[Version 8.1,01/2017]

ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Flunixin (as flunixin meglumine)	50.0 mg
(Equivalent to 82.9 mg de flunixin meglumine)	

Excipients:

Phenol	5 mg
Sodium formaldehyde sulfoxylate	5 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Colorless liquid

4. CLINICAL PARTICULARS

4.1 Target species

Cattle, horses and pigs.

4.2 Indications for use, specifying the target species

Cattle

Control of inflammation, pyrexia and/or pain associated to bovine respiratory disease, gastrointestinal disorders and mastitis.

Horses

Control of inflammation, pyrexia and/or pain associated with musculo-skeletal disorders, or associated to colic.

Pigs

Recommended as adjunctive therapy in the treatment of metritis-mastitis agalactia syndrome (MMA) in sows.

4.3 Contraindications

Do not use in the following cases:

- Hypersensitivity to the active substance, to other NSAIDs or to any of the excipient(s).
- animals that suffer from cardiac, hepatic or renal diseases.
- animals that present digestive ulcers or bleeding.
- when blood dyscrasia signs or haemostasis alterations are present.
- In case of colic caused by ileus and associated to dehydration.
- animals suffering chronic musculo-skeletal disorders

- 48 hours before expected parturition in cows
- In dehydrated, hypovolaemic or hypotensive animals.

4.4 Special warnings for each target species

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

NSAIDs could produce inhibition of fagocitosis and consequently, in case of treatment of inflammation associated to bacterial infections, an adequate antimicrobial therapy must be established.
Its use is not authorized in lactating mares producing milk for human consumption.

4.5 Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dose or the treatment length.
Intra-arterial injection to horses and cows should be avoided. Horses accidentally injected by intra-arterial route may show adverse reactions. Signs can be ataxia, incoordination, hyperventilation, hysteria, and muscular weakness. All are transitory signs and disappear within a few minutes without antidote medication.
In pigs during intramuscular administration deposition in adipose tissues must be avoided.

The use in animals below six weeks of age or in old animals can lead to an additional risk. When it cannot be avoided, animals may need a lower dose and a close clinical monitoring.
Administer at room temperature.
Intravenous administration must be slowly injected.

During treatment ensure sufficient water supply.

In animals subject to general anesthesia, it is preferable not to use NSAIDs that inhibit prostaglandins synthesis, until they are completely recovered.
The use of NSAIDs in racing animals is not allowed.

NSAIDs have potential to delay parturition through a tocolytic effect by prostaglandin inhibition .The use of flunixin immediately after parturition could interfere uterine involution and the expulsion of fetal membranes resulting in placenta retention. See also point 4.7

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

People with known hypersensitivity to flunixin and /or propyleneglycol should avoid contact with the veterinary medicinal product.

This medicine can produce dermic and ocular irritation. Avoid contact with skin and eyes. Use gloves and protective glasses during manipulation.

In case of accidental spillage onto skin wash immediately with water.
In case of accidental spillage onto eyes, seek medical advice immediately and show the package leaflet or label to the physician.

In case of accidental self-injection, it can cause acute pain and inflammation. Immediately wash and disinfect the wound, seek medical advice immediately and show the package leaflet or label to the physician.

4.6 Adverse reactions (frequency and seriousness)

In very rare occasions transient local reactions can be observed at the injection point and other common reactions of NSAIDs such as:

- Gastric irritation and gastric ulcers
- Potential risk of renal toxicity, increased in dehydrated, hypovolemic or hypotense animals.
- Other effects as vomiting ataxia and hyperventilation.

In horses and bovine species, quick intravenous injection can cause anaphylactic shock.

The product must be injected slowly by intravenous route and at room temperature. Administration must be stopped immediately if adverse effects occur and, if necessary, start treatment for shock.

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 on target species in lactating or pregnant animals are not available.
Use only according to the benefit-risk assessment by the responsible veterinarian.
The product must be used during 36 h after parturition only after the veterinary surgeon risk/benefit assessment and animals must be monitored to avoid retained placenta.

