ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Ketoprofen	150 mg

Excipients:

Benzyl alcohol (E1519)	10 mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.

A clear colourless to yellowish solution

4. CLINICAL PARTICULARS

4.1. Target species

Cattle, pigs and horses

4.2. Indications for use, specifying the target species

Cattle:
- Reduction of inflammation and pain associated with post-partum, musculoskeletal disorders and lameness.
- Reduction of fever associated with bovine respiratory disease in combination with antimicrobial therapy where appropriate.
- Reduction of inflammation, fever and pain in acute clinical mastitis in combination with antimicrobial therapy where appropriate.

Pigs:
- Reduction of pyrexia in cases of respiratory disease and Postpartum Dysglactia SyndromePDS- (Metritis Mastitis Agalactia syndrome) in sows, in combination with antimicrobial therapy, where appropriate.

Horses:
- Reduction of inflammation and pain associated with osteoarticular and musculoskeletal disorders (lameness, laminitis, osteoarthritis, synovitis, tendinitis, etc.).
- Reduction of postoperative pain and inflammation.
- Reduction of visceral pain associated with colic.

4.3. Contraindications

Do not use in cases of gastro-intestinal ulceration or bleeding, in order not to aggravate their situation.
Do not use in cases of cardiac, hepatic, or renal disease.
Do not use in cases of known hypersensitivity to ketoprofen or acetyl-salcylic acid or to any of the excipients.
Do not use in cases of blood dyscrasia, coagulopathy or haemorrhagic diathesis. Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

4.4. Special warnings for each target species

None.

4.5. Special precautions for use

Special precautions for use in animals

Do not exceed the recommended dose. Do not exceed the recommended treatment period.
The use of ketoprofen is not recommended in foals less than one month of age.
When administering to animals of less than 6 weeks of age, ponies or in aged animals it is necessary to adjust the dose accurately as well as to perform a close clinical follow-up. Avoid intra-arterial injection.
Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Since gastric ulceration is a common finding in PMWS (Post-weaning Multisystemic Wasting Syndrome), the use of ketoprofen in pigs affected by this pathology is not recommended, in order not to aggravate their situation. In horses, avoid extravascular administration.

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

Hypersensitivity reactions (skin rash, urticaria) could occur. People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.
Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with the skin, eyes and mucous membranes. In case of accidental skin, eye or mucous membrane contact, wash the affected area thoroughly with clean running water immediately. Seek medical advice if irritation persists.
Wash hands after use.

4.6. Adverse reactions (frequency and seriousness)

Intramuscular injection of ketoprofen can cause mild, transient, necrotic subclinical muscular lesions that gradually resolve in the days after completion of treatment. Administration in the neck region minimizes the extension and severity of these lesions.

In horses, transient local reactions, which disappeared after 5 days, were observed after one administration of the product at the recommended volume by extravascular route.

Due to the mechanism of action of ketoprofen, after repeated administrations, erosive and ulcerative lesions of the gastrointestinal tract may occur.

In common with all NSAIDs due to their action of inhibition of prostaglandins' synthesis, there can be the possibility in certain individuals of gastric or renal intolerance.

If side effects occur treatment must be stopped and the advice of a veterinarian should be sought.

4.7. Use during pregnancy, lactation or lay

Pregnancy:
Studies in laboratory animals (rats, mice, rabbits) and cattle have not produced any evidence of adverse effects. Can be used in pregnant cows.
The safety of the veterinary medicinal product has not been established during pregnancy in sows and mares. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Lactation:
Can be used in lactating cows and sows.
The use is not recommended in lactating mares.

4.8. Interaction with other medicinal products and other forms of interaction

- Concurrent administration of diuretics or potentially nephrotoxic drugs should be avoided since there is an increase of renal disturbances, including renal failure. This is secondary to the diminished blood flow caused by the inhibition of prostaglandins synthesis.
- Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, anticoagulants or diuretics concurrently or within 24 hours of administration of the product since the risk of gastrointestinal ulceration and other adverse reactions may be exacerbated.
- The treatment free period should however take into account the pharmacological properties of the products used previously.
- Ketoprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects.

