture in the autumn at the time of or shortly after housing. Dosing may be required to be started at the beginning of the fluke season when animals are still outdoors depending on the specific farm situation.

Treatment of acute outbreaks:
The herd should be treated immediately after diagnosis and veterinary advice should be sought for subsequent dosing intervals.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

A single oral dose of 150-200 mg triclabendazole/kg of body weight (more than 12 times the recommended dose rate) 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Meat and offal: 56 days.

Milk: Not authorised for use in lactating animals producing milk for human consumption.
When used in non-lactating animals, milk for human consumption may only be taken from 48 hours after calving. If calving occurs before 35 days after treatment, milk for human consumption may only be taken after 35 days plus 48 hours after the treatment.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QP52AC01

4.2 Pharmacodynamics

Triclabendazole inhibits cellular transport mechanisms and binds to a different tubulin receptor, possibly the tubulozole receptor, than do other benzimidazoles, which bind to the colchicine receptor. Triclabendazole also inhibits protein synthesis.

4.3 Pharmacokinetics

Triclabendazole is readily absorbed and oxidised to its sulfoxide and sulfone.
Triclabendazole sulfoxide reaches peak concentrations approximately 1 day after administration of the veterinary medical product and the sulfone reaches peak concentrations approximately 3 days after administration. Both metabolites bind strongly to plasma protein, particularly albumin.

Metabolites are excreted via the bile, primarily as conjugates. More than 90 % of the total dose of the veterinary medicinal product is excreted in the faeces, about 5 % in the urine and 1 % in milk. Elimination is virtually complete by 10 days after administration.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

None known.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after first opening the immediate packaging: 12 months.

5.3 Special precautions for storage

Store in the original container.
Keep the container tightly closed.

5.4 Nature and composition of immediate packaging

High density polyethylene bottle (0.8 L, 2.2 L, 5.0 L and 12.0 L).
High density polyethylene induction seal cap. Polypropylene spigot cap (0.8 L, 2.2 L and 5 L). .
Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater.

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Elanco GmbH.

7. MARKETING AUTHORISATION NUMBER(S)

VPA22020/003/001

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 5 September 2008

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

{MM/YYYY}

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

0.8 litre Bottle

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240 mg/ml oral suspension for cattle

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance: Triclabendazole 240 mg

3. PACKAGE SIZE

0.8 litre

4. TARGET SPECIES

Cattle.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral Suspension.

7. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 56 days.

Milk: Not authorised for use in lactating animals producing milk for human consumption.
When used in non-lactating animals, milk for human consumption may only be taken from 48 hours after calving. If calving occurs before 35 days after treatment, milk for human consumption may only be taken after 35 days plus 48 hours after the treatment.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened use within 12 months.

Discard/Date:

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 GmbH

14. MARKETING AUTHORISATION NUMBERS

VPA22020/003/001

15. BATCH NUMBER

Lot {number}

B. PACKAGE LEAFLET

0.8 litre bottle
PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Fasinex 240 mg/ml oral suspension for cattle

2. Composition

Each ml contains:

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 white to cream coloured aqueous suspension.

3. Target species

Cattle.

4. Indications for use

For the treatment and control of acute, subacute and chronic fasciolosis due to early immature, immature and adult liver fluke (*Fasciola hepatica)* in cattle.

5. Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

Special warnings:

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 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.

Special precautions for safe use in the target species:

Only for use for liver fluke strains susceptible to triclabendazole.
Not intended for use within 35 days of calving. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with a veterinary practitioner.
Efficacy of this veterinary medicinal product against liver fluke is reduced if triclabendazole resistant strains are present.
Where a dosing gun is used to administer the veterinary medicinal product, care must be taken to avoid the occurrence of dosing gun pharyngitis.

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.

Special precautions for the protection of the environment:

Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

Pregnancy and lactation:

Can be used during pregnancy.
Laboratory studies have not produced any evidence of teratogenic or foetotoxic effects. Do not use in lactating animals producing milk for human consumption.

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 (more than 12 times the recommended dose rate) 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

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:

HPRA Pharmacovigilance
Website: www.hpra.ie

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

Oral use.

