SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE 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

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Pour-on solution.
Clear red liquid free from haziness and visible particles.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle

4.2 Indications for use, specifying the target species

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.

4.3 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.

4.4 Special warnings 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.

4.5 Special precautions for use

Special precautions for use in animals
See also section 4.7.
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 in signalling the initiation of parturition. The use of the product in the immediate post-partum period may interfere with uterine involution 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 pre-ruminating 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.

4.6 Adverse reactions (frequency and seriousness)

Transient swelling, erythema, dandruff, broken/brittle hair, hair thinning, alopecia 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).

4.7 Use during pregnancy, lactation or lay

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

4.8 Interaction with other medicinal products and other forms of interaction

Do not administer other NSAIDs 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.

4.9 Amounts to be administered and administration route

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 of the bottle is calibrated in kilograms of body weight. To ensure administration of a correct dose, bodyweight should be determined as accurately as possible.
Practice the administration instructions a few times to become familiar with operating the package before dosing animals.

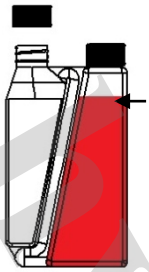
Step 1: On first use remove cap and peelable seal from the dosing chamber. Do not remove cap from the bottle

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.

Step 3: Pour the measured volume on the midline of the animal's back extending from the withers to tail head. Localised application to smaller areas should be avoided.

Step 1

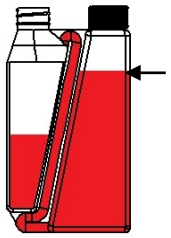
On first use remove cap and peelable seal from the dosing chamber.



Do not remove cap from the bottle.

Step 2

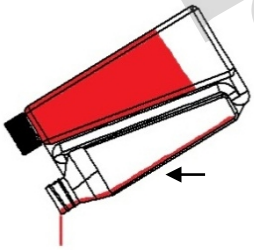
Dosing Chamber



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.

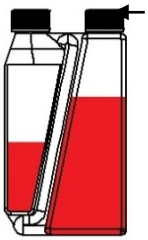
A small amount of liquid will remain on the walls of the chamber, but the chamber is calibrated to account for this.

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

Overfill reduction instructions

Step 1

Re-apply cap to dosing chamber and tighten.

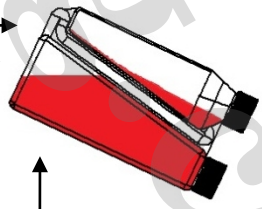


Re-apply cap to bottle and tighten (if necessary).

Step 2

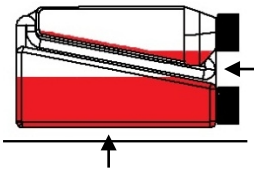
Transfer Tube

Air Pocket



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

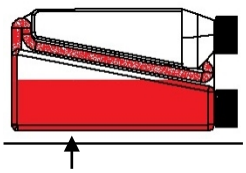
Step 3



Transfer Tube

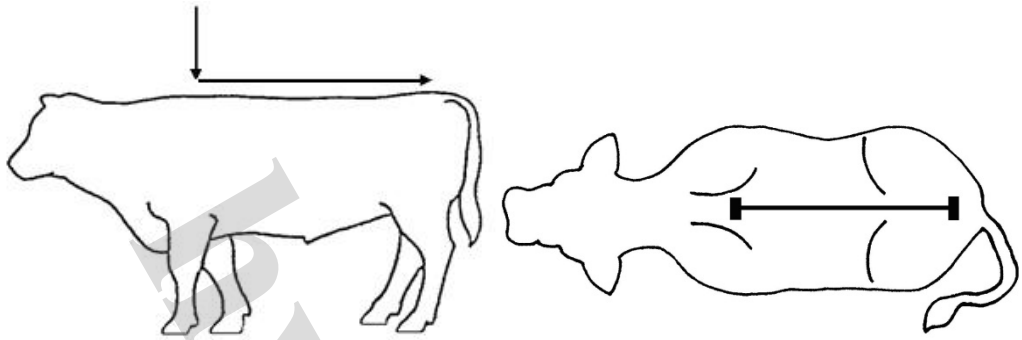
Hold the bottle horizontally to allow product to cover the end of the transfer tube inside the dosing chamber.

Step 4



Squeeze and release the bottle repeatedly.

Product will return to the bottle through the transfer tube.



4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

Localised dermal inflammatory reactions 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.

4.11 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.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products; non-steroids; fenamates; flunixin
ATCvet code: QM01AG90

5.1 Pharmacodynamic properties

The active substance flunixin (as a 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 the groups.

5.2 Pharmacokinetic particulars

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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pyrrolidone
Levomenthol
Propylene glycol dicaprylocaprate
Allura red AC (E129)
Glycerol monocaprylate

6.2 Major incompatibilities

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

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening of the immediate package: 6 months.

6.4 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

6.5 Nature and composition of immediate packaging

High density polyethylene (HDPE) bottles with polypropylene (PP) closures which have a peelable foil laminate induction innerseal and a liner. The bottles are equipped with a graduated dosing chamber and are supplied individually in a cardboard carton.
3 container sizes: 100 ml, 250 ml and 1000 ml.

Not all pack sizes may be marketed.

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

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

7. MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

8. MARKETING AUTHORISATION NUMBER

Vm 01708/4608

9. DATE OF FIRST AUTHORISATION

8 May 2014

10. DATE OF REVISION OF THE TEXT

August 2020

Approved: 14 August 2020