4.9. Amounts to be administered and administration route

Intramuscular or intravenous use.

- Cattle:
3 mg ketoprofen/kg body weight, i.e. 1ml of product per 50 kg body weight/ day, administered via the intravenous or intramuscular route, preferably in the neck region.
The duration of treatment is 1-3 days, and should be established according to the severity and duration of symptoms.

- Pigs:
3 mg of ketoprofen/kg body weight i.e. 1 ml of the product per 50 kg body weight/ day, administered via the intramuscular route on a single occasion. Depending on the response observed and based on the benefit-risk analysis by the responsible veterinarian treatment may be repeated at intervals of 24 hours for a maximum of three treatments. Each injection should be given at a different site.

- Horses:
2.2 mg of ketoprofen/kg body weight, i.e. 0.75 ml of the product. per 50 kg body weight/ day, administered via the intravenous route.
The duration of treatment is 1-5 days, and should be established according to the severity and duration of symptoms. In the case of colic one injection is normally sufficient. A second administration of ketoprofen requires a clinical re-examination.

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

Overdose with non-steroidal anti-inflammatory drugs can lead to gastro-intestinal ulceration, loss of proteins, hepatic and renal impairment.

In tolerance studies performed in pigs, up to 25% of the animals treated at three times the maximum recommended dose (9 mg/kg bw) for three days or at the recommended dose (3 mg/kg bw) for triple the maximum recommended time (9 days) showed erosive and/or ulcerative lesions in both the aglandular (pars oesophagica) and glandular parts of the stomach. Early signs of toxicity include loss of appetite and pasty faeces or diarrhoea.

The intramuscular administration of the product to cattle, at up to 3 times the recommended dose or for 3 times the recommended duration of the treatment (9 days) did not result in clinical signs of intolerance. However, inflammation as well as necrotic subclinical lesions were detected at the injection site of the treated animals as well as an increase in CPK levels. The histopathological examination showed erosive or ulcerative abomasal lesions related to both dosage regimes.

Horses have been found to tolerate intravenous dosages of ketoprofen up to 5 times the recommended dose for three times the recommended duration (15 days) with no evidence of toxic effects.

If clinical signs of overdose are observed, there is no specific antidote, therefore symptomatic treatment should be initiated.

4.11. Withdrawal periods

Cattle:
Meat and offal: 2 days

Milk: zero hours

Horses:
Meat and offal: 1 day
Milk: Not authorised for use in mares producing milk for human consumption

Pig:
Meat and offal: 3 days

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Anti-inflammatory and Antirheumatic Products, Non-Steroids, Propionic acid derivatives,
ATC vet code: QM01AE03

5.1. Pharmacodynamic properties

Ketoprofen, 2-(phenyl 3-benzoyl) propionic acid is a non-steroidal anti-inflammatory drug belonging to the arylpropionic acid group. The primary mechanism of action for ketoprofen is considered to be inhibition of the cyclooxygenase pathway of arachidonic acid metabolism, leading to decreased production of inflammatory mediators, such as prostaglandins and thromboxanes. This mechanism of action results in its anti-inflammatory, anti-pyretic and analgesic activity. These properties are also attributed to its inhibiting effect on bradykinin and superoxide anions together with its stabilizing action on lysosomal membranes.
The anti-inflammatory effect is enhanced by the conversion of the (R)-enantiomer to (S)enantiomer. It is known that the (S)-enantiomer supports the ant-inflammatory effect of ketoprofen.
The maximum anti-inflammatory effects of ketoprofen occur at 4 hours after a dose and last for 24 hours, illustrating that the anti-inflammatory effects are not related to plasma concentrations in horses.

5.2. Pharmacokinetic particulars

After intramuscular administration of the product (single dose of 3 mg ketoprofen/kg body weight), ketoprofen is rapidly absorbed, and has a high bioavailability.

Ketoprofen binds extensively to plasma proteins (>90%).