0.8 L, 2.2 L and 5.0 L pack sizes only:
Unscrew the cap from the container and replace it with the white spigot cap provided. If using an automatic drenching-gun, attach the tube from the application device to the white spigot cap. After use, remove the white spigot cap and close the container with the cap.

All pack sizes:
Recommended dose rate: 12 mg triclabendazole / kg bodyweight i.e. 5 ml the veterinary medicinal product per 100 kg bodyweight. If animals are to be treated collectively rather than individually, groups should be formed according to the weight bands on the dosing table and the animals dosed accordingly. Shake well. The veterinary medicinal product is given once. The administration may be repeated several weeks or months after the first treatment depending on the epidemiological situation. For the 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.

On land where sheep are being treated according to a preventative programme and where cattle are also grazing these areas, The veterinary medicinal product should be administered to the cattle on the same treatment dates as the sheep. Fasinex 5 % should be used in sheep. Treatment times should be customised under veterinary advice for each individual farm.

Bought in animals:
All bought in animals should be dosed before joining the main herd unless there is evidence of triclabendazole resistance in those cattle.

Housed cattle:
Dose cattle, which have grazed fluke infected pasture in the autumn at the time of or shortly after housing. Dosing may be required to be started at the beginning of the fluke season when animals are still outdoors depending on the specific farm situation.

Treatment of acute outbreaks:
The herd should be treated immediately after diagnosis and veterinary advice should be sought for subsequent dosing intervals.

Clean drenching equipment before and after use.

		<0.8L>
Animal weight	Dose of **FASINEX 240**	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

For each additional 100 kg add 5 ml

9. Advice on correct administration

To ensure a correct dosage, 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.
The veterinary medicinal product is given orally after thorough shaking and is suitable for use through most types of automatic drenching guns.
The veterinary medicinal product is not permitted for the use in lactating animals producing milk for human consumption.

10. Withdrawal periods

Meat and offal: 56 days.

Milk: Not authorised for use in lactating animals producing milk for human consumption.
When used in non-lactating animals, milk for human consumption may only be taken from 48 hours after calving. If calving occurs before 35 days after treatment, milk for human consumption may only be taken after 35 days plus 48 hours after the 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.

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.

14. Marketing authorisation numbers and pack sizes

VPA22020/003/001

High density polyethylene bottle (0.8 L, 2.2 L, 5.0 L and 12.0 L).
High density polyethylene induction seal cap. Polypropylene spigot cap (0.8 L, 2.2 L and 5 L).
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

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

Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany
+44 3308221732
PV.IRL@elancoah.com

Manufacturer responsible for batch release:

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

17. Other information

POM (Prescription Only)

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - COMBINED LABEL AND PACKAGE LEAFLET

2.2, 5.0 and 12.0 litre bottles

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240 mg/ml oral suspension for cattle

2. COMPOSITION

Triclabendazole 240 mg

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

A white to 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 of acute, subacute and chronic infection due to early immature, immature, and mature stages of *Fasciola hepatica*. If infected animals are treated before disease has developed, fasciolosis can be prevented.

6. CONTRAINDICATIONS

Contraindications

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

7. SPECIAL WARNINGS

Special warnings

Special warnings:
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 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.

Special precautions for safe use in the target species:

Only for use for liver fluke strains susceptible to triclabendazole. Not intended for use within 35 days of calving. Intensive use or misuse of anthelmintics can give rise to resistance. To reduce this risk, dosing programmes should be discussed with a veterinary practitioner.
Efficacy of this veterinary medicinal product against liver fluke is reduced if triclabendazole resistant strains are present.
Where a dosing gun is used to administer the veterinary medicinal product, care must be taken to avoid the occurrence of dosing gun pharyngitis.

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.

Special precautions for the protection of the environment:
Do not contaminate ponds, waterways or ditches with the veterinary medicinal product or empty containers.

Pregnancy and lactation:

Can be used during pregnancy.
Laboratory studies have not produced any evidence of teratogenic or foetotoxic effects. Do not use in lactating animals producing milk for human consumption.

