SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flunex 50 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Flunixin 50.0 mg
(equivalent to 82.9 mg of 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**
Phenol	5.0 mg
Disodium edetate	
Propylene glycol	
Trisodium phosphate dodecahydrate	
Hydrochloric acid, dilute	
Sodium hydroxide	
Water for injections	

Clear and colourless to light yellow solution, free from visible particles.

3. CLINICAL INFORMATION

3.1 Target species

Cattle, pigs and horses

3.2 Indications for use for each target species

Cattle:
Reduction of clinical signs during respiratory infections in association with appropriate anti-infective treatment.

Pigs:
Adjunctive therapy of postpartum dysgalactia (Mastitis-metritis-agalactia) syndrome in sows.
Reduction of fever in respiratory diseases in addition to an appropriate antibiotic.
Horses:
Alleviation of inflammation and pain associated with musculoskeletal disorders.
Alleviation of visceral pain associated with colic.

3.3 Contraindications

Do not use in animals with chronic musculoskeletal disorders.
Do not use in animals with liver, cardiac or renal disease.
Do not use in animals with gastro-intestinal ulceration or bleeding.
Do not use in cases of bleeding disorders.
Do not use in cases of hypersensitivity to the active substance, to other NSAIDs or to any of the excipients.
Do not use in animals suffering from colic caused by ileus and associated with dehydration.
Do not use in cattle within 48 hours before expected parturition in cows.
See section “Use during pregnancy, lactation or lay”.Do not use in dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

3.4 Special warnings

Non-steroidal, anti-inflammatory drugs are not permitted under the rules of Racing and under rules covering 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 eight days before racing, he should feel sure that he has catered for all but the most exceptional case”.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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.
It is known that non-steroidal anti-inflammatory drugs can potentially delay labour through a tocolytic effect, inhibiting prostaglandins which are important for signalling the onset of labour. The use of the veterinary medicinal product in the period immediately following birth may interfere with uterine involution and the expulsion of the foetal membranes. This can lead to placental retention.Do not exceed the recommended dose or duration of treatment.
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.
Ponies may be more sensitive to adverse reactions caused by NSAIDs and therefore the product should be used with caution in these animals. In horses, the cause of colic must be well determined and treated with adequate concomitant therapy.
Avoid intraarterial administration.
Horses to which the veterinary medicinal product is accidentally administered intraarterially may demonstrate ataxia, incoordination, hyperventilation, hysteria, muscle weakness. These are transitory signs that disappear within a few minutes, without the administration of an antidote.
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
The veterinary medicinal product may cause allergic reactions in sensitised individuals.
People with known hypersensitivity to substances belonging to the non-steroidal anti-inflammatory group should avoid contact with the veterinary medicinal product.
Laboratory studies with flunixin have shown evidence of foetotoxic effects in rats.
Pregnant women should use the product with caution to avoid accidental self-injection.
The veterinary medicinal product can cause skin and eye irritation. Avoid contact with the skin and eyes. In the event of skin contact, wash exposed area immediately with soap and water.
In the event of contact with the eyes, rinse immediately with plenty of water.
If skin / eye irritation persists, seek medical advice immediately and show the package leaflet or the label to the physician.
To avoid risk of ingestion, it is recommended not to eat or drink when using the veterinary medicinal product.
In case of accidental self-injection or ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

Cattle, pigs and horses:

Undetermined frequency: (cannot be estimated from the available data)	Bleeding Gastrointestinal irritation[1] Gastrointestinal ulceration[1] Vomiting[1] Renal damage [1,2] Hepatic damage[1,2] Delayed parturition[3], increase of stillbirths[3], retained placenta[4]

[1]Mainly in dehydrated or hypovolaemic animals
[2]As with other NSAIDs, rare renal or idiosyncratic hepatic adverse reactions may be observed.
[3]through a tocolytic effect by inhibiting prostaglandins that are important in signalling the initiation of parturition
[4]in cases of the use of the veterinary medicinal product in the immediate post-partum period

Cattle and horses:

Rare (1 to 10 animals / 10,000 animals treated):	Anaphylactic (with collapse) [1] Death[1]

[1]mainly during rapid intravenous injection

Cattle:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Injection site reaction[1]

[1]after intramuscular administration

Horses:

Undetermined frequency (cannot be estimated from the available data)	blood in faeces[1], diarrhea (liquid)[1]

[1]after intravenous injection

In case of untoward effects stop treatment and seek medical advice.

