PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/ml Solution for Injection

Flunixin Meglumine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Flunixin (as Flunixin Meglumine) 5.0 % w/v

Excipients: Phenol (preservative) 0.50 % w/v

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml

100 ml

5. TARGET SPECIES

Cattle, horses and pigs.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read package leaflet before use

Cattle:

2ml per 45kg bodyweight (equivalent to 2.2mg flunixin per kg) administered intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days.

Horses:

By intravenous injection for musculo-skeletal disorders at the following rate:

1ml per 45kg bodyweight (1.1mg flunixin/kg) once daily for up to 5 days according to clinical response.

By intravenous injection for colic at the following rate:

1ml per 45kg bodyweight (1.1 mg flunixin/kg) repeated once or twice if colic recurs.

For the treatment of endotoxaemia or septic shock associated with gastric torsion and with other conditions in which the circulation of blood to the gastro-intestinal tract is compromised: 0.25mg/kg every 6-8 hours, by intravenous injection.

Pigs:

2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

8. WITHDRAWAL PERIOD

Withdrawal period(s)

Cattle (meat):	5 days
Horses:	7 days
Pigs:	22 days
Milk (cattle):	24 hours

9. SPECIAL WARNING(S), IF NECESSARY

Contra-indications / Warnings

Do not exceed the stated dose or the duration of treatment.

Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is hypersensitivity to the product.

Do not use the product within 48 hours before expected parturition.

Do not administer to pregnant mares.

Do not administer to pregnant sows, gilts at mating and in breeding boars.

10. EXPIRY DATE

EXP end of:

Following withdrawal of the first dose use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not freeze.

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

[Distribution category]

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

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

Marketing Authorisation Holder:

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4582

17. MANUFACTURER'S BATCH NUMBER

Batch number

PARTICULARS TO APPEAR ON THE THE IMMEDIATE PACKAGE

Label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/ml Solution for Injection

Flunixin Meglumine

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance: Flunixin (as Flunixin Meglumine) 5.0 % w/v

Excipients: Phenol (preservative) 0.50 % w/v

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50 ml

100 ml

5. TARGET SPECIES

Cattle, horses and pigs.

6. INDICATION(S)

Not applicable.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Cattle: 2ml per 45kg bodyweight (equivalent to 2.2mg flunixin per kg) administered intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days.

Horses: By intravenous injection at the following rate:

For musculo-skeletal disorders:1ml per 45kg bodyweight (1.1mg flunixin/kg) once daily for up to 5 days according to clinical response.

For colic: 1ml per 45kg bodyweight (1.1 mg flunixin/kg) repeated once or twice if colic recurs.

For treatment of endotoxaemia or septic shock , see package leaflet.

Pigs: 2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

8. WITHDRAWAL PERIOD

Withdrawal period(s)

Cattle (meat): 5 days; Horses: 7 days; Pigs: 22 days; Milk (cattle): 24 hours.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP end of:

Following withdrawal of the first dose use within 28 days.

Once broached,/opened, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

Do not freeze.

Keep the container in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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.

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

[Distribution category]

For animal treatment only.

POM-V

To be supplied only on veterinary prescription.

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

MA Holder:

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4582

17. MANUFACTURER’S BATCH NUMBER

Batch number:

PACKAGE LEAFLET FOR:

Finadyne 50 mg/ml Solution for Injection

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 for the batch release:

TriRx Segré
La Grindolière, Zone Artisanale
Segré, 49500 Segré-en-Anjou Bleu
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/ml Solution for Injection

Flunixin Meglumine

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

Active substance:	% w/v
Flunixin (as Flunixin Meglumine)	5.0
Excipients:	
Phenol (preservative)	0.50

4. INDICATION(S)

In Cattle:

For the control of acute inflammation associated with respiratory disease.

Finadyne has also been shown to have some benefit in the treatment of experimental acute bovine pulmonary emphysema (Fog Fever).

Finadyne Solution may be used as adjunctive therapy in the treatment of acute mastitis.

In Horses:

For the alleviation of inflammation and pain associated with musculo-skeletal disorders.