4.8 Interaction with other medicinal products and other forms of interaction

Avoid concurrent administration of potentially nephrotoxic antibiotics (aminoglycoside antibiotics, methoxyfluarane)
Flunixin may decrease the renal excretion of some drugs, increasing its toxicity as with the aminoglycosides.
The simultaneous use with other drugs with high protein -binding potential may create a competition and displace flunixin, causing toxic effects.
Previous treatments with other NSAIDs can result in additional or increased adverse reactions, therefore a 24 hours of treatment free period must be respected before the use of flunixin. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.
The product should not be administered in conjunction with other NSAIDs or glucocorticoids, since the toxicity of both would increase, mainly gastrointestinal, increasing the risk of gastrointestinal ulcers.

Flunixin may decrease the effect of some antihypertensive drugs, that inhibit prostaglandin synthesis, such as diuretics, angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs) and beta-blockers.
Patients requiring adjunctive therapy should be carefully monitored in order to determine the compatibility of flunixin with other drugs.

Do not mix with other drugs prior to administration.

4.9 Amounts to be administered and administration route

Administration route:

Cattle and horses: intravenous
Pigs: Intramuscular

Cattle: The recommended dose rate is 2.2 mg of flunixin/kg bw (Equivalent to 2 ml / 45kg bw.) Administration can be repeated, with a 24 h interval, for 3 consecutive days according to clinical recovery.

Horses: The dose rate recommended for musculo-skeletal disorders is 1.1 mg of flunixin/ kg bw (equivalent to 1 ml / 45 kg bw) once daily. The treatment can be administered by intravenous route for up to 5 days according to clinical response.

The recommended dose rate to alleviate, visceral pain associated with colic in horses is 1.1 mg of flunixin/ kg bw (equivalent to 1 ml / 45 kg bw). In most cases, a single injection is sufficient to control the signs of colic, once the cause determined and appropriate treatment has been administered. However, if clinical signs persist or recur , a second or third injection can be administered , with an interval of 6 to 12 hours.

Pigs: the recommended dose is 2.2 mg of flunixin/ kg bw (equivalent to 2 ml /45 kg bw) by deep IM injection (5 cm). Flunixin should not be injected in fat tissue. 1 or 2 injections can be administered, with 12 hours interval. The amount of treatments to be administered (one or two) depend on the clinical response.
The maximum volume of injection is 4 ml

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

Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdosage is associated with gastrointestinal toxicity that can lead to vomiting, diarrhea, bleeding. Signs of incoordination or ataxia can also occur.
Tolerance studies in target species showed the medicine is well tolerated and only local reactions such as transient irritation at the injection point were recorded.

4.11 Withdrawal period(s)

Cattle: Meat: 4 days
Milk: 1 day (24 hours)

Horses: Meat: 4 days
Do not use in mares producing milk for human consumption

Pigs: Meat: 28 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: non-steroidal anti-inflammatory drug (NSAID) with non-narcotic, analgesic and anti-pyretic activity.
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.

Flunixin meglumine acts as a reversible non-selective and inhibitor of cyclooxygenase (both COX-1 and COX-2), an enzyme that turns araquidonic acid into unstable cyclic endoperoxides, which become prostaglandins, prostacyclins and thromboxans. Some of these prostanoids, as prostaglandins, are involved in the physiopathological mechanisms of the inflammation, pain and fever; therefore, inhibition would be the cause of their therapeutic effects. Due to the involvement of prostaglandins in other physiological processes, COX inhibition would also be the cause of different side effects, such as gastrointestinal or renal damage.

Although flunixin has no direct effect on endotoxins but reduces the production of prostaglandins, which are part of the complex processes involved in the development of endotoxic shock.
However, the lifetime of prostaglandins is extremely short (about 5 minutes) and, for this reason, this inhibition of synthesis has a very quick effect.
Flunixin has no influence on prostaglandin F2 alpha (PGF2), nor immunosuppressive effects or other typical effects of glucocorticoids
Prolongation of bleeding time after administration of flunixin is negligible compared to the effect of aspirin.
Flunixin is not narcotic.
Strength effect of flunixin in musculoskeletal disorders is 4 times the phenylbutazone strength.

