1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne Transdermal 50 mg/ml pour-on solution for cattle
EL: Finixin Transdermal 50 mg/ml pour-on solution for cattle
DK: Finadyne Transdermal vet 50 mg/ml pour-on solution for cattle
EE, FI, LT, LV, PL, SE: Finadyne vet. 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:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Levomenthol	50 mg
Allura red AC (E129)	0.2 mg
Pyrrolidone	
Propylene glycol dicaprylocaprate	
Glycerol monocaprylate	

Clear red liquid free from haziness and visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle

3.2 Indications for use for each 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.

3.3 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 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.

3.4 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.

3.5 Special precautions for use

Special precautions for safe use in the target species:

See also section 3.7.
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.

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, seek medical advice and show the package leaflet or the label to the physician.
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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Cattle:

Common (1 to 10 animals / 100 animals treated):	Application site swelling[1], application site erythema[1], application site dry skin (dandruff)[1], application site hair change (broken/brittle hair, hair thinning)[1], application site alopecia[1], application site thickening[1] Uncomfortable[2]; Agitation[2]; Irritability [2]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Anaphylaxis[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 veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Pregnancy and lactation:
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.

3.8 Interaction with other medicinal products and other forms of interaction

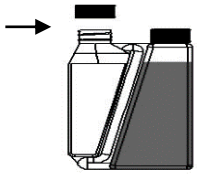
Do not administer other NSAIDs concurrently or within 24 hours of each other.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects. Concurrent administration of potentially nephrotoxic drugs should be avoided.

3.9 Administration routes and dosage

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 a correct dosage, 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.

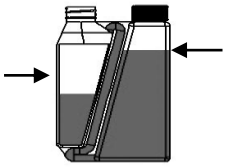
Step 1: On first use remove cap and peelable seal from the dosing chamber.

Do not remove cap from the bottle.

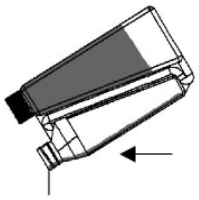


Step 2: Hold the bottle upright and at eye level while slowly and gently squeezing the bottle to fill the dosing chamber to the selected mark.
If the dosing chamber is overfilled follow the Overfill Reduction Instructions.

Dosing Chamber

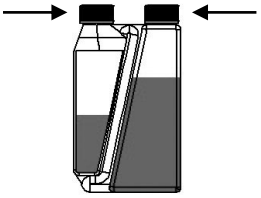


Step 3: Pour the measured volume on the midline of the animal's back extending from withers to tail head.
A small amount of liquid will remain on the walls of the chamber, but the chamber is calibrated to account for this.
Avoid squeezing the container section while the solution is poured from the dosing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



Overfill reduction instructions

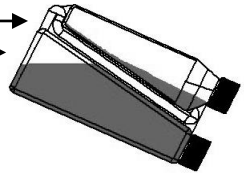
Step 1: Re-apply cap to dosing chamber and tighten.



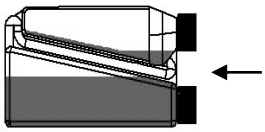
Re-apply cap to bottle and tighten (if necessary).

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

Transfer Tube
Air Pocket



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



Transfer Tube

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

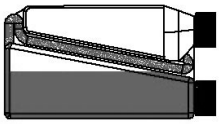
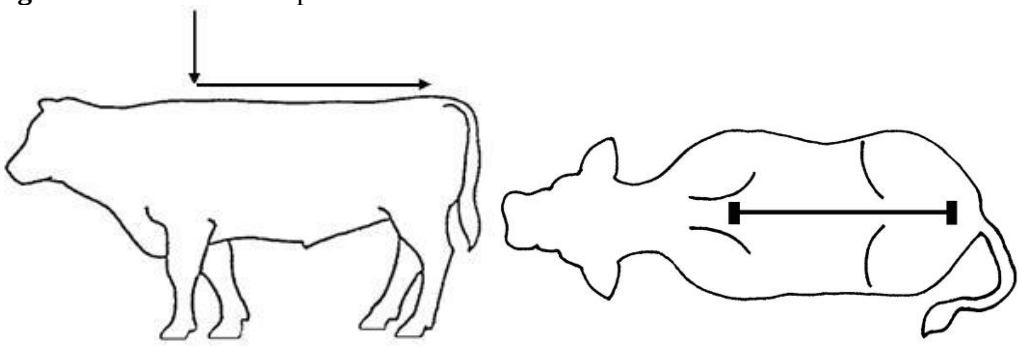


Figure 1- Recommended pour-on location



3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Localised dermal inflammatory reactions and necrosis have been reported at 5 mg/kg.
Erosive and ulcerative abomasal lesions were observed in animals administered the veterinary medicinal 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.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 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.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AG90

4.2 Pharmacodynamics

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.

4.3 Pharmacokinetics

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.

Environmental properties

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

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

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

5.2 Shelf life

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

5.3 Special precautions for storage

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

5.4 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.

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

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Medicines should not be disposed of via wastewater or household waste.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

[*To be completed nationally.*]

7. MARKETING AUTHORISATION NUMBER(S)

[*To be completed nationally.*]

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: DD/MM/YYYY

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>
<{DD/MM/YYYY}>
<{DD month YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database.

(*https://medicines.health.europa.eu/veterinary*).