

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Wellicox 50 mg/ml solution for injection for cattle, pigs and horses
Allewinix 50 mg/ml solution for injection for cattle, pigs and horses (UK)

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Flunixin 50 mg
(as meglumine)

Excipients:

Phenol 5 mg
Sodium formaldehyde sulfoxylate 2.5 mg
Disodium edetate 0.1 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

Colourless to pale yellow solution, clear and free from particles, with a slight odour of phenol.

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, pigs and horses.

4.2 Indications for use, specifying the target species

Cattle:

- Alleviation of clinical signs of respiratory disease when used concurrently with appropriate anti-infective therapy.

Pigs:

- To support appropriate antibiotic therapy in the treatment of Mastitis-Metritis-Agalactia syndrome.
- Alleviation of fever associated with respiratory disease when used in conjunction with specific antibiotic therapy.

Horses:

- Alleviation of inflammation and pain associated with musculo-skeletal disorders.
- Alleviation of visceral pain associated with colic.

4.3 Contraindications

Do not use in animals suffering from chronic musculo-skeletal disorders.

Do not use in animals suffering from cardiac, hepatic or renal disease.

Do not use in animals with gastro-intestinal lesions (gastro-intestinal ulceration or bleeding).

Do not use in case of haemorrhagic disorders.

Do not use in case of hypersensitivity to flunixin meglumine, other NSAIDs or any of the excipients.

Do not use in animals suffering from colic caused by ileus and associated with dehydration.

Do not use the product within 48 hours before expected parturition in cows. In such cases an increase in the number of stillbirths has been observed.

Do not exceed the stated dose or the duration of treatment

See also section 4.7.

4.4 Special warnings for each target species

The underlying cause of the inflammatory condition or colic must be determined and treated with appropriate concomitant therapy.

4.5 Special precautions for use

Special precautions for use in animals

Use in any animal less than 6 weeks of age (cattle and horses) 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 NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.

Avoid use in any dehydrated, hypovolaemic or hypotensive animal except in the case of endotoxaemia or septic shock.

In rare cases, shock (potentially fatal), may occur after intravenous injection, due to a high quantity of propylene glycol in the medicinal product. The product must be injected slowly and at body temperature. Stop injection at the first signs of intolerance and treat for shock if necessary.

Due to its anti-inflammatory properties, flunixin may mask clinical signs and therefore possible resistance to antibiotic treatment.

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 fetal membranes resulting in retained placentae.

See also section 4.7

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

The product may cause a reaction in sensitive persons.

People with known hypersensitivity to substances belonging to the non-steroidal anti-inflammatory group should avoid contact with the veterinary medicinal product.

Hypersensitivity reactions may be serious.

Avoid contact with skin or eyes.

In case of skin contact, wash exposed area with soap and plenty of water. If symptoms persist, seek medical advice.

In case of contact with the eyes, wash eyes thoroughly with clean water and seek medical advice.

Avoid risk of ingestion, do not eat or drink when using the product and wash hands after use. In case of ingestion of the product seek medical advice.

In case of accidental self injection, seek medical advice immediately and show the package leaflet or the label to the physician.

4.6 Adverse reactions (frequency and seriousness)

As with other non-steroidal anti-inflammatory drugs, idiosyncratic renal or hepatic untoward effects may be observed.

In rare cases, fatal anaphylactic reactions (collapse) have been observed in cattle and horses, mainly during rapid intravenous injection.

Untoward effects include bleeding, gastro-intestinal lesions (irritation, gastric ulceration), vomiting and renal damage mainly in dehydrated or hypovolaemic animals can occur very rarely.

In the horse, after intravenous injection, blood in the faeces has been reported very rarely as well as liquid diarrhoea.

In cattle, a reaction at the injection site may be observed very rarely following intramuscular injection

The product may delay parturition and increase stillbirths 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 result in retained placentae.

See also section 4.7.

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

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 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).

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 product may be used in these animals except within the 48 hours preceding parturition (see sections 4.3 and 4.6).

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.

4.8 Interaction with other medicinal products and other forms of interaction

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

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.

4.9 Amounts to be administered and administration route

Intramuscular use for cattle and pigs.

Intravenous use for cattle and horses.

The body weight should be accurately determined before the administration

Cattle:

2 mg of flunixin per kg bodyweight, equivalent to 2 ml of solution per 50 kg bodyweight, administered once daily by intravenous or intramuscular injection for 1 to 3 consecutive days.

Volumes greater than 20 ml should be divided and administered at least at 2 different injection sites.

Pigs:

- To support appropriate antibiotic therapy in the treatment of Mastitis-Metritis-Agalactia syndrome:

2 mg of flunixin per kg bodyweight, equivalent to 2 ml of solution per 50 kg bodyweight, administered once daily by intramuscular injection for 1 to 3 consecutive days.