5.2 Pharmacokinetic particulars

Following flunixing meglumine administration to horses and ponies by intravenous route at dose 1,1 mg/kg a bicompartmental kinetic pattern was established . It showed a rapid distribution (Vd of 0.16l/kg) and a high degree of protein binding (99%). The elimination half-life was 1-2 h. $AUC_{0\text{-}15h}$ was 19.43 mg-h/ml. Excretion quickly took place, mainly via urine, reaching the maximum concentration at 2 hours after administration. 12 hours after intravenous injection, 61% of the administered dose was recovered in urine.

In cattle, after intravenous administration of 2.2 mg / kg, peak plasma levels between 15 and 18 µg / 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, whereas, at 24 hours, concentrations were below 0.1 □g / ml. Flunixin meglumine is rapidly distributed to organs and body fluids (with high persistence in the inflammatory exudate), with a distribution volume of 0.7 to 2.3 l / kg. The elimination half-life was approximately 4 to 7 hours. Excretion took place mainly through urine and feces. 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 2.2 mg flunixin meglumine / kg, a maximum plasma concentration of about 3 µg / ml was detected about 20 minutes after injection. The bioavailability, expressed as a fraction of the dose absorbed was 93%. The distribution volume was 2 L / kg, whereas the elimination half-life was 3.6 hours. Excretion (mostly as unchanged drug) took place primarily in the urine, although it was also detected in the feces.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Phenol
Propylene glycol
Sodium formaldehyde sulfoxylate
Disodium edetate

HCl
Sodium hydroxide
Water for injection

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 30ºC

6.5 Nature and composition of immediate packaging

Sterile and translucent polypropylene cylindrical vials appropriate for parenteral solutions (European Pharmacopoeia), with butyl rubber cap, grey aluminum capsule and Flip-Off seal.

Package sizes:
Box with 1 vial of 50 ml
Box with 1 vial of 100 ml
Box with 1 vial of 250 ml

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

Any unused product or waste material should be disposed of in accordance with national requirements.

7. MARKETING AUTHORISATION HOLDER

S.P. VETERINARIA, S. A.
Ctra. Reus-Vinyols, Km. 4.1.
Apartado de correos nº: 60 - 43330 RIUDOMS (Tarragona)

8. MARKETING AUTHORISATION NUMBER(S)

1755 ESP (Spain)

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

29 June 2007 (Spain)

10 DATE OF REVISION OF THE TEXT

DD/MM/YYYY

PROHIBITION OF SALE, SUPPLY AND/OR USE

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE

Carton and label vials 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:

Flunixin (as flunixin meglumine)	50.0 mg
(Equivalent to 82.9 mg de flunixin meglumine)	

Excipients:

Phenol	5 mg
Sodium formaldehyde sulfoxylate	5 mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, horses and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Cattle and horses: intravenous
Pigs: intramuscular

8. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle: Meat: 4 days
Milk: 1 day (24 hours)

Horses: Meat: 4 days

Do not use in mares producing milk for human consumption

Pigs: Meat: 28 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP: month/year
Once opened use within 28 days.
Use by…

11. SPECIAL STORAGE CONDITIONS

.
Store below 30ºC

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

S.P. Veterinaria, s.a.
Ctra. Reus - Vinyols Km 4.1.
Apartado nº 60 - 43330 Riudoms (Tarragona)

16. MARKETING AUTHORISATION NUMBER(S)

Reg. no.

17. MANUFACTURER'S BATCH NUMBER

Batch: {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 ml box and label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Flunixin (as flunixin meglumine) 50.0 mg/ml

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

Each ml contains:

Active substance:
Flunixin (as flunixin meglumine) 50.0 mg
(Equivalent to 82.9 mg de flunixin meglumine)

Excipients:
Phenol 5 mg
Sodium formaldehyde sulfoxylate 5 mg

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Cattle and horses: intravenous
Pigs: intramuscular

5. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Cattle: Meat 4 days.
Milk: 1 day.

