PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

0.8L FRONT AND BACK LABEL (Front, Page 1 & Base)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240, 24% w/v Oral Suspension for Cattle.

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 24% w/v triclabendazole

Contains preservatives:
methyl parahydroxybenzoate (E218) 1.1 mg,
propyl parahydroxybenzoate (E216) 0.4 mg
and benzyl alcohol (E1519) 5.0 mg

3. PHARMACEUTICAL FORM

A cream coloured aqueous suspension for oral administration containing 240 mg/ml triclabendazole

4. PACKAGE SIZE

0.8 Litre

Bottles of 0.8, 2.2, 5.0 and 12.0 litres registered. Not all pack sizes may be marketed.

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

When used at the recommended dose rate FASINEX 240 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: 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. **FASINEX 240** is given as an oral drench and is suitable for use through most types of automatic drenching guns. **FASINEX 240** can safely be given to young,

pregnant or stressed cattle, cattle not producing milk intended for human consumption or
dry cattle. However, the product is not permitted for use in lactating animals producing milk for human consumption. For lactating dairy cattle see under **Withdrawal Periods.**

Recommended dose rate: 12 mg triclabendazole/kg bodyweight i.e. 5 ml **FASINEX 240** per 100 kg bodyweight. For full details of Dosing Programmes, Contraindications, warnings etc. & User Warnings, please read the full label.

<Pictogram of a cow > Animal weight	<Pictogram of measuring device> Dose of **FASINEX**	**<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 **FASINEX 240** 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.

8. WITHDRAWAL PERIOD (S)

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.

9. CONTRAINDICATIONS, SPECIAL WARNING(S), IF NECESSARY

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:

A. Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
B. 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.

User Warnings: Do not eat, drink or smoke whilst handling this 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.

The product may adversely affect aquatic organisms. Do not contaminate ponds,

waterways or ditches with the product or empty containers.
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.

10. EXPIRY DATE

EXP {month/year}

Date of discard:

11. SPECIAL STORAGE CONDITIONS

Shake thoroughly before use.

Store in tightly closed original container.

Once opened, use within 12 months.

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal product 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

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"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4006

17. MANUFACTURER'S BATCH NUMBER

BN {number}

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

OTHER INFORMATION

Date of revision of the text:

September 2020

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

2.2L FRONT AND BACK LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240, 24% w/v Oral Suspension for Cattle.

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 24% w/v triclabendazole

Contains preservatives:
methyl parahydroxybenzoate (E218) 1.1 mg,
propyl parahydroxybenzoate (E216) 0.4 mg
and benzyl alcohol (E1519) 5.0 mg

3. PHARMACEUTICAL FORM

A cream coloured aqueous suspension for oral administration containing 240 mg/ml triclabendazole

4. PACKAGE SIZE

2.2 Litre

Bottles of 0.8, 2.2, 5.0 and 12.0 litres registered. Not all pack sizes may be marketed.

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

When used at the recommended dose rate FASINEX 240 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: 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. **FASINEX 240** is given as an oral drench and is suitable for use through most types of automatic drenching guns. **FASINEX 240** can safely be given to young,
pregnant or stressed cattle, cattle not producing milk intended for human consumption or dry cattle. However, the product is not permitted for use in lactating animals producing milk for human consumption. For lactating dairy cattle see under **Withdrawal Periods.**

Recommended dose rate: 12 mg triclabendazole/kg bodyweight i.e. 5 ml **FASINEX 240** per 100 kg bodyweight. For full details of Dosing Programmes, Contraindications, warnings etc. & User Warnings, please read the full label.

<Pictogram of a cow > Animal weight	<Pictogram of measuring device> Dose of **FASINEX**	**<2.2L>** 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

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 **FASINEX 240** 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

8. WITHDRAWAL PERIOD (S)

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.

9. CONTRAINDICATIONS, SPECIAL WARNING(S), IF NECESSARY

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:

C. Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
D. 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.

User Warnings: Do not eat, drink or smoke whilst handling this 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.

The product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.
Clean drenching equipment before and after use.

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

10. EXPIRY DATE

EXP {month/year}

Date of discard:

11. SPECIAL STORAGE CONDITIONS

Shake thoroughly before use.

Store in tightly closed original container.

Once opened, use within 12 months.

STORE 

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal product 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

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"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4006

17. MANUFACTURER'S BATCH NUMBER

BN {number}

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

OTHER INFORMATION

Date of revision of the text:

September 2020

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

5.0L and 12L FRONT AND BACK LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240, 24% w/v Oral Suspension for Cattle.

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 24% w/v triclabendazole

Contains preservatives:
methyl parahydroxybenzoate (E218) 1.1 mg,
propyl parahydroxybenzoate (E216) 0.4 mg
and benzyl alcohol (E1519) 5.0 mg

3. PHARMACEUTICAL FORM

A cream coloured aqueous suspension for oral administration containing 240 mg/ml triclabendazole

4. PACKAGE SIZE

5.0 Litre

Bottles of 0.8, 2.2, 5.0 and 12.0 litres registered. Not all pack sizes may be marketed.

