ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne Transdermal 50 mg/ml pour-on solution for cattle
Flunixin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg flunixin equivalent to 83 mg flunixin meglumine.

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

100 ml
250 ml
1 L

5. TARGET SPECIES

Cattle

6. INDICATIONS

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Pour-on use.
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:

Meat and offal: 7 days
Milk: 36 hours

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

User Warnings
Personal protective equipment consisting of impermeable gloves, protective clothing and approved safety glasses should be worn when handling the product. Ingestion of the product may be harmful. Avoid children from getting access to the product or treated animals.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 6 months.

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4608

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING UNITS

PLASTIC BOTTLE LABEL 100 ml, 250 ml, 1000 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne Transdermal 50 mg/ml pour-on solution for cattle
Flunixin (as flunixin meglumine)

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 50 mg flunixin equivalent to 83 mg flunixin meglumine

3. PHARMACEUTICAL FORM

Pour-on solution

4. PACKAGE SIZE

100 ml
250 ml
1 L

5. TARGET SPECIES

Cattle

6. INDICATIONS

7. METHOD AND ROUTES OF ADMINISTRATION

Pour-on use
Read the package leaflet before use.

8. WITHDRAWAL PERIODS

Withdrawal periods:
Meat and offal: 7 days

Milk: 36 hours

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

User Warnings
Personal protective equipment consisting of impermeable gloves, protective clothing and approved safety glasses should be worn when handling the product. Ingestion of the product may be harmful. Avoid children from getting access to the product or treated animals.

10. EXPIRY DATE

EXP {month/year}
Once opened, use by:

11. SPECIAL STORAGE CONDITIONS

12. SPECIAL 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. To be supplied only on veterinary prescription.

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

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER

Vm 01708/4608

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Finadyne Transdermal 50 mg/ml pour-on solution for cattle

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

Marketing authorisation holder:
MSD Animal Health UK Ltd.
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

Manufacturer responsible for batch release:
Vet Pharma Friesoythe GmbH
Sedelsberger Str. 2-4
26169 Friesoythe
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne Transdermal 50 mg/ml pour-on solution for cattle
Flunixin

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:
Flunixin 50 mg equivalent to 83 mg flunixin meglumine

Excipients:

Levomenthol:	50 mg
Allura red AC (E129)	0.2 mg

Clear red liquid free from haziness and visible particles.

4. INDICATIONS

For the reduction of pyrexia associated with bovine respiratory disease.
For the reduction of pyrexia associated with acute mastitis.
For the reduction of pain and lameness associated with interdigital phlegmon, interdigital dermatitis and digital dermatitis.

5. CONTRAINDICATIONS

Do not use in animals suffering from cardiac, hepatic or renal disease, or where there is evidence of gastrointestinal ulceration or bleeding.
Do not use in severely dehydrated, hypovolaemic animals as there is a potential risk of increased renal toxicity.
Do not use the product within 48 hours before expected parturition in cows.
Do not use in case of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

Transient swelling, erythema, dandruff, broken/brittle hair, hair thinning, hair loss or skin thickening have been commonly reported at the application site. No specific treatment is generally required.
Some animals may display temporary signs of irritation, agitation or discomfort following application of the product. In very rare cases anaphylactic reactions, which may be serious, may occur and should be treated symptomatically.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon. Alternatively you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle.

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

Pour-on use. For single application. The recommended treatment dose is 3.33 mg flunixin/kg bodyweight (equivalent to 1 ml/15 kg bodyweight). The dosing chamber is calibrated in kilograms of body weight. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible.

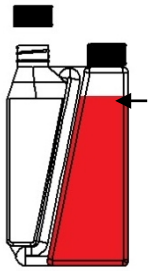
9. ADVICE ON CORRECT ADMINISTRATION

Practice the administration instructions a few times to become familiar with operating the package before dosing animals.

Administration instructions

Step 1

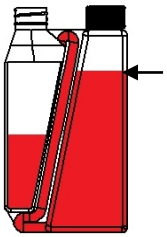
On first use remove cap and peelable seal from the dosing chamber.



Do not remove cap from the bottle.

Step 2

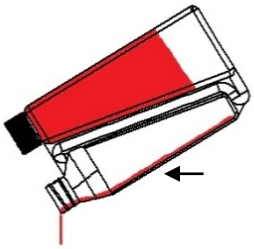
Dosing Chamber



Hold the bottle upright and at eye level while slowly and gently squeezing the bottle to fill the dosing chamber to the selected mark.

If the dosing chamber is overfilled follow the Overfill Reduction Instructions.

Step 3



Pour the measured volume on the midline of the animal's back extending from withers to tail head.

A small amount of liquid will remain on the walls of the chamber, but the chamber is calibrated to account for this.

