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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

100 ml
250 ml
1 L

4. TARGET SPECIES

Cattle

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Pour-on use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 7 days
Milk: 36 hours

8. EXPIRY DATE

Exp. {mm/yyyy}
Once opened, use within 6 months.

9. SPECIAL STORAGE PRECAUTIONS

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

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

14. MARKETING AUTHORISATION NUMBERS

Vm 01708/3013

15. BATCH NUMBER

Lot {number}

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.

Proposed text to appear on printed packaging for UK(NI) under Article 13 of Veterinary Medicine Regulations 2019/6 only if joint labelled with UK(GB)
Excipients:
Levomenthol 50 mg
Allura red AC (E129) 0.2 mg

Keep the bottle in the outer carton.

Disposal: Read package leaflet.
POM-V To be supplied only on veterinary prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

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

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Pour-on use
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 7 days
Milk: 36 hours

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by:

7. SPECIAL STORAGE PRECAUTIONS

8. NAME OF THE MARKETING AUTHORISATION HOLDER

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

9. BATCH NUMBER

Lot {number}

To appear on immediate labelling under Article 13 of Veterinary Medicine Regulations 2019/6 for UK(NI)

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.

Proposed text to appear on printed packaging for UK(NI) under Article 13 of Veterinary Medicine Regulations 2019/6 only if joint labelled with UK(GB)

Once opened, use within 6 months.
Keep the bottle in the outer carton.

100 ml
250 ml
1 L

For animal treatment only.
POM-V To be supplied only on veterinary prescription.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. COMPOSITION

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.

3. Target species

Cattle.

4. INDICATIONS FOR USE

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 veterinary medicinal product within 48 hours before expected parturition in cows. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. SPECIAL WARNINGS

Special warnings:
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 safe use in the target species:
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.

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

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 veterinary medicinal 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 handling the veterinary medicinal 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, seek medical advice and show the package leaflet or the label to the physician.
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:
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.

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

7. ADVERSE EVENTS

Cattle:

Common (1 to 10 animals / 100 animals treated):
Application site swelling[1], application site skin erythema (skin reddening)[1], application site dry skin (dandruff)[1], application site hair change (broken/brittle hair, hair thinning)[1], application site alopecia (hair loss)[1], application site thickening.[1] Uncomfortable[2]; Agitation[2]; Irritability[2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylaxis (severe form of allergic reaction)[3]

[1] These changes have been reported as transient. No specific treatment is generally required.
[2] Temporary signs
[3] May be serious, may occur and should be treated symptomatically

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 local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTES 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 a correct dosage, bodyweight should be determined as accurately as possible.

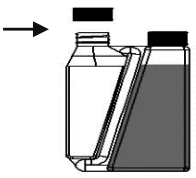
9. ADVICE ON CORRECT ADMINISTRATION

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

Administration instructions

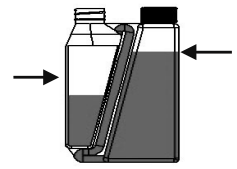
Step 1: On first use remove cap and peelable seal from the dosing chamber.

Do not remove cap from the bottle.

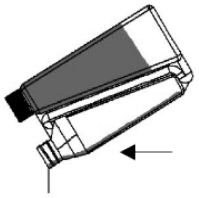


Step 2: Hold the bottle upright and at eye level while slowly and gently squeezing the bottle to fill the dosing chamber to the selected mark.
If the dosing chamber is overfilled follow the Overfill Reduction Instructions.

Dosing Chamber

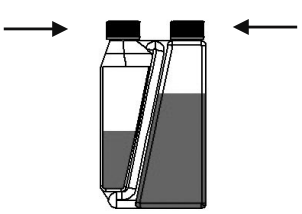


Step 3: Pour the measured volume on the midline of the animal's back extending from withers to tail head.
A small amount of liquid will remain on the walls of the chamber, but the chamber is calibrated to account for this. Avoid squeezing the container section while the solution is poured from the dosing chamber.

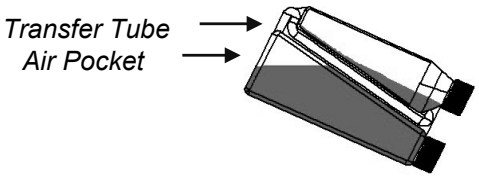


Overfill reduction instructions

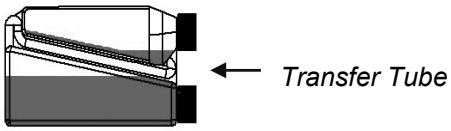
Step 1: Re-apply cap to dosing chamber and tighten.



Step 2: Tilt the bottle to allow an air pocket to form at the beginning of the transfer tube inside the bottle.



Step 3: Hold the bottle horizontally to allow veterinary medicinal product to cover the end of the transfer tube inside the dosing chamber.



Step 4: Squeeze and release the bottle repeatedly. Veterinary medicinal product will return to the bottle through the transfer tube.

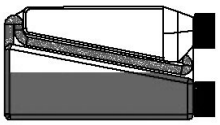
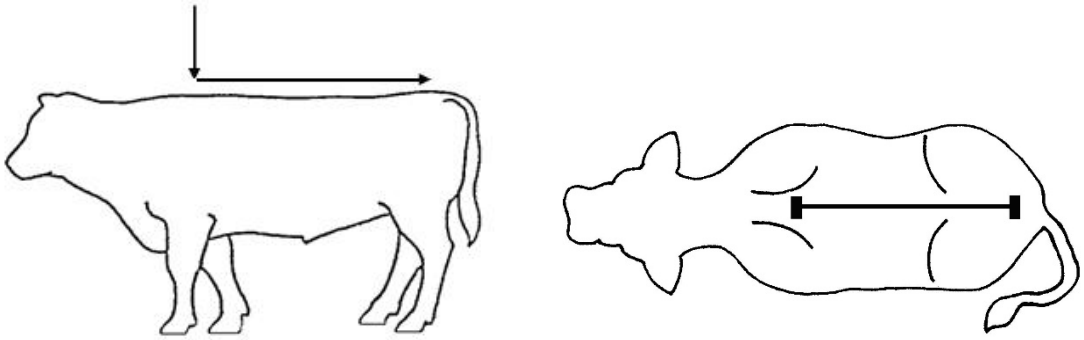


Figure 1- Recommended pour-on location



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 this veterinary medicinal product after the expiry date which is stated on the bottle. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: 6 months. A space is provided on the label to write the date on which any remaining product should be discarded.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Marketing authorisation number:
Vm 01708/3013

One bottle of 100 ml, 250 ml or 1 L.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

May 2023

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

16. Contact details

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 Strasse 2-4
26169 Friesoythe
Germany

Contact details to report suspected adverse reactions:
Intervet Ireland Ltd.
Tel.: +353 (0)1 2970220

Distributor in Northern Ireland:
Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24, Ireland

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

17. Other information

Environmental properties:
Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

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 7.8 h. 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 veterinary medicinal product.

Approved: 30 June 2023