Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Content per 1 ml

Active Substance		
Flunixin (as flunixin meglumine)	50	mg (83 mg)
Excipients		
Phenol	5	mg
Sodium formaldehyde sulfoxylate	2.2	mg
Propylene glycol	207.2	mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
Clear, colourless to light yellow solution, free of foreign matter.

4 CLINICAL PARTICULARS

4.1 Target Species

Cattle, horses and pigs.

4.2 Indications for use, specifying the 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.

4.3 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 animals known to be hypersensitive to the active substance.
Do not use in horses producing milk for human consumption.
Do not administer to pregnant mares or pregnant sows.
Do not use the 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 Clause 4.7 & 4.8.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

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 product in the immediate post-partum period may interfere with uterine involution and expulsion of foetal membranes resulting in retained placentae. See also section 4.7.

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. Flunazine 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.

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 care 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.
Persons with known hypersensitivity to the active substance should avoid contact with the product.

4.6 Adverse reactions (frequency and seriousness)

Use of NSAIDs, including flunixin, may predispose or lead to gastrointestinal irritation, and in severe cases, ulceration.
There is a possibility for bleeding, gastro-intestinal irritation and lesions, papillonecrosis of the kidney and changes in blood parameters.
There are occasional reports of injection site reactions in horses; and in both horses and calves, collapse following rapid intravenous injection.
There are occasional reports of anaphylactic reactions which can sometimes be fatal.

4.7 Use during pregnancy, lactation or lay

Post marketing studies in cattle have indicated that the use of the product within the first 36 hours post-partum leads to an increased incidence of retained placentae. The 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.

4.8 Interaction with other medicinal products and other forms of interactions

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.

4.9 Amounts to be administered and administration route

Cattle
The recommended dose is 1-2 ml Flunazine 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 Flunazine 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 Flunazine 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 per 45 kg bodyweight (equivalent to 2.2 mg flunixin per kg) once by intramuscular injection. The 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.

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

Overdosage is associated with gastrointestinal toxicity.

4.11 Withdrawal period(s)

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

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

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Flunixin Meglumine is a non-steroidal, non-narcotic analgesic with anti-inflammatory and anti-pyretic properties that belongs to the group of fenamates.
ATC vet code QM01AG90.

5.1 Pharmacodynamic properties

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 by 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.

5.2 Pharmacokinetic particulars

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 IV administration of a dose of 1.1 mg/kg in horses, the half-life of the distribution phase is around 0.2 hours.

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

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium Formaldehyde Sulfoxylate
Propylene glycol
Disodium edetate
Sodium Hydroxide (for pH adjustment)
Hydrochloric acid (for pH adjustment)
Water for injection

6.2 Major incompatibilities

In the absence of compatibility studies this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 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.

6.4 Special precautions for storage

Do not store above 25°C.

6.5 Nature and composition of immediate packaging

50 ml and 100 ml clear Type I glass Multidose vials, with Bromobutyl rubber bung.
Not all pack sizes may be marketed.

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7 MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2, 3 & 4 Airton Close
Airton Road
Tallaght
Dublin 24
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA22033/061/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 21 February 2002
Renewal of the last authorisation: 21 February 2007

10 DATE OF REVISION OF THE TEXT

August 2020