Avoid squeezing the container section while the solution is poured from the dosing chamber.

Localised application to smaller areas should be avoided.

Overfill reduction instructions

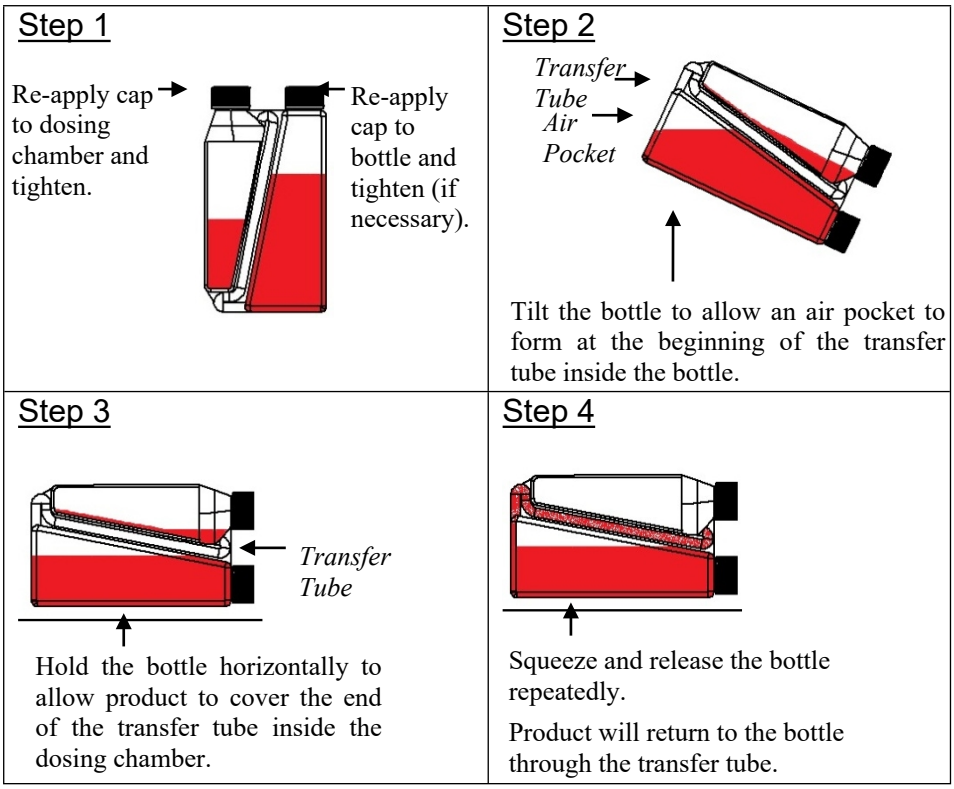
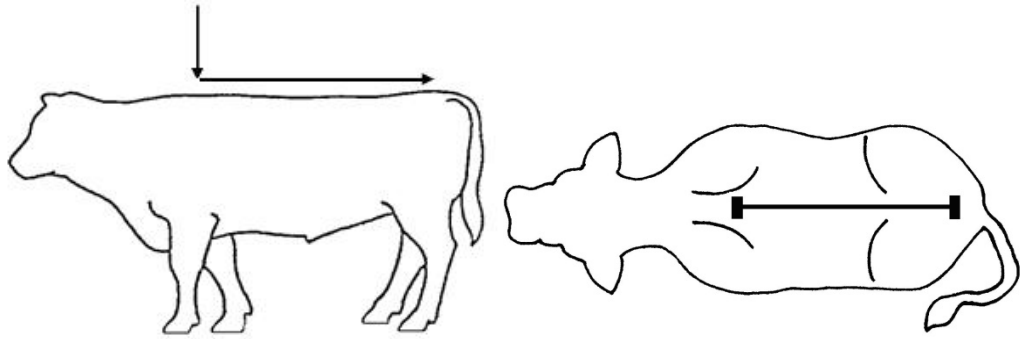


Figure 1- Recommended pour-on location



10. WITHDRAWAL PERIODS

Meat and offal: 7 days.
Milk: 36 hours.
Due to the possibility of cross-contamination of non-treated animals with this product due to grooming (licking), treated animals should be kept separately from non-treated animals throughout the withdrawal period. Non-compliance with this recommendation may lead to residues in non-treated animals.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
This veterinary medicinal product does not require any special storage conditions.
Do not use after the expiry date stated on the bottle after EXP. The expiry date refers to the last day of that month.
Shelf-life after first opening the immediate package: 6 months. A space is provided on the label to write the date on which any remaining product should be discarded.

12. SPECIAL WARNINGS

Special warning for each target species:
Apply only to dry skin and prevent exposure to wetting for at least 6 hours after application.
In case of bacterial infections, concurrent antibiotic therapy should be considered.