The concentrations of Ketoprofen are more sustained in inflammatory exudates than in plasma. It reaches high concentrations and persists in inflamed tissue, due to the fact that Ketoprofen is a weak acid. Ketoprofen is metabolized in the liver to inactive metabolites and it is excreted mainly in urine (primarily as glucuroconjugated metabolites) and, to a lesser extent, in faeces. Small amounts of ketoprofen can be detected in the milk of treated animals.

In cattle, following the intramuscular administration of the product (single dose of 3 mg ketoprofen/kg body weight), the active drug substance is rapidly absorbed, reaching its

average C_{max} in plasma (mean value: 7.2 µg/ml) between 0.5 and 1 hour (t_{max}) after initiation of treatment. The fraction of dose absorbed is very high (92.51±10.9%).
Following the intravenous administration in cattle, elimination half-life ($t_{1/2}$) is of 2.1 h. The distribution volume (Vd) of 0.41 L/kg, and plasma clearance (Cl) of 0.14 L/h/kg.
In pigs, following the intramuscular injection of a single dose of 3 mg/ketoprofen/kg body weight, the active drug substance is rapidly absorbed, reaching its average C_{max} in plasma (mean value: 16 µg/ml) between 0.25 and 1.5h (t_{max}) after initiation of the treatment. The fraction of dose absorbed is 84.7±33%.
Following the intravenous administration in pigs, elimination half-life ($t_{1/2}$) is of 3.6 h. The distribution volume (Vd) of 0.15 L/kg, and plasma clearance (Cl) of 0.03 L/h/kg.

In horses Ketoprofen is 92.8% protein bound and it has a moderate Vd of approximately 0.5 L/kg and short plasma elimination half-lives of 1 to 1.5 hours. The active substance is hepatically metabolized by conjugation reactions, with only 25% of a dose eliminated as unchanged in urine.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Benzyl alcohol (E1519)
Arginine
Citric acid monohydrate (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: 30 months
Shelf-life after first opening the immediate packaging: 28 days

6.4. Special precautions for storage

Keep the vial in the outer carton in order to protect from light.

6.5. Nature and composition of immediate packaging

Amber type II glass vials of 50 ml, 100 ml and 250 ml closed with bromobutyl stoppers and aluminium caps.

Pack sizes:
Cardboard box containing 1 vial of 50 ml
Cardboard box containing 1 vial of 100 ml
Cardboard box containing 1 vial of 250 ml

Cardboard box containing 12 vials of 50 ml
Cardboard box containing 10 vials of 100 ml
Cardboard box containing 10 vials of 250 ml

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.
c/Venus, 26
08228 Terrassa (Barcelona)
Spain

8. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: DD/MM/YYYY

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

For animal treatment only - Veterinary prescription.
Administration by a veterinary surgeon or under their direct responsibility.
For intravenous use, exclusive administration by the veterinarian.

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box with vial(s) of 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses
Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Ketoprofen 150 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 50 ml
1 x 100 ml
1 x 250 ml
12 x 50 ml
10 x 100 ml
10 x 250 ml

5. TARGET SPECIES

Cattle, pigs and horses

6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 2 days
Milk: zero hours

Horses:
Meat and offal: 1 day
Milk: Not authorised for use in mares producing milk for human consumption

Pig:
Meat and offal: 3 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

Keep the vial in the outer carton 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

Labiana Life Sciences, S.A.
c/Venus, 26
08228 Terrassa (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

17. MANUFACTURER’S BATCH NUMBER

Lot: {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

50 ml, 100 ml and 250 ml Vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses
Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Ketoprofen 150 mg

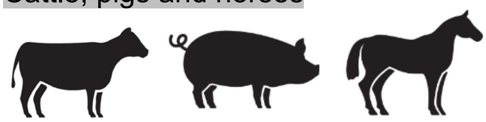
3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

50 ml
100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and horses



6. INDICATION(S)

7. METHOD AND ROUTES OF ADMINISTRATION

Intramuscular or intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Cattle:
Meat and offal: 2 days
Milk: zero hours

Horses:
Meat and offal: 1 day

Milk: Not authorised for use in mares producing milk for human consumption

Pig:
Meat and offal: 3 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

Keep the vial in the outer carton in order to protect from light..

