SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dugnixon 50 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:
Active substance
Flunixin 50.0 mg
(Equivalent to flunixin meglumine 82.9 mg)

Excipients
Phenol 5.0 mg
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Colourless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses and pigs.

4.2. Indications for use, specifying the target species

Cattle
For the control of acute inflammation associated with respiratory disease.
The product has also been shown to have some benefit in the treatment of experimental acute bovine pulmonary emphysema (Fog Fever).
The product 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.
For the alleviation of visceral pain associated with colic in the horse.

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

4.3. Contraindications

Do not exceed the stated dose or the duration of treatment.
Do not use in animals suffering from cardiac, hepatic or renal disease or where there is the possibility of gastro-intestinal ulceration or bleeding.
Do not use in known cases of hypersensitivity to flunixin meglumine, other NSAIDs

or to any of the excipients.
Do not use the product within 48 hours before expected parturition in cows in such cases an increase in the number of still births has been observed.
Do not administer to pregnant mares.
Do not administer to pregnant sows, gilts at mating and in breeding boars.
Do not use in animals suffering from colic caused by ileus and associated with dehydration.

4.4. Special warnings for each target species

None

4.5. Special precautions for use.

Special precautions for use in animals

Avoid intra-arterial injection.
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 a reduced dosage and careful clinical management.
Do not use in dehydrated or hypovolaemic animals except in the case of endotoxaemia or septic shock.
It is preferable that NSAIDs which inhibit prostaglandin synthesis are not administered to animals undergoing general anaesthesia until fully recovered.
The cause of the inflammatory condition or colic should be determined and treated with appropriate concurrent therapy.
The product should not be used in piglets weighing less than 6 kg.
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

- Flunixin meglumine is a non-steroidal anti-inflammatory drug (NSAID).
- The product may cause an allergic reaction in people sensitised to NSAIDs.
- People with known hypersensitivity to NSAIDs should avoid contact with the product. Hypersensitivity reactions may be serious.
- This product may cause skin and eye irritation.
- Avoid contact with skin or eyes.
- In case of skin or eye contact, wash exposed area with plenty of clean water. If symptoms persist, seek medical advice.
- In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
- Do not eat or drink when using the product.
- Wash hands after use.

4.6. Adverse reactions (frequency and seriousness)

Adverse reactions include gastro-intestinal irritation, ulceration and, in dehydrated or hypovolaemic animals, potential for renal damage.
In pigs transient irritation may occur at the injection site, this resolves spontaneously within 14 days.
As with other non-steriodal anti-inflammatory drugs, idiosyncratic renal or hepatic adverse effects may be observed.

4.7. Use during pregnancy, lactation or lay

The product may be used in pregnant and lactating cattle.
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 use in pregnant mares or pregnant sows. Safety studies in pregnant mares and pregnant sows have not been conducted.

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.
Some NSAIDs may be highly bound to plasma proteins and compete with other highly bound drugs which can lead to toxic effects.
Concurrent administration of potentially nephrotoxic drugs, particulary aminoglycosides, should be avoided.
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.

4.9. Amounts to be administered and administration route

Cattle
2.2 mg flunixin per kg bodyweight (equivalent to 2 ml of product per 45 kg BW) administered intravenously. Repeat as necessary at 24 hour intervals for up to 5 consecutive days.

Horses
By intravenous injection for musculo-skeletal disorders at the following rate:
1.1 mg flunixin per kg bodyweight (equivalent to 1 ml of product per 45 kg BW) once daily for up to 5 days according to clinical response.

By intravenous injection for colic at the following rate:
1.1 mg flunixin per kg bodyweight (equivalent to 1 ml of product per 45 kg BW) repeated once or twice if colic recurs.
For the treatment of endotoxaemia or septic shock associated with gastric torsion and with other conditions in which the circulation of blood to the gastro-intestinal tract is compromised: 0.25 mg/kg every 6-8 hours, by intravenous injection.

Pigs
2.2 mg flunixin per kg bodyweight (equivalent to 2 ml of product per 45 kg BW) once by intramuscular injection, in the neck, in conjunction with appropriate antimicrobial therapy. The injection volume should be limited to a maximum of 5 ml per injection site.
An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.
When intramuscular injection is used, the dose should be divided between two injection sites on either side of the neck.

In order to prevent excessive broaching of the rubber stopper, the 50 ml and 100 ml vials should not be broached more than 25 times and the 250 ml vial not more than 50 times.

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

Overdosage studies in the target species have shown the product to be well-tolerated. Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdosage is associated with gastrointestinal toxicity. Concurrent use of nephrotoxic drugs should be avoided.

4.11. Withdrawal period(s)

Cattle (meat and offal):	5 days
Cattle (milk)	24 hours
Horses (meat and offal):	7 days
Pigs (meat and offal):	22 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Musculo-skeletal system, anti-inflammatory and anti-rheumatic products, non-steriods, flunixin

ATC vet code: QM01AG90.

5.1. Pharmacodynamic properties

Flunixin meglumine is a non steroidal antiinflamatory drug (NSAID) with anti-inflammatory, analgesic and anti-pyretic properties.

5.2. Pharmacokinetic properties

Following flunixing meglumine administration to horses by intravenous route at dose 1,1 mg/kg a bicompartmental kinetic pattern was established . It showed a rapid distribution and a high degree of protein binding. The elimination half life is short 1-2 h. $AUC_{0\text{-}15h}$ was 19.43 mg-h/ml. Excretion quickly took place, mainly via urine.

In cattle, after intravenous administration of 2.2 mg / kg, peak plasma levels between 15 and 18 □g / ml were obtained after 5 to 10 minutes after injection. Between 2 and 4 hours after administration, a second peak plasma concentration (possibly due to

enterohepatic circulation) was observed. Flunixin meglumine is rapidly distributed to organs and body fluids (with high persistence in the inflammatory exudate), with a high distribution volume. The elimination half-life was approximately 4 to 7 hours. Excretion took place mainly through urine and faeces. In milk, the drug was not detected, and where it was detected, the levels were insignificant (<10 ng / ml).

In pigs following the intramuscular administration of flunixin meglumine the drug is completely absorbed, extensively distributed and eliminated slowly.
Excretion (mostly as unchanged drug) took place primarily in the urine, although it was also detected in the faeces.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Phenol
Propylene glycol
Sodium Formaldehyde Sulfoxylate Dihydrate
Disodium edetate
Hydrochloric acid (for pH adjustment)
Sodium hydroxide
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:
2 years.

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

6.4. Special precautions for storage

Store below 25ºC
Keep the vial in the outer container in order to protect from light.

6.5. Nature and composition of immediate packaging

50 ml and 100 ml sterile and translucent polypropylene vials with grey butyl rubber cap, grey aluminium cap and Flip-Off seal.

250 ml sterile and translucent polypropylene vials with pink butyl rubber cap, grey aluminium cap and Flip-Off seal.

Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal 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

Global Vet Health S.L.
Calle Capcanes 12 Bajos
Poligono Agro-Reus
E-43206 Reus
Spain

8. MARKETING AUTHORISATION NUMBER

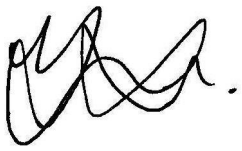
Vm 36167/4005

9. DATE OF FIRST AUTHORISATION

20 December 2017

10. DATE OF REVISION OF THE TEXT

April 2022



Approved: 04 April 2022