- Alleviation of fever associated with respiratory diseases:

2 mg of flunixin per kg bodyweight, equivalent to 2 ml of solution per 50 kg bodyweight, administered once daily by intramuscular injection.

Maximum dosage volume per injection site should not exceed 5 ml. Volumes greater than 5 ml should be divided and administered at different injection sites.

Horses:

- Alleviation of inflammation and pain associated with musculo-skeletal disorders:
1 mg of flunixin per kg bodyweight, equivalent to 1 ml of solution per 50 kg bodyweight, administered once daily by intravenous injection for 1 to 5 consecutive days.

- Alleviation of visceral pain associated with colic:
1 mg of flunixin per kg bodyweight, equivalent to 1 ml of solution per 50 kg bodyweight, administered once daily by intravenous injection. Treatment may be repeated once or twice if colic recurs.

The cap can be breached up to 10 times. When treating large groups of animals at one time, use an automatic dosing device.

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

Overdose is associated with gastrointestinal toxicity. Signs of ataxia and incoordination may also appear.

In horses, following 3 times the recommended dose (3 mg/kg bodyweight) administered by the intravenous route, a transient increase in blood pressure may be observed.

In cattle, administration of 3 times the recommended dose (6 mg/kg bodyweight) administered by the intravenous route did not induce untoward effects.

In pigs, following a dose of 2 mg flunixin/kg, administered twice a day, painful reactions at the injection site and an increase in the number of leucocytes was reported.

4.11 Withdrawal period(s)

Cattle:

Meat and offal: 10 days (IV route) / 31 days (IM route).

Milk: 24 hours (IV route) / 36 hours (IM route).

Pigs:

Meat and offal: 20 days.

Horses:

Meat and offal: 10 days.

Milk: the product is not authorised for use in lactating animals producing milk for human consumption.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and anti-rheumatic products, non steroids - Fenamates

ATCvet code: QM01AG90

5.1 Pharmacodynamic properties

Flunixin (as meglumine) demonstrates potent inhibition of the cyclo-oxygenase system (COX). The enzyme converts arachidonic acid to unstable cyclic endoperoxides, which are converted to prostaglandins, prostacyclin and thromboxane. Some of these prostanoids, such as prostaglandins are mediators for inflammation, pain and fever. The inhibition of the synthesis of such components would be responsible for the therapeutic effects of flunixin meglumine.

Since prostaglandins also play a part in other physiological processes, COX inhibitors may be responsible for some untoward effects such as gastrointestinal and renal damage.

Prostaglandins are involved in the complex process of endotoxaemic shock

5.2 Pharmacokinetic particulars

In cattle, after intramuscular injection at a dose of 2 mg/kg, a maximum concentration of 2.5 µg/ml is observed approximately 30 minutes after injection.

After intravenous injection flunixin distributes rapidly. The elimination is slow (approximately 4 hours).

Flunixin is highly bound to plasma proteins (>99%).

In pigs, after intramuscular injection at a dose of 2 mg/kg, a maximum concentration of 4 µg/ml is observed approximately 30 minutes after injection.

After intravenous injection flunixin distributes rapidly. The elimination is slow (approximately 8 hours).

Flunixin is highly bound to plasma proteins (>98%).

In the horse, after intravenous injection at a dose of 1 mg/kg flunixin distributes rapidly. The elimination half-life is 1.6 hours.

Flunixin is eliminated mainly via the kidneys as conjugated form.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol

Sodium formaldehyde sulfoxylate

Disodium edetate

Sodium hydroxide

Propylene glycol

Dilute hydrochloric acid for pH-adjustment

Water for injections

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 in a glass bottle: 3 years

Shelf-life after first opening the immediate packaging: 28 days

6.4 Special precautions for storage

Do not store above 25°C after first opening the immediate packaging.

6.5 Nature and composition of immediate packaging

50, 100 or 250 ml colourless Type II glass vial sealed with chlorobutyl rubber stoppers and a flip-off cap on top of an aluminium crimp seal.

50, 100 or 250 ml translucent PP/Ethylene vinyl alcohol/PP multi-layer plastic vials with bromobutyl rubber stopper with aluminium cap.

1 vial per cardboard box.
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 veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Ceva Animal Health Ltd
Unit 3, Anglo Office Park
White Lion Road
Amersham
Buckinghamshire
HP7 9FB

8. MARKETING AUTHORISATION NUMBER

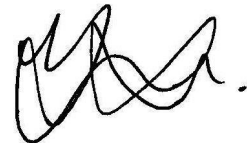
Vm 15052/4144

9. DATE OF FIRST AUTHORISATION

16 April 2013

10. DATE OF REVISION OF THE TEXT

October 2020



Approved: 27 October 2020