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

Studies in laboratory animals have produced evidence of foetotoxicity from flunixin after oral administration (rabbit and rat) and intramuscular administration (rat) at maternotoxic doses as well as an increase in the gestation period (rat).

Pregnancy and lactation:
The safety of flunixin has not been assessed in pregnant mares, breeding stallions and bulls. Do not use in these animals.
The safety of flunixin was demonstrated in pregnant cows and sows, as well as boars. The veterinary medicinal product may be used in these animals except within the 48 hours preceding parturition (see sections 3.3 and 3.6).
The veterinary medicinal 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

The concurrent administration of other NSAIDs concurrently or within 24 hours of each other should be avoided, as it may increase the toxicity, mainly gastro-intestinal, even with low doses of acetylsalicylic acid.
The concurrent administration of corticoids may increase toxicity of the two products and increase the risk of gastro-intestinal ulceration. It should therefore be avoided.
Flunixin may reduce the effect of some anti-hypertensive medicinal products such as diuretics, Angiotensin Conversion Enzyme (ACE) inhibitors, and beta blockers, by inhibition of prostaglandin synthesis.
The concurrent administration of potentially nephrotoxic drugs, particularly aminoglycosides, should be avoided.
Flunixin may reduce renal elimination of some drugs and increase their toxicity, such as aminoglycosides for example.

3.9 Administration routes and dosage

For intravenous use in cattle and horses.
For intramuscular use in pigs.

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.

Pigs
- Postpartum dysgalactia syndrome (Mastitis-metritis-agalactia):
2 ml per 50 kg bodyweight (equivalent to 2 mg flunixin/kg) by intramuscular injection for 1 to 3 consecutive days.
- Reduction of fever in respiratory conditions:
2 ml per 45 kg bodyweight (equivalent to 2.2 mg flunixin/kg) once by intramuscular injection, in the neck, in addition to an appropriate antibiotic.

The injection volume should be limited to a maximum of 5 ml per injection site.

Horses
- Alleviation of inflammation and pain associated with musculoskeletal disorders:
1 ml per 45 kg bodyweight (equivalent to 1.1 mg flunixin/kg) by intravenous injection once daily for up to 5 days according to clinical response.
- Alleviation of pain associated with colic:
1 ml per 45 kg bodyweight (equivalent to 1.1 mg flunixin/kg) by intravenous injection. Treatment may be 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.

To ensure a correct dosage, body weight should be determined as accurately as possible.
The stopper may be safely punctured up to 25 times with a 18 G needle size and up to 100 times with a 21 G needle size. For multiple vial entry, an aspirating needle or multi-dose syringe is recommended to avoid excessive broaching of the stopper.

3.10 Symptoms of overdose (and where applicable, emergency procedures and 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. Concurrent use of nephrotoxic drugs should be avoided.

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

Cattle:
Meat and offal: 5 days
Milk: 24 hours

Pigs:
Meat and offal: 22 days

Horses:
Meat and offal: 7 days
Milk: Not authorised for use in animals producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code:

QM01AG90

4.2 Pharmacodynamics

Flunixin meglumine is a potent, non-steroidal, non-narcotic analgesic with antiinflammatory, anti-endotoxic and anti-pyretic activities.

4.3 Pharmacokinetics

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: 30 months
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.
Keep the vial in the outer carton in order to protect from light.

5.4 Nature and composition of immediate packaging

Colourless type II glass vials closed with bromobutyl rubber stoppers and sealed with aluminium cap or flip-off cap.

Pack sizes:
Cardboard box with 1 vial of 50 ml
Cardboard box with 1 vial of 100 ml
Cardboard box with 1 vial of 250 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

Medicines should not be disposed of via wastewater.
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.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Industrial Veterinaria SA

7. MARKETING AUTHORISATION NUMBER

Vm 36547/5001

8. DATE OF FIRST AUTHORISATION

27 September 2024

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

September 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall

Approved: 25 November 2024