For the alleviation of visceral pain associated with colic in the horse.

In Pigs:

For use as an adjunctive therapy in the treatment of swine respiratory diseases.

5. CONTRAINDICATIONS

Do not exceed the stated dose or the duration of treatment.

Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is hypersensitivity to the product.

Do not administer to pregnant mares.

Do not administer to pregnant sows, gilts at mating and in breeding boars.

Do not use the product within 48 hours before expected parturition in cows.

6. ADVERSE REACTIONS

Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID). Untoward effects include gastrointestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage.

In pigs transient irritation may occur at the injection site, this resolves spontaneously within 14 days.

Anaphylactic-type reactions have been reported in horses and cattle, resulting in collapse following intravenous injection. Such reactions, on very rare occasions have been life-threatening in spontaneous pharmacovigilance reports.

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 serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horses and pigs.

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

Cattle

2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin per kg) administered intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days.

Horses

By intravenous injection for musculo-skeletal disorders at the following rate:

1 ml per 45 kg bodyweight (1.1 mg flunixin/kg) once daily for up to 5 days according to clinical response.

By intravenous injection for colic at the following rate:

1 ml per 45 kg bodyweight (1.1 mg flunixin/kg) repeated once or twice if colic recurs.

For the treatment of endotoxaemia or septic shock associated with gastric torsion and with other conditions in which the circulation of blood to the gastro-intestinal tract is compromised: 0.25 mg/kg every 6-8 hours, by intravenous injection.

Pigs

2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

An appropriately graduated syringe must be used to allow accurate administration of the required dose volume.

This is particularly important when injecting small volumes.

When intramuscular injection is used, the dose should be divided between two injection sites on either side of the neck.

9. ADVICE ON CORRECT ADMINISTRATION

In order to prevent excessive broaching of the rubber stopper, it is not recommended that the stopper is broached more than 25 times.

10. WITHDRAWAL PERIOD(S)

Animals must not be slaughtered for human consumption during treatment.

Cattle: 5 days from the last treatment.

Horses: 7 days from the last treatment.

Pigs: 22 days from the last treatment.

Milk for human consumption must not be taken during treatment. Milk for human consumption may only be

taken from cattle after 24 hours from the last treatment.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Do not store above 25°C.

Do not freeze.

Keep the container in the outer carton.

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first broaching the immediate packaging: 28 days.

When the container is broached (opened) for the first time, using the in-use shelf life which is specified on this package insert, the date on which any remaining in the container should be discarded should be worked out. The discard date should be written in the space provided on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Avoid intra-arterial injection.

Inject slowly as life-threatening symptoms of shock can occur due to the content of propylene glycol. The product should have a temperature close to body temperature. Stop injection immediately if first symptoms of shock occur and start treatment for shock if necessary.

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. See also section “Use during pregnancy and lactation”.

Use in any animal less than 6 weeks of age or in aged animals may involve additional risk. If such use cannot be avoided animals may require a reduced dosage and careful clinical management.

Do not use in hypovolaemic animals except in the case of endotoxaemia or septic shock.

It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.

The cause of colic should be determined and treated with concurrent therapy.

The product should not be used in piglets weighing less than 6 kg.

Non-steroidal, anti-inflammatory drugs are not permitted under the rules of Racing and under rules covering other competitive events.

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 product to the animal

Avoid contact with skin or eyes.

In case of skin contact, wash exposed area with water.

In case of eye contact, wash eyes thoroughly with clean water and seek medical advice.

Take care against accidental self injection.

Wash hands after use.

Use during pregnancy and lactation:

The product may be used in pregnant and lactating cattle.

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.

Do not use in pregnant mares or pregnant sows.

Safety studies in pregnant mares and pregnant sows have not been conducted.

Interaction with other medicinal products:

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.

Overdose:

Overdosage studies in the target species have shown the product to be well-tolerated. Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdosage is associated with gastrointestinal toxicity. Concurrent use of nephrotoxic drugs should be avoided.

Environmental properties

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

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

May 2022

15. OTHER INFORMATION

Vm 01708/4582

POM-V

To be supplied only on veterinary prescription.

Approved 07 June 2022