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

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”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Labiana Life Sciences, S.A.
c/Venus, 26
08228 Terrassa (Barcelona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

17. MANUFACTURER’S BATCH NUMBER

Lot: {number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Labiprofen 150 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:
Labiana Life Sciences S.A. - Venus 26 - 08228 Terrassa (Barcelona) - Spain.

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Labiprofen 150 mg/ml solution for injection for cattle, pigs and horses
Ketoprofen

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Each ml contains:
Active substance:

Ketoprofen	150 mg
Excipients:	
Benzyl alcohol (E1519)	10 mg

Solution for injection. A clear colourless to yellowish solution.

4. INDICATIONS

Cattle:
- Reduction of inflammation and pain associated with post-partum, musculoskeletal disorders and lameness.
- Reduction of fever associated with bovine respiratory disease in combination with antimicrobial therapy where appropriate.
- Reduction of inflammation, fever and pain in acute clinical mastitis in combination with antimicrobial therapy where appropriate.

Pigs:
- Reduction of pyrexia in cases of respiratory disease and Postpartum Dysglactia SyndromePDS- (Metritis Mastitis Agalactia syndrome) in sows, in combination with antimicrobial therapy, where appropriate.

Horses:
- Reduction of inflammation and pain associated with osteoarticular and musculoskeletal disorders (lameness, laminitis, osteoarthritis, synovitis, tendinitis, etc.).
- Reduction of postoperative pain and inflammation.
- Reduction of visceral pain associated with colic.

5. CONTRAINDICATIONS

Do not use in cases of gastro-intestinal ulceration or bleeding, in order not to aggravate their situation.
Do not use in cases of cardiac, hepatic, or renal disease.
Do not use in cases of known hypersensitivity to ketoprofen or acetyl-salcylic acid or to any of the excipients.
Do not use in cases of blood dyscrasia, coagulopathy or haemorrhagic diathesis. Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs) concurrently or within 24 hours of each other.

6. ADVERSE REACTIONS

Intramuscular injection of ketoprofen can cause mild, transient, necrotic subclinical muscular lesions that gradually resolve in the days after completion of treatment. Administration in the neck region minimizes the extension and severity of these lesions.

In horses, transient local reactions, which disappeared after 5 days, were observed after one administration of the product at the recommended volume by extravascular route.

Due to the mechanism of action of ketoprofen, after repeated administrations, erosive and ulcerative lesions of the gastrointestinal tract may occur.

In common with all NSAIDs due to their action of inhibition of prostaglandins' synthesis, there can be the possibility in certain individuals of gastric or renal intolerance.

If side effects occur treatment must be stopped and the advice of a veterinarian should be sought.

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.

Alternatively, you can report via your national reporting system {national system details}.

7. TARGET SPECIES

Cattle, pigs and horses

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

Intramuscular or intravenous use.

- Cattle:
3 mg ketoprofen/kg body weight, i.e. 1ml of product per 50 kg body weight/ day, administered via the intravenous or intramuscular route, preferably in the neck region.
The duration of treatment is 1-3 days, and should be established according to the severity and duration of symptoms.

- Pigs:
3 mg of ketoprofen/kg body weight i.e. 1 ml of the product per 50 kg body weight/ day, administered via the intramuscular route on a single occasion. Depending on the response observed and based on the benefit-risk analysis by the responsible veterinarian treatment may be repeated at intervals of 24 hours for a maximum of three treatments. Each injection should be given at a different site.

- Horses:

2.2 mg of ketoprofen/kg body weight, i.e. 0.75 ml of the product. per 50 kg body weight/ day, administered via the intravenous route.
The duration of treatment is 1-5 days, and should be established according to the severity and duration of symptoms. In the case of colic one injection is normally sufficient. A second administration of ketoprofen requires a clinical re-examination.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIODS

Cattle:
Meat and offal: 2 days
Milk: zero hours

Horses:
Meat and offal: 1 day
Milk: Not authorised for use in mares producing milk for human consumption

Pig:
Meat and offal: 3 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton in order to protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and vial after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the vial: 28 days.

