PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Container label text}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meflosyl® 5% Solution for Injection

Flunixin meglumine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Flunixin (as flunixin meglumine) – 50 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50ml
100 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous administration

For uses, warnings and full information please read the package leaflet before use.

8. 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

-

10. EXPIRY DATE

Exp:

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Keep container in outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Zoetis UK Limited

1st Floor, Birchwood Building

Springfield Drive

Leatherhead

Surrey

KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4085

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Folding carton text}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meflosyl® 5% Solution for Injection

Flunixin meglumine

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Flunixin (as flunixin meglumine)	50 mg

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

50ml
100 ml

5. TARGET SPECIES

Horses

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intravenous administration.

For uses, warnings and full information please read the package leaflet before use.

1 ml per 45 kg administered intravenously.

For musculo-skeletal disorders give once daily for up to 5 days depending on clinical response. For colic, repeat on one or two further occasions if symptoms recur.

For endotoxaemia or 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 per kg bodyweight (1 ml per 200 kg) every 6-8 hours.

8. 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

-

10. EXPIRY DATE

Exp:

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C. Protect from light.

Keep container in 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

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

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

Zoetis UK Limited

1st Floor, Birchwood Building

Springfield Drive

Leatherhead

Surrey

KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4085

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR: Meflosyl® 5% 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:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Manufacturer responsible for batch release:
Zoetis Manufacturing and Research Spain S.L.
Ctra. Camprodon s/n “la Riba”
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meflosyl® 5% Solution for Injection

Flunixin meglumine

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Meflosyl 5% Solution for Injection is a sterile aqueous solution containing 50 mg flunixin as flunixin meglumine, 5 mg phenol as an antimicrobial preservative, 3.3 mg sodium formaldehyde sulfoxylate dihydrate and 0.1 mg disodium edetate dihydrate as an antioxidant per ml.

4. INDICATIONS

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

5. CONTRAINDICATIONS

Do not exceed the recommended dose or duration of treatment.

Do not administer to pregnant mares.

Do not use in animals suffering from cardiac, hepatic or renal disease where there is a possibility of gastro-intestinal ulceration or bleeding.

Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.

6. ADVERSE REACTIONS

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

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

Horses

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

Musculo-skeletal disorders: The recommended dose is 1 ml of the product per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) once daily by intravenous injection. Treatment should be given for up to 5 days depending on clinical response.

Colic: The recommended dose for the alleviation of visceral pain associated with colic is 1 ml of the product per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg), by intravenous injection.
Treatment may be repeated on one or two further occasions if signs of colic recur. The cause of colic should be determined and treated with appropriate therapy.

For the treatment of endotoxaemia or 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 per kg bodyweight (1 ml per 200 kg) every 6-8 hours.

9. ADVICE ON CORRECT ADMINISTRATION

-

10. WITHDRAWAL PERIODS

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

Do not store above 25°C. Protect from light.

Keep container in outer carton.

Following withdrawal of the first dose, use the product within 28 days. Discard unused material.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the vial should be discarded should be determined. This discard date should be written in the space provided.

12. SPECIAL WARNING(S)

Special warnings for each target species:

Non-steroidal anti-inflammatory drugs are not permitted under the Rules of Racing and under rules governing other competitive events. The Royal College of Veterinary Surgeons has given advice 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 8 days before racing, he should feel sure that he has catered for all but the most exceptional case”.

Special precautions for use in animals:

Avoid intra-arterial injection.

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.

Avoid 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.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID). The product may cause an allergic reaction in people sensitised to NSAIDs.

People with known hypersensitivity to NSAIDs should avoid contact with the product. Hypersensitivity reactions may be serious.

To avoid possible sensitisation reactions and/or skin irritation, avoid contact with skin. Gloves should be worn during application. Wash hands after use. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

This product may cause eye irritation. Avoid contact with eyes. In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.

Keep out of the sight and reach of children.

Pregnancy and lactation:

Do not use in pregnant mares. Safety studies in pregnant mares have not been conducted.

Interactions with other medicinal products and other forms of interaction

Monitoring of drug compatibility is required in case of adjunctive therapy.

Do not administer other non-steroidal anti-inflammatory drugs (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. Overdosage is associated with gastro-intestinal toxicity.

Incompatibilities

Do not mix with other medications prior to administration.

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

September 2020

15. OTHER INFORMATION

POM-V

To be supplied only on veterinary prescription.

For animal treatment only.

50 ml and 100 ml vials. Not all pack sizes may be marketed.

Vm 42058/4085

Approved 04 September 2020