LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/g Oral Paste

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each gram contains: Flunixin 50 mg (as flunixin meglumine 83 mg).

3. PHARMACEUTICAL FORM

Oral Paste

4. PACKAGE SIZE

6 x 10 g

5. TARGET SPECIES

Horses.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.

1.1 mg flunixin per kg body weight once daily for up to 5 days according to clinical response.

Each 10 g syringe is sufficient for one day's treatment for a 454 kg (1000 lb.) horse. The syringe is calibrated in 100 kg increments to facilitate dosing of horses of different weights.

Prior to first use, the syringe must be primed. Set the ring on the graduated syringe plunger to the zero (0) position. Remove the cap and press the plunger to remove air. Discard any small volume of paste that may be expelled. The syringe is now ready for use.

8. WITHDRAWAL PERIOD

Withdrawal period: Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C.
Do not freeze.
Replace cap after use.
Keep syringes in the outer box.

Store syringes in an upright position.

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

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 sight and reach 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

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4599

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

SYRINGE LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/g Oral Paste

2. STATEMENT OF ACTIVE SUBSTANCE(S)

Each gram contains: Flunixin 50 mg (as flunixin meglumine 83 mg).

3. PHARMACEUTICAL FORM

Oral Paste

4. PACKAGE SIZE

10 g

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Not to be used in horses intended for human consumption.
Read the package leaflet before use.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25 °C. Do not freeze.
Replace cap after use.
Keep syringes in the outer box.

Store syringes in an upright position.

12. SPECIFIC 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.
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 sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.
Milton Keynes
MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4599

17. MANUFACTURER'S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Finadyne 50 mg/g Oral Paste

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

Manufacturers responsible for batch release:
TriRx Segré
La Grindolière, Zone Artisanale
Segré, 49500 Segré-en-Anjou Bleu
France

and

Intervet Productions
Rue de Lyons
27460 Igoville
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Finadyne 50 mg/g Oral Paste

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

Each gram contains:
Flunixin 50 mg (as flunixin meglumine 83 mg).

White to off-white paste.

4. INDICATION(S)

For the alleviation of inflammation and pain associated with musculoskeletal disorders in the horse.

5. CONTRAINDICATIONS

Do not exceed the stated dose or duration of treatment.
Do not use in animals suffering from cardiac, hepatic or renal disease, or where there is the possibility of gastrointestinal ulceration or bleeding.
Do not use in cases of hypersensitivity to the active substance.
Do not administer steroidal or other non-steroidal anti-inflammatory drugs concurrently or within 24 hours of each other.
Do not use in hypovolaemic animals except in the case of endotoxaemia or septic shock.

6. ADVERSE REACTIONS

Allergic reactions (allergic skin reactions, anaphylaxis) may occur after administration of the veterinary medicinal product in very rare cases.

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.

7. TARGET SPECIES

Horse.

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

Oral use.

1.1 mg flunixin per kg body weight once daily for up to 5 days according to clinical response.

Each syringe is sufficient for one day’s treatment for a 454 kg (1000 lb.) horse.
The 10 g syringe is calibrated in 100 kg increments to facilitate dosing of horses of different weights.

9. ADVICE ON CORRECT ADMINISTRATION

Prior to first use, the syringe must be primed. Set the ring on the graduated syringe plunger to the zero (0) position. Remove the cap and press the plunger to remove

air. Discard any small volume of paste that may be expelled. The syringe is now ready for use.

10. WITHDRAWAL PERIOD(S)

Not to be used in horses intended for human consumption.
Treated horses may never be slaughtered for human consumption.
The horse must have been declared as not intended for human consumption under national horse passport legislation.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Do not store above 25 °C.
Do not freeze.
Replace cap after use.

Keep syringes in the outer box.
Store syringes in an upright position.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Non-steroidal anti-inflammatory drugs are not permitted substances under the rules of racing and under rules covering other competitive events. The Royal College of Veterinary Surgeons has given guidance to the Veterinary profession regarding the use of anti-inflammatory drugs in competing horses. It states that if a veterinarian recommends the discontinuation of any such drug not less than eight days before racing he should feel sure he has catered for all but the most exceptional case.

Special precautions for use:
Use in animals 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.
In animals undergoing general anaesthesia it is preferable to wait until they are fully recovered before the veterinary medicinal product is administered.
NSAIDs can cause inhibition of phagocytosis. During use in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be administered.
Avoid use in dehydrated, hypovolaemic or hypersensitive animals as there is a potential risk of increased renal toxicity.
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 medicinal product to the animals:
Avoid contact with eyes and direct contact with skin. Gloves should be worn during application.
In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
The product may cause reactions in sensitive individuals. If you have known hypersensitivity to non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.
Wash hands and exposed skin after use.

Special precautions for the protection of the environment:
Flunixin is toxic to avian scavengers although foreseen low exposure leads to low risk.

Pregnancy:
The safety of the veterinary medicinal product has not been established during pregnancy.

Interaction with other medicinal products and other forms of interaction:
Concurrent administration of potentially nephrotoxic drugs should be avoided.
Some NSAIDs may be highly bound to plasma proteins and may compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations which can lead to toxic effects.

Overdose (symptoms, emergency procedures, antidotes):
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.

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

October 2022

15. OTHER INFORMATION

For animal treatment only.

Pack size:

Cardboard box with 6 x 10 g syringes.

POM-V To be supplied only on veterinary prescription.

Vm 01708/4599

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

Approved 16 November 2022