

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

MEFLOSYL 5% INJECTION

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Ingredients

Flunixin (as meglumine) 50 mg

Relevant Excipients

Phenol (as preservative) 5.0 mg

For a full list of excipients see section 6.1.

3 PHARMACEUTICAL FORM

Solution for injection.

4 CLINICAL PARTICULARS

4.1 Target Species

Horse, cattle.

4.2 Indications for use, specifying the target species

Horse

Meflosyl 5% Injection is indicated 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.

Cattle

Meflosyl 5% Injection is indicated for the control of acute inflammation associated with respiratory disease. It has been shown to have some benefit in the treatment of experimental acute bovine pulmonary emphysema (Fog Fever).

In cattle, Meflosyl 5% Injection is indicated as adjunctive therapy in the treatment of acute mastitis.

4.3 Contraindications

- Do not administer to pregnant mares.
- Do not administer to animals less than three days of age.
- Use is contra-indicated in animals suffering from cardiac, hepatic or renal disease, where there is the possibility of gastro-intestinal ulceration or bleeding, or where there is hypersensitivity to the product.

4.4 Special warnings for each target species

Not applicable

4.5 Special precautions for use

Special precautions for use in animals

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.

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

Concurrent administration of potentially nephrotoxic drugs should be avoided.

Do not administer NSAID's concurrently or within 24 hours of each other.

Do not exceed the stated dose or the duration of treatment. Avoid intra-arterial injection.

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

Should anyone be injected with this product, a doctor should be consulted immediately and be informed of the nature of the product.

The product and any materials used during administration of the product should be kept out of reach of children.

4.6 Adverse reactions (frequency and seriousness)

During clinical studies, no significant side-effects were reported.

When administered intramuscularly, some transient tissue-reactions cannot be excluded.

Isolated reports of local reactions following i.m. injection, particularly in the neck, have been received. These include localised swelling, sweating, induration and stiffness.

In case of intra-arterial injection (in the horse), side effects like ataxia, hyperventilation, excitation or muscle weakness may occur. These symptoms are of transient nature and disappear without antidote within a few minutes.

Untoward effects include gastro-intestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage

4.7 Use during pregnancy, lactation or lay

Meflosyl 5% injection is safe for use in pregnant and lactating cattle. 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 drug compatibility is required in case of adjunctive therapy.

Do not mix with other medicaments prior to administration.

Some NSAID's may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.

4.9 Amounts to be administered and administration route

Horse

The recommended dose for use in musculo-skeletal disorders is 1 ml Meflosyl 5% injection per 45 kg bodyweight (equivalent to 1.1 mg flunixin per kg) once daily by intravenous injection. Treatment should be given for up to 5 days according to clinical response.

The recommended dose for the alleviation of visceral pain associated with equine colic is 1ml per 45 kg bodyweight (equivalent to 1.1mg flunixin per kg) by intravenous injection. Clinical studies have shown that, in many cases, pain is alleviated within 15 minutes. Treatment may be repeated once or twice if signs of colic recur. During clinical studies, approximately 10% of the horses required one or two additional treatments. The cause of colic should be determined and treated with concomitant therapy.

Cattle

The recommended dosage is 2 ml Meflosyl 5% injection per 45 kg bodyweight (equivalent to 2.2 mg flunixin per kg) by intravenous injection, repeated as necessary at 24 hour intervals for up to 5 consecutive days. The cause of acute inflammatory condition should be determined and treated with concomitant therapy.

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

A threefold intramuscular dose 3.3 mg/kg daily for 10 consecutive days was safe. No changes were observed in haematology, serum chemistry or urinalysis values.

Flunixin meglumine is a non-steroidal anti-inflammatory drug. Typically, over dosage is associated with signs of gastrointestinal toxicity.

4.11 Withdrawal Period(s)

Horses

- During treatment and within 7 days after the last injection, horses should not be slaughtered for human consumption.

Cattle

- During treatment and within 7 days after the last injection, cattle should not be slaughtered for human consumption.
- Milk from treated cattle may be taken for human consumption, only from 36 hours after the last injection.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic Group: Antiinflammatory and antirheumatic products; Non-steroids; Flunixin.

ATC Vetcode: QM01AG90.

Flunixin meglumine is a potent, non narcotic, non steroidal analgesic agent with anti-inflammatory, antipyretic and anti-endotoxic activity.

5.1 Pharmacodynamic properties

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 F2-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.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol
Disodium Edetate
Sodium Formaldehyde Sulfoxylate
Diethanolamine
Phenol
Hydrochloric Acid
Water for Injection

6.2 Incompatibilities

Do not mix with any other medicinal product.

6.3 Shelf-life

36 months.
Following withdrawal of the first dose use the product within 28 days. Discard unused product.

6.4 Special precautions for storage

Store below 25°C.

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.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Pfizer Healthcare Ireland Trading as:
Pfizer Animal Health
Ringaskiddy
Co. Cork
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10019/157/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

6th February 2007

10 DATE OF REVISION OF THE TEXT

5th August 2011