

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Front Container Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flypor 4% w/v Pour-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 4% w/v permethrin (tech.) (cis:trans / 80:20)

3. PHARMACEUTICAL FORM

Pour-on Solution.

4. PACKAGE SIZE

1 and 3 Litres.

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

For the control of flies and lice, and for the treatment of mange on cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD (S)

9. SPECIAL WARNING(S), IF NECESSARY

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container.
Do not store above 25°C.

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

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

FOR EXTERNAL USE ONLY.

POM-VPS

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4008

17. MANUFACTURER’S BATCH NUMBER

PARTICULARS TO APPEAR ON THE OUTER AND IMMEDIATE PACKAGE

Carton Box / Polyethylene Bottle Back Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flypor 4% w/v Pour-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 4% w/v permethrin (tech.) (cis:trans / 80:20)

3. PHARMACEUTICAL FORM

Pour-on Solution.

4. PACKAGE SIZE

1 Litre.

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

For the control of flies and lice, and for the treatment of mange on cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: Flies, Lice and Mange:

Apply at the rate of 1ml per 10kg bodyweight (up to a maximum of 40ml).

FLYPOR should be applied using the dispensing chamber incorporated into the special applicator bottle. The chamber is calibrated up to 40ml.

Directions for using the applicator bottle: Leave cap on bottle neck in position. Remove cap and foil seal from dispensing chamber. Gently squeeze bottle until required amount of product has entered the dispensing chamber. Pour measured liquid along animal's head, neck and back. Replace cap on dispensing chamber after use. **Do not squeeze the bottle while pouring.**

FLIES: Apply approximately one quarter of the calculated dose to the top of the head; the remainder should be applied along the neck and mid-backline. A single dose is normally sufficient to control flies for up to 8 weeks. The first treatment should be carried out when the number of flies starts to increase.

In cases of heavy infestation, the dose rate may be repeated at 4 week intervals.

As with all insecticides, the degree of fly-killing and repellent activity afforded by FLYPOR is influenced by prevailing weather conditions and the species of flies involved.

LICE: Apply in the same way as the fly dosage. A single dose is normally sufficient to control all lice. In certain cases of heavy infestation the dose may be repeated after 4 weeks.

MANGE: The calculated dose should be applied directly to all visibly affected areas; any remaining should be poured along the back line in the normal way. The dose should be repeated after 4 weeks.

Important: Do not treat calves under one week old.

< Pictogram of a Cow> <Symbol of a Measure Jug> <1 litre>

Bodyweight	Dosage	Doses per pack
Up to 100kg	10ml	100
101 to 200kg	20ml	50
201 to 300kg	30ml	33
Over 300kg	40ml	25

8. WITHDRAWAL PERIOD (S)

Meat - Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 3 days from the last treatment.

Milk - Cattle producing milk for human consumption should be treated immediately after milking to allow as long an interval as possible (at least 6 hours) before the next milking.

There is no need to withhold milk from subsequent milkings.

9. SPECIAL WARNING(S), IF NECESSARY

PRECUATIONS

Avoid the eyes when applying product to the head.

Care should be taken when applying the product, as it may have an adverse effect on

certain plastics.

Operator Warnings:

Wear protective clothing, rubber gloves and boots when applying the product. Avoid contact with the eyes.

If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

Do not eat, drink or smoke whilst using the product.

Wash hands and exposed skin before eating, drinking or smoking and after work.

Use in a well ventilated area.

Do not inhale the vapour.

10. EXPIRY DATE

Use by end.

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container.

Do not store above 25°C.

Store away from food, drink and animal feedstuffs.

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

Environmental Warnings:

Dangerous to fish and aquatic life.

Do not contaminate ponds, waterways or ditches with the product or empty container.

Dispose of unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

FOR ANIMAL TREATMENT ONLY.

FOR EXTERNAL USE ONLY.

TO BE SUPPLIED ONLY ON VETERINARY PRESCRIPTION.

POM-VPS

For POM-VPS products a veterinary prescription may only be supplied by a Registered Qualified Person (RQP) as follows (i) a registered veterinary surgeon (ii) a registered pharmacist (iii) a registered Suitably Qualified Person (SQP).

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

KEEP OUT OF THE REACH AND SIGHT OF CHILDREN.

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16. MARKETING AUTHORISATION NUMBER(S)

Vm 00879/4008

17. MANUFACTURER'S BATCH NUMBER

GTIN (01):

Bn:

PARTICULARS TO APPEAR ON THE OUTER / IMMEDIATE PACKAGE

Carton Box / Polyethylene Flex-pack Back Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flypor 4% w/v Pour-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 4% w/v permethrin (tech.) (cis:trans / 80:20)

3. PHARMACEUTICAL FORM

Pour-on Solution.

4. PACKAGE SIZE

3 Litre.

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

For the control of flies and lice, and for the treatment of mange on cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: Flies, Lice and Mange:

Apply at the rate of 1ml per 10kg bodyweight (up to a maximum of 40ml).

FLIES: Using the GREEN POUR-ON NOZZLE on the Elanco Cattle Pour-On Gun, apply approximately one quarter of the calculated dose to the top of the head; the remainder should be applied along the neck and mid-backline.