Horses: Meat: 4days.
Do not use in horses producing milk for human consumption.

Pigs: Meat: 28 days.

6. BATCH NUMBER

Batch:

7. EXPIRY DATE

EXP: {month/year}
Once opened use within 28 days
Use by…

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only – to be supplied on veterinary prescription

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Fluvex 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 and manufacturer responsible for batch release:

S.P. VETERINARIA, S. A.
Ctra. Reus - Vinyols Km 4.1.
Apartado nº 60 - 43330 Riudoms (Tarragona)

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

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

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Each ml contains:

Active substance:

Flunixin (as flunixin meglumine)	50.0 mg
(Equivalent to 82.9 mg de flunixin meglumine)	

Excipients:

Phenol	5 mg
Sodium formaldehyde sulfoxylate	5 mg

Colorless liquid

4. INDICATION(S)

Cattle
Control of inflammation, pyrexia and/or pain associated to bovine respiratory disease, gastrointestinal disorders and mastitis.

Horses
Control of inflammation, pyrexia and/or pain associated with musculo-skeletal disorders, or associated to colic.

Pigs
Recommended as adjunctive therapy in the treatment of metritis-mastitis agalactia syndrome (MMA) in sows.

5. CONTRAINDICATIONS

Do not use in the following cases:
- hypersensitivity to the active substance, to other NSAIDs or to any of the excipient(s).
- animals that suffer from cardiac, hepatic or renal diseases.
- animals that present digestive ulcers or bleeding.
- when blood dyscrasia signs or haemostasis alterations are present.

- In case of colic caused by ileus and associated to dehydration.
- animals suffering chronic musculo-skeletal disorders
- 48 hours before expected parturition in cows

In dehydrated, hypovolaemic or hypotensive animals.

6. ADVERSE REACTIONS

In very rare occasions transient local reactions can be observed at the injection point and other common reactions of NSAIDs such as:

- Gastric irritation and gastric ulcers
- Potential risk of renal toxicity, increased in dehydrated, hypovolemic or hypotense animals.
- Other effects as vomiting ataxia and hyperventilation.

In horses and bovine species, quick intravenous injection can cause anaphylactic shock.

The product must be injected slowly by intravenous route and at room temperature. Administration must be stopped immediately if adverse effects occur and, if necessary, start treatment for shock.

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).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle, horses and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle and horses: intravenous
Pigs: Intramuscular

Cattle: The recommended dose rate is 2.2 mg of flunixin/kg bw (Equivalent to 2 ml / 45kg bw.). Administration can be repeated, with a 24 h interval, for 3 consecutive days according to clinical recovery.

Horses: The dose rate recommended for musculo-skeletal disorders is 1.1 mg of flunixin/ kg bw (equivalent to 1 ml / 45 kg bw) once daily. The treatment can be administered by intravenous route for up to 5 days according to clinical response.

The recommended dose rate to alleviate, visceral pain associated with colic in horses is 1.1 mg of flunixin/ kg bw (equivalent to 1 ml / 45 kg bw). In most cases, a single injection is sufficient to control the signs of colic, once the cause determined and appropriate treatment has been administered. However, if clinical signs persist or recur, a second or third injection can be administered, with an interval of 6 to 12 hours.

Pigs: the recommended dose is 2.2 mg of flunixin/ kg bw (equivalent to 2 ml / 45 kg bw) by deep IM injection (5 cm). Flunixin should not be injected in fat tissue. 1 or 2 injections can be administered, with 12 hours interval. The amount of treatments to be administered (one or two) depend on the clinical response.
The maximum volume of injection is 4 ml

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Cattle: Meat: 4 days
Milk: 1 day (24 hours)

Horses: Meat: 4 days
Do not use in mares producing milk for human consumption

Pigs: Meat: 28 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Store below 30ºC
Do not use after the expiry date stated on the carton and vial label
(EXP: month/year)

Shelf-life after first opening the container 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The cause of the inflammatory condition or colic must be determined and treated with an appropriate concomitant treatment.

