SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Vetixin 5% Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

2.1 Active Constituents

	mg per ml
Flunixin (as flunixin meglumine)	50

2.2 Relevant Constituents of the Excipients

Phenol	5
Sodium formaldehyde sulfoxylate	2.2
Disodium Edetate	0.1

For full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Solution for injection.
Clear aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle and horses

4.2 Indications for use, specifying the target species

Cattle: For the control of acute inflammation associated with respiratory disease. It has also been shown to have some benefit in the treatment of experimental acute bovine pulmonary emphysema (Fog Fever).May be used as adjunctive therapy in the treatment of acute mastitis.

Horses: For the alleviation of inflammation and pain associated with musculo-skeletal disorders.

It is also indicated for the alleviation of visceral pain associated with colic.

4.3 Contraindications

Do not exceed the stated dose or duration of treatment.

Use is contra-indicated 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 or hypersensitivity to the product.

Do not administer other NSAIDs concurrently or within 24 hours of each other.

Avoid intra-arterial injection, which may result in collapse.

Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.

Do not use in hypovolaemic animals except in the case of endotoxaemia or septic shock.

4.4 Special warnings for each target species

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.

Repeated use in Equine colic may mask signs of pain.

4.5 Special precautions for use

i. Special precautions for use in animals

Administer by slow intravenous injection
Do not mix with other medicaments prior to administration.
Do not administer to racehorses within 8 days of racing.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs to produce an increase in non-bound pharmacologically active concentrations, which can lead to toxic effects.
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.
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.

ii. Special precautions to be taken by the person administering the medicinal product to animals

Avoid eye contact and direct contact with skin
To avoid possible sensitisation reactions, avoid contact with skin. Gloves should be worn during application.

Wash hands after use.
In the case of accidental contact with eyes, rinse immediately with plenty of water and seek medical advice.
The product may cause reactions in sensitive individuals. If you have known hypersensitivity for non-steroidal anti-inflammatory products, do not handle the product. Reactions may be serious.
Avoid accidental self-injection.

4.6 Adverse reactions (frequency and seriousness)

Prolonged use of NSAIDs, including flunixin, may predispose or lead to gastro-intestinal irritation, and in severe cases, ulceration.

4.7 Use during pregnancy, lactation or lay

Do not administer to pregnant mares. Studies to demonstrate safety in pregnant mares have not been conducted.

4.8 Interaction with other medicinal products and other forms of interaction

Monitor drug compatibility closely where adjunctive therapy is required. NSAIDs may potentiate the effects of warfarin and other drugs.

Due to their common mode of action, flunixin may potentiate and be potentiated by other NSAIDs, which act by interfering with prostagalandin synthesis.

4.9 Amount(s) to be administered and administration route

Cattle: The recommended dose is 2 ml Vetixin Injection per 45 kg bodyweight (equivalent to 2.2 mg flunixin per kg) injected intravenously and repeated as necessary at 24 hour intervals for up to 5 consecutive days. The cause of the acute inflammatory condition should be determined and treated with concomitant therapy.

Horses: *For use in equine musculo-skeletal disorders:* the recommended dose is 1 ml Vetixin Injection per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) injected intravenously and repeated as necessary at 24 hour intervals for up to 5 consecutive days according to clinical response.
For use in equine colic: the recommended dose is 1 ml Vetixin Injection 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.

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

Do not exceed the recommended dose or treat animals for more than 5 consecutive days. Tolerance trials in cattle and horses confirmed excellent tolerance at twice the recommended dose.

4.11 Withdrawal period(s)

Horses: 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.

Cattle
Meat: Animals may not be slaughtered for human consumption during treatment.
Cattle may be slaughtered for human consumption only 8 days after the last treatment.

Milk: Milk from lactating cows should be discarded during treatment. Milk from cows should only be taken for human consumption from 12 hours following cessation of treatment.

5. PHARMACOLOGICAL PROPERTIES

ATC VetCode: QM01AG90

5.1 Pharmacodynamic properties

Flunixin meglumine is a non-steroidal, non-narcotic analgesic with anti-inflammatory, anti-endotoxic and anti-pyretic properties. It acts by interfering with the arachidonic acid pathway of prostaglandin synthesis.

5.2 Pharmacokinetic particulars

No data available.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Sodium formaldehyde sulfoxylate
Disodium Edetate
Water for injection

6.2 Incompatibilities

None known

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 25ºC.
Following withdrawal of the first dose, use product within 28 days.
Discard unused material.

6.5 Nature and composition of immediate packaging

Container material: Type II glass

Container colour: Clear

Container volume: Multidose vials of 50 ml and 100 ml capacity

Secondary packaging: Cardboard container.

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, if appropriate

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

Bimeda Chemicals Limited
Broomhill Road
Tallaght
Dublin 24
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

Vm 02676/4166

9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION

Date: 25 November 1996 / 25 November 2006.

10. DATE OF LAST REVISION OF THE TEXT

Date: October 2012