When a vial 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 vial should be discarded should be worked out. This discard date should be written in the space provided.

12. SPECIAL WARNINGS

Special precautions for use in animals:
Do not exceed the recommended dose. Do not exceed the recommended treatment period.
The use of ketoprofen is not recommended in foals less than one month of age.
When administering to animals of less than 6 weeks of age, ponies or in aged animals it is necessary to adjust the dose accurately as well as to perform a close clinical follow-up. Avoid intra-arterial injection.
Avoid use in any dehydrated, hypovolaemic or hypotensive animals as there is a potential risk of increased renal toxicity.
Since gastric ulceration is a common finding in PMWS (Post-weaning Multisystemic Wasting Syndrome), the use of ketoprofen in pigs affected by this pathology is not recommended, in order not to aggravate their situation. In horses, avoid extravascular administration.

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

Hypersensitivity reactions (skin rash, urticaria) could occur. People with known hypersensitivity to the active substance or to any of the excipients should avoid contact with the veterinary medicinal product.
Avoid accidental self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid contact with the skin, eyes and mucous membranes. In case of accidental skin, eye or mucous membrane contact, wash the affected area thoroughly with clean running water immediately. Seek medical advice if irritation persists.
Wash hands after use.

Pregnancy and lactation:
Studies in laboratory animals (rats, mice, rabbits) and cattle have not produced any evidence of adverse effects. Can be used in pregnant cows.
The safety of the veterinary medicinal product has not been established during pregnancy in sows and mares. Use only accordingly to the benefit-risk assessment by the responsible veterinarian.
Can be used in lactating cows and sows.
The use is not recommended in lactating mares.

Interaction with other medicinal products and other forms of interaction:
- Concurrent administration of diuretics or potentially nephrotoxic drugs should be avoided since there is an increase of renal disturbances, including renal failure. This is secondary to the diminished blood flow caused by the inhibition of prostaglandins synthesis.
- Do not administer other non-steroidal anti-inflammatory drugs (NSAIDs), corticosteroids, anticoagulants or diuretics concurrently or within 24 hours of administration of the product since the risk of gastrointestinal ulceration and other adverse reactions may be exacerbated.
- The treatment free period should however take into account the pharmacological properties of the products used previously.
- Ketoprofen is highly bound to plasma proteins and may compete with other highly bound drugs which can lead to toxic effects.

Overdose (symptoms, emergency procedures, antidotes):
Overdose with non-steroidal anti-inflammatory drugs can lead to gastro-intestinal ulceration, loss of proteins, hepatic and renal impairment.

In tolerance studies performed in pigs, up to 25% of the animals treated at three times the maximum recommended dose (9 mg/kg bw) for three days or at the recommended dose (3 mg/kg bw) for triple the maximum recommended time (9 days) showed erosive and/or ulcerative lesions in both the aglandular (pars oesophagica) and glandular parts of the stomach. Early signs of toxicity include loss of appetite and pasty faeces or diarrhoea.

The intramuscular administration of the product to cattle, at up to 3 times the recommended dose or for 3 times the recommended duration of the treatment (9 days) did not result in clinical signs of intolerance. However, inflammation as well as necrotic subclinical lesions were detected at the injection site of the treated animals as well as an increase in CPK levels. The histopathological examination showed erosive or ulcerative abomasal lesions related to both dosage regimes.

Horses have been found to tolerate intravenous dosages of ketoprofen up to 5 times the recommended dose for three times the recommended duration (15 days) with no evidence of toxic effects.

If clinical signs of overdose are observed, there is no specific antidote, therefore symptomatic treatment should be initiated.

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 in wastewater or household waste.
Ask your veterinary surgeon or pharmacist 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

MM/YYYY

15. OTHER INFORMATION

Package sizes:
Box containing 1 vial of 50 ml
Box containing 1 vial of 100 ml
Box containing 1 vial of 250 ml
Box containing 12 vials of 50 ml
Box containing 10 vials of 100 ml
Box containing 10 vials of 250 ml

Not all pack sizes may be marketed.

For animal treatment only.

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.