ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE
Box 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dugnixon 50 mg/ml solution for injection for cattle, pigs and horses
Flunixin (as flunixin meglumine)

2. STATEMENT OF ACTIVE SUBSTANCES

Flunixin 50.0 mg/ml
(Equivalent to flunixin meglumine 82.9 mg)

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 ml, 100 ml, 250 ml

5. TARGET SPECIES

Cattle, horses and pigs.

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf-life after first broaching the vial: 28 days
Once broached, use by…

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Global Vet Health S.L.
Calle Capçanes 12 Bajos
Polígono Agro-Reus
E-43206 Reus
Spain

16. MARKETING AUTHORISATION NUMBER

Vm 36167/4005

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

IE: POM
UK: POM-V

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dugnixon 50 mg/ml solution for injection for cattle, pigs and horses
Flunixin (as flunixin meglumine)

2. STATEMENT OF ACTIVE SUBSTANCES

Flunixin	50.0 mg/ml
(Equivalent to flunixin meglumine	82.9 mg)

4. PACKAGE SIZE

100 ml and 250 ml

5. TARGET SPECIES

Cattle, horses and pigs.

7. METHOD AND ROUTES OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:

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

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}>
Once broached use by…

11. SPECIAL STORAGE CONDITIONS

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. To be supplied only on veterinary prescription.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Global Vet Health S.L.
Calle Capçanes 12 Bajos
Polígono Agro-Reus
E-43206 Reus
Spain

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

IE: POM
UK: POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dugnixon 50 mg/ml solution for injection for cattle, pigs and horses
Flunixin (as flunixin meglumine)

2. QUANTITY OF THE ACTIVE SUBSTANCE

50 mg/ml

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 ml

4. ROUTES OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period:

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

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once broached use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

IE: POM
UK: POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Dugnixon 50 mg/ml solution for injection for cattle, pigs and horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder:
Global Vet Health S.L.
Calle Capçanes 12 Bajos
Polígono Agro-Reus
E-43206 Reus
Spain

Manufacturer responsible for batch release:
SP VETERINARIA SA
Ctra Reus Vinyols km 4.1
RIUDOMS 43330
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dugnixon 50 mg/ml solution for injection for cattle, pigs and horses
Flunixin (as flunixin meglumine)

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

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

Excipients
Phenol 5.0 mg

4. INDICATIONS

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.

5. 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.

6. ADVERSE REACTIONS

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.

If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horses and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

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.

9. ADVICE ON CORRECT ADMINISTRATION

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.

10. WITHDRAWAL PERIOD

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store below 25ºC
Keep the vial in the outer container in order to protect from light.

Shelf-life after first opening the immediate packaging:
28 days
When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the carton should be discarded should be worked out. This discard date should be written in the space provided.
Do not use this veterinary medicinal product after the expiry date which is stated on the vial and carton after “EXP”. The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

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.

Flunixin is toxic to avian scavengers. Do not administer to animals susceptible to enter wild fauna food chain. In case of death or sacrifice of treated animals, ensure that they are not made available to wild fauna.

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.

Pregnancy/Lactation/Lay/Fertility:
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.

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

Overdose (symptoms, emergency procedures, antidotes):
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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2022

15. OTHER INFORMATION

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.

IE: POM: Prescription Only Medicine
UK: POM-V: Prescription Only Medicine

Approved 18 November 2022