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 (more than 12 times the recommended dose rate) 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:

HPRA Pharmacovigilance
Website: www.hpra.ie

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

Dosage for each species, routes and method of administration

Oral use.

0.8 L, 2.2 L and 5.0 L pack sizes only:
Unscrew the cap from the container and replace it with the white spigot cap provided. If using an automatic drenching-gun, attach the tube from the application device to the white spigot cap. After use, remove the white spigot cap and close the container with the cap.

All pack sizes:
Recommended dose rate: 12 mg triclabendazole / kg bodyweight i.e. 5 ml of the veterinary medicinal product per 100 kg bodyweight. If animals are to be treated collectively rather than individually, groups should be formed according to the weight bands on the dosing table and the animals dosed accordingly. Shake well. The veterinary medicinal product is given once. The administration may be repeated several weeks or months after the first treatment depending on the epidemiological situation. For the 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.

On land where sheep are being treated according to a preventative programme and where cattle are also grazing these areas, The veterinary medicinal product should be administered to the cattle on the same treatment dates as the sheep. Fasinex 5% should be used in sheep. Treatment times should be customised under veterinary advice for each individual farm.

Bought in animals:
All bought in animals should be dosed before joining the main herd unless there is evidence of triclabendazole resistance in those cattle.

Housed cattle:

Dose cattle, which have grazed fluke infected pasture in the autumn at the time of or shortly after housing. Dosing may be required to be started at the beginning of the fluke season when animals are still outdoors depending on the specific farm situation.

Treatment of acute outbreaks:
The herd should be treated immediately after diagnosis and veterinary advice should be sought for subsequent dosing intervals.

Clean drenching equipment before and after use.

Animal weight	Dose of **FASINEX 240**	**<2.2 L>** Number of doses per pack
>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
>200-250 kg	**12.5 ml**	176
>250-300 kg	**15 ml**	146
>300-400 kg	**20 ml**	110
>400-500 kg	**25 ml**	88
>500-600 kg	**30 ml**	73
>600-700 kg	**35 ml**	62
>700-800 kg	**40 ml**	55
>800-900 kg	**45 ml**	48

Animal weight	Dose of **FASINEX 240**	**<5.0 L>** Number of doses per pack
>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
>200-250 kg	**12.5 ml**	400
>250-300 kg	**15 ml**	333
>300-400 kg	**20 ml**	250

>400-500 kg	**25 ml**	200
>500-600 kg	**30 ml**	166
>600-700 kg	**35 ml**	142
>700-800 kg	**40 ml**	125
>800-900 kg	**45 ml**	111

Animal weight	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

For each additional 100 kg add 5 ml

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

To ensure a correct dosage, 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.
The veterinary medicinal product is given orally after thorough shaking and is suitable for use through most types of automatic drenching guns.
The veterinary medicinal product is not permitted for the use in lactating animals producing milk for human consumption.

11. WITHDRAWAL PERIODS

Withdrawal periods

Meat and offal: 56 days.

Milk: Not authorised for use in lactating animals producing milk for human consumption.

When used in non-lactating animals, milk for human consumption may only be taken from 48 hours after calving. If calving occurs before 35 days after treatment, milk for human consumption may only be taken after 35 days plus 48 hours after the 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.

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.

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

VPA22020/003/001

Pack sizes

High density polyethylene bottle (0.8 L, 2.2 L, 5.0 L and 12.0 L).
High density polyethylene induction seal cap. Polypropylene spigot cap (0.8 L, 2.2 L and 5 L).
Not all pack sizes may be marketed.

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

{MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database.

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Elanco GmbH, Heinz-Lohmann-Str. 4, 27472 Cuxhaven, Germany
+44 3308221732
PV.IRL@elancoah.com

Manufacturer responsible for batch release:

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

18. OTHER INFORMATION

Other information

POM (Prescription Only)

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

20. EXPIRY DATE

Exp {mm/yyyy}

Once opened use within 12 months.

Discard/Date:

21. BATCH NUMBER

Lot {number}