Special precautions for use in animal:
Non-Steroidal Anti-Inflammatory Drugs (NSAIDs) are known to have the potential to delay parturition through a tocolytic effect by inhibiting prostaglandins that are important for the initiation of parturition. The use of the product in the immediate post-calving period may interfere with involution of the uterus and expulsion of foetal membranes, resulting in retained placentae.
Safety studies have not been conducted in bulls intended for breeding. Laboratory studies in rats have not shown any evidence of reproductive toxicity. Use only in accordance with a benefit/risk assessment by the responsible veterinarian.
Use in calves which have not yet started rumination and in aged animals may involve additional risk. If such use cannot be avoided, animals may require a reduced dosage and careful clinical management.
Apply only to undamaged skin.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Non-Steroidal Anti-inflammatory Drugs (NSAIDs) may cause hypersensitivity (allergy).
People with known hypersensitivity to NSAIDs should avoid contact with the product.
The product has been shown to cause severe and irreversible eye damage and to cause slight skin irritation. Ingestion of, or dermal contact with the product may be harmful.
Avoid contact with eyes, including hand-to-eye contact. Avoid contact with the skin.
Avoid contact with the treated area (allowing for spreading of the product) without protective gloves, for at least three days or until the application site is dry (if longer).
Avoid children getting access to the product or treated animals.
Personal protective equipment consisting of impermeable gloves, protective clothing and approved safety glasses should be worn when using this product.
In case of accidental ingestion or mouth contact, immediately rinse the mouth with plenty of water and seek medical advice.
In case of eye contact, rinse eyes immediately with copious amounts of clean water and seek medical advice.
In case of skin contact, wash thoroughly with soap and water.
Do not smoke, eat or drink while handling the product. Wash hands after use.
Pregnancy and lactation:

Can be used during pregnancy and lactation except for 48 hours prior to calving.
Due to an increased risk of retained placentae, the product should only be administered within the first 36 hours after calving following a benefit/risk assessment performed by the responsible veterinarian and treated animals should be monitored for retained placentae.

Interaction with other medicinal products and other forms of interaction:
Do not administer other veterinary products of the same class (Non-Steroidal Anti-Inflammatory Drugs) concurrently or within 24 hours of each other.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects. Concurrent administration of potentially nephrotoxic drugs should be avoided.

Overdose (symptoms, emergency procedures, antidotes):
Localised inflammatory reactions of the skin and necrosis have been reported at 5 mg/kg.
Erosive and ulcerative abomasal lesions were observed in animals administered the product at 3 times the recommended treatment dose.
Occult faecal blood was observed in some animals administered the product at 5 times the recommended treatment dose.
No emergency procedures are necessary.

Incompatibilities:
In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

For animal treatment only.

Keep out of the sight and reach of children.

3 container sizes: 100 ml, 250 ml and 1000 ml.
Not all pack sizes may be marketed.

Information intended for the veterinary practitioner:

The active substance flunixin (as meglumine salt) is a carboxylic acid, non-steroidal anti-inflammatory drug (NSAID) with non-narcotic analgesic and antipyretic activities. It demonstrates potent inhibition of the cyclo-oxygenase system (COX-1 and COX-2). COX converts arachidonic acid to instable cyclic endoperoxides, which are converted to prostaglandins, prostacyclin and thromboxane. The inhibition of the synthesis of such components is responsible for the analgesic, antipyretic and anti-inflammatory properties of flunixin meglumine.

In one study, Finadyne Transdermal was investigated in 64 cows with mastitis and efficacy for reducing rectal temperature was compared to placebo, which was used in 66 cows. At six hours post-treatment 95.3% of cows treated with Finadyne Transdermal showed a decrease in rectal temperature of more than 1.1°C, compared with 34.9% in the placebo group. After 6 hours, when antibiotic treatment had been added, there were no differences in rectal temperature between groups.

After dermal application, flunixin is moderately absorbed through the skin of cattle (bioavailability about 44%). In cattle (except for calves), volumes of distribution are generally low due to the high degree (approximately 99%) of plasma protein binding. The apparent plasma elimination half-life following pour-on administration is about 7.8h. The metabolism of flunixin is rather limited, most of the drug corresponding to the unchanged parent compound and the remaining metabolites derived from hydroxylation. In cattle, elimination occurs primarily through biliary excretion.
After pour-on treatment, faster absorption of flunixin was observed in warmer conditions compared to colder conditions. In warm conditions (environmental temperatures between 13°C and 30°C) the T_{max} was about 2 hours whereas it was about 6 hours in cold conditions (environmental temperatures between -3°C and 7°C).
Anti-pyretic effect has been demonstrated from 4 hours after application of the product.