A single dose is normally sufficient to control flies for up to 8 weeks. The first treatment should be carried out when the number of flies starts to increase.

In cases of heavy infestation, the dose rate may be repeated at 4 week intervals.

As with all insecticides, the degree of fly-killing and repellent activity afforded by FLYPOR is influenced by prevailing weather conditions and the species of flies involved.

LICE: Apply in the same way as the fly dosage. A single dose is normally sufficient to control all lice. In certain cases of heavy infestation the dose may be repeated after 4 weeks.

MANGE: The calculated dose should be applied directly to all visibly affected areas; any remaining should be poured along the back line in the normal way. The dose should be repeated after 4 weeks.

Important: Do not treat calves under one week old.

< Pictogram of a Cow> <Symbol of a Measure Jug> <3 litre>

Bodyweight	Dosage	Doses per pack
Up to 100kg	10ml	300
101 to 200kg	20ml	150
201 to 300kg	30ml	100
Over 300kg	40ml	75

ELANCO CATTLE POUR-ON GUN

FLYPOR must be applied only with the Elanco Cattle Pour-On Gun as the product may have a detrimental effect on certain components of conventional dosing guns.

Full operating and maintenance instructions including details on the use of nozzles are supplied with each Pour-On Gun.

Please read carefully before use. Maintain Gun carefully to ensure accurate dosage.

8. WITHDRAWAL PERIOD (S)

Withdrawal Periods:

Meat - Animals must not be slaughtered for human consumption during treatment.

Cattle may be slaughtered for human consumption only after 3 days from the last treatment.

Milk - Cattle producing milk for human consumption should be treated immediately after milking to allow as long an interval as possible (at least 6 hours) before the next milking.

There is no need to withhold milk from subsequent milkings.

9. SPECIAL WARNING(S), IF NECESSARY

PRECAUTIONS

Avoid the eyes when applying product to the head.

Care should be taken when applying the product, as it may have an adverse effect on certain plastics.

Operator Warnings:

Wear protective clothing, rubber gloves and boots when applying the product. Avoid contact with the eyes.

If splashed in the eye or on the skin, wash with plenty of clean, running water immediately.

Do not eat, drink or smoke whilst using the product.

Wash hands and exposed skin before eating, drinking or smoking and after work.

Use in a well ventilated area.

Do not inhale the vapour.

10. EXPIRY DATE

Use by end.

11. SPECIAL STORAGE CONDITIONS

Store in tightly closed original container.

Do not store above 25°C.

Store away from food, drink and animal feedstuffs.

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

Environmental Warnings:

Dangerous to fish and aquatic life.

Do not contaminate ponds, waterways or ditches with the product or empty container.

Dispose of unused product and empty containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

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GTIN (01):

Bn:

PARTICULARS TO APPEAR ON THE OUTER / OUTER PACKAGE

Display Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flypor 4% w/v Pour-on Solution

2. STATEMENT OF ACTIVE SUBSTANCES

Contains 4% w/v permethrin (tech.) (cis:trans / 80:20)

3. PHARMACEUTICAL FORM

Pour-on Solution.

4. PACKAGE SIZE

4 x 3.0 Litre

5. TARGET SPECIES

Cattle.

6. INDICATION(S)

For the control of flies and lice, and for the treatment of mange on cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dosage: Flies, Lice and Mange:

Apply at the rate of 1ml per 10kg bodyweight (up to a maximum of 40ml).

FLIES: Using the GREEN POUR-ON NOZZLE on the Elanco Cattle Pour-On Gun, apply approximately one quarter of the calculated dose to the top of the head; the remainder should be applied along the neck and mid-backline.

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LICE: Apply in the same way as the fly dosage. A single dose is normally sufficient to control all lice. In certain cases of heavy infestation the dose may be repeated after 4 weeks.

MANGE: The calculated dose should be applied directly to all visibly affected areas; any remaining should be poured along the back line in the normal way. The dose should be repeated after 4 weeks.

Important: Do not treat calves under one week old.

< Pictogram of a Cow> <Symbol of a Measure Jug> <12 L>
(4 x 3 L)

Bodyweight	Dosage	Doses per 12 L pack
Up to 100 kg	10ml	1200
101 to 200kg	20ml	600
201 to 300kg	30ml	400
Over 300kg	40ml	300

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Do not eat, drink or smoke whilst using the product.

Wash hands and exposed skin before eating, drinking or smoking and after work.
Use in a well ventilated area.
Do not inhale the vapour.

10. EXPIRY DATE

Use by end.

11. SPECIAL STORAGE CONDITIONS

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Do not store above 25°C.
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12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Environmental Warnings:

Dangerous to fish and aquatic life.
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GTIN (01):

Bn:

18. OTHER INFORMATION

Contents of this value pack:

- 4 x 3.0 L Flypor Pour-On for Cattle
- 1 x Elanco Cattle 60 ml Pour-On Gun
- 1 x spigot cap
- 1 x set shoulder straps

A handwritten signature in black ink, consisting of several vertical strokes followed by a horizontal line and a long, sweeping flourish that extends to the right.

Approved 09 September 2020