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

When used at the recommended dose rate FASINEX 240 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: 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. **FASINEX 240** is given as an oral drench and is suitable for use through most types of automatic drenching guns. **FASINEX 240** can safely be given to young, pregnant or stressed cattle, cattle not producing milk intended for human consumption or dry cattle. However, the product is not permitted for use in lactating animals producing milk for human consumption. For lactating dairy cattle see under **Withdrawal Periods.**

Recommended dose rate: 12 mg triclabendazole/kg bodyweight i.e. 5 ml **FASINEX 240** per 100 kg bodyweight. For full details of Dosing Programmes, Contraindications, warnings etc. & User Warnings, please read the full label.

5L Bottle:

<Pictogram of a cow > Animal weight	<Pictogram of measuring device> Dose of **FASINEX**	<**5.0L**> 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

Add 5 ml **FASINEX 240** for additional 100 kg
12L Bottle:

<Pictogram of a cow > Animal weight	<Pictogram of measuring device> Dose of **FASINEX**	**<12.0L>** 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 **FASINEX 240** 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.

8. WITHDRAWAL PERIOD (S)

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.

9. CONTRAINDICATIONS, SPECIAL WARNING(S), IF NECESSARY

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:

E. Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
F. 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.

User Warnings: Do not eat, drink or smoke whilst handling this 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.

The product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.
Clean drenching equipment before and after use.

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

10. EXPIRY DATE

EXP {month/year}

Date of discard:

11. SPECIAL STORAGE CONDITIONS

Shake thoroughly before use.

Store in tightly closed original container.

Once opened, use within 12 months.

STORE 

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal product 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

For animal treatment only.

To be supplied only on veterinary prescription.

POM-VPS

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

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4006

17. MANUFACTURER'S BATCH NUMBER

BN {number}

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

OTHER INFORMATION

Date of revision of the text:

September 2020

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

5.0L and 12L FRONT AND BACK LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Fasinex 240, 24% w/v Oral Suspension for Cattle.

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 24% w/v triclabendazole

Contains preservatives:
methyl parahydroxybenzoate (E218) 1.1 mg,
propyl parahydroxybenzoate (E216) 0.4 mg
and benzyl alcohol (E1519) 5.0 mg

3. PHARMACEUTICAL FORM

A cream coloured aqueous suspension for oral administration containing 240 mg/ml triclabendazole

4. PACKAGE SIZE

5.0 Litre

Bottles of 0.8, 2.2, 5.0 and 12.0 litres registered. Not all pack sizes may be marketed.

5. TARGET SPECIES

Cattle

6. INDICATION(S)

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

When used at the recommended dose rate FASINEX 240 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: 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. **FASINEX 240** is given as an oral drench and is suitable for use through most types of automatic drenching guns. **FASINEX 240** can safely be given to young, pregnant or stressed cattle, cattle not producing milk intended for human consumption or dry cattle. However, the product is not permitted for use in lactating animals producing milk for human consumption. For lactating dairy cattle see under **Withdrawal Periods.**

Recommended dose rate: 12 mg triclabendazole/kg bodyweight i.e. 5 ml **FASINEX 240** per 100 kg bodyweight. For full details of Dosing Programmes, Contraindications, warnings etc. & User Warnings, please read the full label.

5L Bottle:

<Pictogram of a cow > Animal weight	<Pictogram of measuring device> Dose of **FASINEX**	<**5.0L**> 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

Add 5 ml **FASINEX 240** for additional 100 kg
12L Bottle:

<Pictogram of a cow > Animal weight	<Pictogram of measuring device> Dose of **FASINEX**	**<12.0L>** 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 **FASINEX 240** 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.

8. WITHDRAWAL PERIOD (S)

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.

9. CONTRAINDICATIONS, SPECIAL WARNING(S), IF NECESSARY

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:

G. Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
H. 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.

User Warnings: Do not eat, drink or smoke whilst handling this 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.

The product may adversely affect aquatic organisms. Do not contaminate ponds, waterways or ditches with the product or empty containers.
Clean drenching equipment before and after use.

SHAKE THE CONTAINER THOROUGHLY BEFORE USE

10. EXPIRY DATE

EXP {month/year}

Date of discard:

11. SPECIAL STORAGE CONDITIONS

Shake thoroughly before use.

Store in tightly closed original container.

Once opened, use within 12 months.

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

Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal product 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

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"

Keep out of reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 00879/4006

17. MANUFACTURER'S BATCH NUMBER

BN {number}

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

OTHER INFORMATION

Date of revision of the text:

September 2020

Approved 09 September 2020