NSAIDs could produce inhibition of fagocitosis and consequently, in case of treatment of inflammation associated to bacterial infections, an adequate antimicrobial therapy must be established.
Its use is not authorized in lactating mares producing milk for human consumption.

Special precautions for use in animals:
Do not exceed the recommended dose or the treatment length.
Intra-arterial injection to horses and cows should be avoided. Horses accidentally injected by intra-arterial route may show adverse reactions. Signs can be ataxia, incoordination, hyperventilation, hysteria, and muscular weakness. All are transitory signs and disappear within a few minutes without antidote medication.
In pigs during intramuscular administration deposition in adipose tissues must be avoided.

The use in animals below six weeks of age or in old animals can lead to an additional risk. When it cannot be avoided, animals may need a lower dose and a close clinical monitoring.
Administer the product at room temperature.
Intravenous administration must be slowly injected.

During treatment ensure sufficient water supply.

In animals subject to general anesthesia, it is preferable not to use NSAIDs that inhibit prostaglandins synthesis, until they are completely recovered.
The use of NSAIDs in racing animals is not allowed.

NSAIDs have potential to delay parturition through a tocolytic effect by prostaglandin inhibition .The use of flunixin immediately after parturition could interfere uterine involution and the expulsion of fetal membranes resulting in placenta retention. See also point 4.7

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to flunixin and /or propyleneglycol should avoid contact with the veterinary medicinal product.

This medicine can produce dermic and ocular irritation. Avoid contact with skin and eyes. Use gloves and protective glasses during manipulation.

In case of accidental spillage onto skin wash immediately with water.
In case of accidental spillage onto eyes, seek medical advice immediately and show the package leaflet or label to the physician.

In case of accidental self-injection, it can cause acute pain and inflammation. Immediately wash and disinfect the wound, seek medical advice immediately and show the package leaflet or label to the physician.

Use during pregnancy, lactation or lay
Studies on target species in lactating or pregnant animals are not available.
Use only according to the benefit-risk assessment by the responsible veterinarian.
The product must be used during 36 h after parturition only after the veterinary surgeon risk/benefit assessment and animals must be monitored to avoid retained placenta.

Interaction with other medicinal products and other forms of interaction:
Avoid concurrent administration of potentially nephrotoxic antibiotics (aminoglycoside antibiotics, methoxyfluarane)
Flunixin may decrease the renal excretion of some drugs, increasing its toxicity as with the aminoglycosides.
The simultaneous use with other drugs with high protein -binding potential may create a competition and displace flunixin, causing toxic effects.
Previous treatments with other NSAIDs can result in additional or increased adverse reactions, therefore a 24 hours of treatment free period must be respected before the use of flunixin. The treatment-free period, however, should take into account the pharmacokinetic properties of the products used previously.
The product should not be administered in conjunction with other NSAIDs or glucocorticoids, since the toxicity of both would increase, mainly gastrointestinal, increasing the risk of gastrointestinal ulcers.

Flunixin may decrease the effect of some antihypertensive drugs, that inhibit prostaglandin synthesis, such as diuretics, angiotensin-converting enzyme inhibitors (ACEIs), angiotensin receptor blockers (ARBs) and beta-blockers.

Patients requiring adjunctive therapy should be carefully monitored in order to determine the compatibility of flunixin with other drugs.

Do not mix with other drugs prior to administration.

Overdose (symptoms, emergency procedures, antidotes):
Flunixin meglumine is a non-steroidal anti-inflammatory drug. Overdosage is associated with gastrointestinal toxicity that can lead to vomiting, diarrhea, bleeding . Signs of incoordination or ataxia can also occur.
Tolerance studies in target species showed the medicine is well tolerated and only local reactions such as transient irritation at the injection point were recorded.

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

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

Medicines should not be disposed of via wastewater or household waste and handed over the appropriate collection systems and disposal facilities for unused or expired medicines.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

DD/MM/YYYY

15. OTHER INFORMATION

Package sizes:
Box with 1 vial of 50 ml
Box with 1 vial of 100 ml
Box with 1 vial of 250 ml
Not all pack sizes may be marketed.