SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Meflosyl 5% Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Flunixin (as flunixin meglumine 83 mg)	50 mg

Excipients:

Phenol	5 mg
Sodium formaldehyde sulfoxylate	2.5 mg
Disodium edetate dihydrate	0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless to faintly yellow liquid, visually free from particles.

4. CLINICAL PARTICULARS

4.1 Target species

Horses.

4.2 Indications for use, specifying the target species

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

4.3 Contraindications

Do not exceed the recommended dose or duration of treatment.
Do not administer to pregnant mares.
Do not use in known cases of hypersensitivity to the active substance or to any of the excipients.
Do not use in animals suffering from cardiac, hepatic or renal disease, where there is a possibility of gastro-intestinal ulceration or bleeding.

4.4 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 less than 8 days before racing, he should feel sure that he has catered for all but the most exceptional case.

4.5 Special precautions for use

i) Special precautions for use in animals

Intra-arterial injection should be avoided.
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.
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.

ii) 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.

4.6 Adverse reactions (frequency and seriousness)

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.
In very rare cases allergic reactions (anaphylaxis) may occur after administration of the veterinary medicinal product.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals 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

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

4.8 Interaction 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.

4.9 Amounts to be administered and administration route

For intravenous administration.

For use in musculo-skeletal disorders, the recommended dose rate is 1.1 mg flunixin/kg bodyweight, equivalent to 1 ml per 45 kg, once daily for up to 5 days depending on clinical response.
For use in equine colic, the recommended dose rate is 1.1 mg flunixin/kg bodyweight, equivalent to 1 ml per 45 kg. Treatment may be repeated once or twice if colic recurs.
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/kg (= 1 ml per 200 kg bodyweight) administered every 6-8 hours.

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

Overdosage studies in the target species have shown the product to be well tolerated. Overdosage is associated with gastro-intestinal toxicity.

4.11 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.

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Flunixin meglumine is a potent, non narcotic, non steroidal analgesic agent with anti-inflammatory, antipyretic and anti-endotoxic activity.
Flunixin meglumine is a potent inhibitor of cyclo-oxygenase and thereby of the endogenous production of prostaglandins.
Flunixin has no influence on natural or per injection administered prostaglandin F_2-alpha.
It has been demonstrated that flunixin has an anti-endotoxin activity, in particular against the effects of endotoxins formed by *E Coli*.

5.2 Pharmacokinetic properties

Absorption/Elimination
Studies in horses have shown that onset of activity occurs within 2 hours (= 15 to 60 minutes) after parenteral administration when used in musculo-skeletal disorders.
Peak response occurs between 12 and 16 hours and the duration of activity is 24-36 hours (30-40 hours).
When used in equine colic, studies have shown alleviation of pain within 15 minutes (intravenous).
The plasma half-life in horse-serum is 1.6 hours following a single dose of 1.1 mg/kg. Measurable amounts are detectable in horse plasma at eight hours post injection.
Flunixin is mainly excreted via the bile. A minor part is eliminated via the urine.

5.3 Environmental properties

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium formaldehyde sulfoxylate
Disodium Edetate Dihydrate
Propylene Glycol
Trisodium phosphate dodecahydrate
Sodium Hydroxide
Water for Injections

6.2 Major incompatibilities

Do not mix with other medications prior to administration.

6.3 Shelf life

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

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

6.4 Special precautions for storage

Do not store above 25°C.
Protect from light
Following withdrawal of the first dose use the product within 28 days.
Discard unused product.

6.5 Nature and composition of immediate packaging

Colourless type I glass vials of 50 and 100 ml. The vials are closed with rubber stoppers and sealed with aluminium caps.
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

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5225

9. DATE OF FIRST AUTHORISATION

27 March 1998

10. DATE OF REVISION OF THE TEXT

December 2025

Gavin Hall
Approved: 18 December 2025