1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Flunazine 50 mg/ml Solution for Injection for cattle, horses and pigs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Flunixin	50 mg
(as Flunixin meglumine	83 mg)

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 mg
Sodium formaldehyde sulfoxylate	2.2 mg
Propylene glycol	207.2 mg
Disodium edetate	
Sodium hydroxide (for pH adjustment)	
Hydrochloric acid (for pH adjustment)	
Water for injection	

Clear, colourless to light yellow solution, free from foreign matter.

3. CLINICAL INFORMATION

3.1 Target species

Cattle
Horses
Pigs

3.2 Indications for use for each target species

Cattle: For the alleviation of acute inflammation associated with bronchopneumonia.

Horses: For the alleviation of inflammation associated with musculoskeletal disorders, especially in acute to subchronic stages. It is also indicated for the alleviation of visceral pain associated with colic.

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

3.3 Contraindications

Do not use in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, where there is evidence of a blood dyscrasia.
Do not use in animals suffering from colic caused by ileus and which is associated with dehydration.
Do not use in animals suffering from chronic musculoskeletal disorders.
Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

Do not use in horses producing milk for human consumption.
Do not administer to pregnant mares or pregnant sows.
Do not use the veterinary medicinal product within 48 hours before expected parturition in cows.
Do not administer to gilts at mating, breeding boars or piglets less than 6 kg bodyweight.
See also section 3.7 and 3.8.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for safe use in the target species:

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 veterinary medicinal product in the immediate post-partum period may interfere with uterine involution and expulsion of foetal membranes resulting in retained placentae. See also section 3.7.
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 careful clinical management.
It is preferable that flunixin is not administered to animals undergoing general anaesthesia until fully recovered.
Concurrent administration of potentially nephrotoxic drugs should be avoided.
Avoid use in dehydrated, hypovolaemic or hypotensive animals, as there is a potential risk of increased renal toxicity.
NSAIDs can cause inhibition of phagocytosis and hence in the treatment of inflammatory conditions associated with bacterial infections, appropriate concurrent antimicrobial therapy should be instigated.
Occasionally, life-threatening anaphylaxis may occur. The veterinary medicinal product should be injected slowly and should be used at body temperature. At the first signs of adverse reaction, administration should be stopped and, if necessary, treatment for shock initiated.
Avoid intra-arterial injection.
Do not exceed the recommended dose or duration of treatment.
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:

Direct contact with the skin should be avoided. In case of spillage on the skin, rinse with water.
Flunixin meglumine is irritating to the eye. Avoid contact with eyes. If contact occurs, rinse immediately with clean running water. Wash hands after use.
Take case to avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
People with known hypersensitivity to flunixin meglumine should avoid contact with the veterinary medicinal product.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Horses, Cattle and Pigs:

Undetermined frequency	Gastrointestinal irritation Gastrointestinal ulceration[1]

(Cannot be estimated from the available data)	Haemorrhage Gastrointestinal lesions Papillary necrosis Changes in blood parameters Anaphylactic type reaction[2]

[1]In severe cases
[2]Which can sometimes be fatal

Horses:

Undetermined frequency (Cannot be estimated from the available data)	Injection site reaction Collapse[1]

[1]Following rapid intravenous injection

Cattle:

Undetermined frequency (Cannot be estimated from the available data)	Collapse[1]

[1]Following rapid intravenous injection

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 the national competent authority via the national reporting system. See also section 16 of the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Post marketing studies in cattle have indicated that the use of the veterinary medicinal product within the first 36 hours post-partum leads to an increased incidence of retained placentae. 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.
Do not administer to pregnant mares or pregnant sows. Safety studies in pregnant mares or pregnant sows have not been conducted.

3.8 Interaction with other medicinal products and other forms of interaction

It is preferable that flunixin is not administered to animals undergoing general anaesthesia until fully recovered.
Do not administer other NSAIDs concurrently or within 24 hours of each other. Due to their common mode of action, flunixin may potentiate and be potentiated by other NSAIDs which act by interfering with prostaglandin synthesis.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects. Flunixin may potentiate the effects of warfarin and other plasma protein binding drugs. Compatibility should be evaluated in animals that need a concurrent treatment.
Concurrent use of potentially nephrotoxic drugs (e.g. aminoglycoside antibiotics) should be avoided.
Gastrointestinal tract ulceration may be exacerbated by corticosteroids in animals given non-steroidal anti-inflammatory drugs.
Monitor drug compatibility closely where adjunctive therapy is required.

3.9 Administration routes and dosage

Intravenous use (cattle, horses)
Intramuscular use (pigs)

Cattle:
The recommended dose is 1 – 2 ml of the veterinary medicinal product per 45 kg bodyweight (equivalent to 1.1 – 2.2 mg flunixin per kg) injected intravenously and repeated as necessary at 24-hour intervals for up to 3 consecutive days. The cause of the acute inflammatory condition should be determined and treated with concomitant therapy.

Horses:
For use in equine musculoskeletal disorders, the recommended dose is 1 ml of the veterinary medicinal product per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) injected intravenously at 24-hour intervals for up to 5 consecutive days according to response.
For use in equine colic, the recommended dose is 1 ml of the veterinary medicinal product per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) injected intravenously and repeated once or twice if signs of colic recur. The cause of colic should be determined and treated with concomitant therapy.

Pigs:
2 ml of the veterinary medicinal product per 45 kg bodyweight (equivalent to 2.2 mg flunixin per kg) once by intramuscular injection. The veterinary medicinal product should be administered as adjunctive therapy with a suitable course of antibacterial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Overdosage is associated with gastrointestinal toxicity.

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

Meat and offal:
Cattle: 10 days
Horses: 28 days
Pigs: 24 days

Milk:
Cattle: 48 hours
Not authorised for use in horses producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QM01AG90

4.2 Pharmacodynamics

Flunixin meglumine acts by interfering with the arachidonic acid pathway of prostaglandin synthesis. Flunixin has no influence on prostaglandins that are already present. The lifespan of prostaglandins however is extremely short (approximately 5 minutes) and because of this, the inhibition of the synthesis of flunixin has a very rapid effect. It has no influence on injected prostaglandin F2 alpha (PGF2α).

In infections causing bronchopneumonia, a massive quantity of prostaglandins is set free leading to hypersecretion.
Flunixin prevents the synthesis of these prostaglandins. It has none of the adverse side effects of corticoids, in particular, no immunosuppressive or abortive effects. The prolongation of the bleeding time after administration of flunixin is negligible in comparison with the effect of aspirin. Flunixin is not narcotic. With skeletal or muscular disorders, the potency of flunixin is four times that of phenylbutazone.

4.3 Pharmacokinetics

Cattle:
After I.V. administration of a dose of 1.1 mg/kg in cattle, the half-life of the distribution phase is 0.3 hours. Flunixin is excreted mainly in the urine and the faeces. The quantity excreted in the milk is negligible (less than 10 ppb).

Horses:
After I.V. administration of a dose of 1.1 mg/kg in horses, the half-life of the distribution phase is around 0.2 hours.

Pigs:
Following IM administration, plasma concentrations are reached within 35 minutes. The half-life in plasma is approximately 8 hours. Flunixin is eliminated mainly in the urine and faeces.

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: 2 years
Shelf life after first opening the immediate packaging: 28 days

5.3 Special precautions for storage

Do not store above 25^{o}C.

5.4 Nature and composition of immediate packaging

50 ml and 100 ml clear Type I glass multidose vials, with bromobutyl rubber bung.

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

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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

Bimeda Animal Health Limited

7. MARKETING AUTHORISATION NUMBER(S)

VPA22033/061/001

8. DATE OF FIRST AUTHORISATION

27/07/2001

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

15/12/2023

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary)