ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rifen 100 mg/ml solution for injection for horses, cattle and pigs

Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

1 ml contains:
Ketoprofen 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml
10 x 50 ml
10 x 100 ml

5. TARGET SPECIES

Horse, cattle, pigs

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Optional for multilingual labels:
Horse: IV/Cattle: IV, deep IM/Pigs: deep IM

Horse:
1 ml per 45 kg body weight IV once daily, up to 3 to 5 consecutive days

Cattle:
3 ml per 100 kg body weight IV or deep IM once daily, up to 3 consecutive days

Pigs:
3 ml per 100 kg body weight (= 0.03 ml/kg) single deep IM

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal:

Horse:	IV	1 day
Cattle:	IV	1 day
	IM	3 days
Pigs:	IM	4 days
Milk (cattle):	Zero hours	

Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days.

11. SPECIAL STORAGE CONDITIONS

Keep the glass vial in the outer carton in order to protect from light.
After first opening the immediate packaging do not store above 25 °C.

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

VetViva Richter GmbH, Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57446/5000

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE
50 ml, 100 ml
Amber glass vials type II, with bromobutyl rubber stopper type I and aluminium caps

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rifen 100 mg/ml solution for injection for horses, cattle and pigs

Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Ketoprofen 100 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

50 ml
100 ml

5. TARGET SPECIES

Horse, cattle, pigs

6. INDICATION(S)

-

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Horse: IV/Cattle: IV, deep IM/Pigs: deep IM

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Meat and offal:

Horse:	IV	1 day
Cattle:	IV	1 day
	IM	3 days
Pigs:	IM	4 days
Milk (cattle):	Zero hours	

Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use within 28 days by ……..

11. SPECIAL STORAGE CONDITIONS

Protect from light.
After first opening the immediate packaging do not store above 25 °C.

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

VetViva Richter GmbH, Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

Vm 57446/5000

17. MANUFACTURER'S BATCH NUMBER

Batch{number}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Rifen 100 mg/ml solution for injection for horses, cattle and pigs

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:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rifen 100 mg/ml solution for injection for horses, cattle and pigs

Ketoprofen

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

1 ml contains:

Active substance:
Ketoprofen 100 mg

Excipients:
Benzyl alcohol (E1519) 10 mg

Clear, colourless to brownish-yellowish solution

4. INDICATION(S)

Horse
Diseases affecting the osteoarticular and muscular-skeletal system associated with acute pain and inflammation:
- Lameness of traumatic origin
- Arthritis
- Osteitis, spavin
- Tendinitis, bursitis
- Naviculitis
- Laminitis
- Myositis

Ketoprofen is also indicated for post-surgical inflammation, symptomatic therapy of colic and fever.

Cattle
Diseases associated with inflammation, pain or fever:
- Respiratory diseases
- Mastitis
- Osteoarticular and muscular-skeletal disorders such as lameness, arthritis and to ease uprise post parturition

- Injuries

For the relief of post-operative pain associated with dehorning in calves.

Pigs

Diseases associated with inflammation, pain or fever:

- Treatment associated with the Postpartum Dysgalactia Syndrome/Mastitis Metritis Agalactia (MMA) Syndrome
- Respiratory tract infections
- Symptomatic treatment of fever

For the short-term relief of post-operative pain associated with minor soft tissue surgery such as castration in piglets.

Where necessary ketoprofen should be combined with appropriate antimicrobial therapy.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance, or to any of the excipients. Do not use in animals suffering from gastrointestinal lesions, haemorrhagic diathesis, impaired hepatic, renal or cardiac function. Do not use with other NSAID drugs concurrently or within 24 hours of each other.

6. ADVERSE REACTIONS

Due to the mechanism of action of NSAIDs (inhibition of prostaglandin synthesis), gastric and intestinal irritation or ulceration or renal intolerance may occur even after appropriate use.
Intramuscular injections may occasionally cause transient irritation.
Repeated administration to pigs may result in reversible inappetence.
In very rare cases, hypersensitivity reactions may occur. Such reactions may evolve to a more severe condition (anaphylaxis), which may be life-threatening and should be treated symptomatically.

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

Horse, cattle, pigs

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

Horse:
2.2 mg ketoprofen/kg body weight/day intravenously once daily, for up to 3 to 5 consecutive days, i.e. 1 ml per 45 kg body weight.

In order to treat colic one injection is normally sufficient. A second administration of ketoprofen requires a reassessment of the patient's clinical status. See point 9, Advice on correct administration.

Cattle:
3 mg ketoprofen/kg body weight/day intravenously or deep intramuscularly once daily for up to 3 consecutive days, i.e. 3 ml per 100 kg body weight.
For the relief of post-operative pain associated with dehorning the product should be administered as a single injection intravenously or deep intramuscularly 10 – 30 minutes before the procedure.

In cattle, the volume per injection site for IM injection should not exceed 9 ml. If the injection volume exceeds 9 ml, this volume should be divided into multiple doses, administered at different injection sites.

Pigs:
3 mg ketoprofen/kg body weight as a single deep intramuscular injection, i.e. 3 ml per 100 kg body weight (= 0.03 ml/kg).

For reduction of post-operative pain the product should be injected 10 - 30 minutes before surgical intervention. Particular care should be taken with regard to the accuracy of dosing including the use of an appropriate dosing device (i.e.: low dose syringe) and proper determination of body weight.

9. ADVICE ON CORRECT ADMINISTRATION

Avoid intra-arterial injection. Do not exceed recommended dose or period of treatment. Special care should be taken when administering the product to animals with severe dehydration, hypovolaemia and hypotension as there is a potential risk of increased renal toxicity.
The use of ketoprofen is not recommended in foals under the age of 15 days. Use in animals 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 management. See point 12 regarding the use of the product in pregnant mares and sows.
Sufficient drinking water must be supplied at all times during treatment.
In colic, a subsequent dose may be given only after a thorough re-examination.

10. WITHDRAWAL PERIOD(S)

Meat and offal:

Horse:	IV	1 day (24 hours)
Cattle:	IV	1 day (24 hours)
	IM	3 days (72 hours)
Pigs:	IM	4 days

Milk (cattle): Zero hours
Not authorised for use in mares producing milk for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Keep the vial in the outer carton in order to protect from light.
Do not use after the expiry date stated on the label.
After first opening the container do not store above 25 °C.
Shelf-life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Treatment of piglets with ketoprofen before castration reduces post-operative pain for 1 hour. To obtain pain relief during surgery co-medication with an appropriate anaesthetic/sedative is needed.
Treatment of calves with ketoprofen before dehorning reduces post-operative pain. Ketoprofen alone will not provide adequate pain relief during the dehorning procedure. To obtain pain relief during dehorning co-medication with an appropriate local anaesthetic is needed.

Pregnancy and lactation
Can be used during pregnancy in cattle but should not be used in pregnant mares. In absence of studies on pigs use only according to the benefit/risk assessment by the responsible veterinarian.
Can be used in lactating cows.

Interaction with other medicinal products and other forms of interaction
The product must not be administered in conjunction with, or within 24 hours of administration of other NSAIDs and glucocorticoids. Concurrent administration of diuretics, nephrotoxic drugs and anticoagulative drugs should be avoided.

Ketoprofen is highly bound to plasma proteins, and may displace or be displaced by other highly protein bound medicines, such as anticoagulants with the possibility of consequent toxic effects due to the unbound fraction of the drug. Due to the fact that ketoprofen may inhibit platelet aggregation and cause gastrointestinal ulceration, it should not be used with other medicines that have the same profile of adverse drug reactions.

Overdose (symptoms, emergency procedures, antidotes)
Overdose with NSAIDs can lead to gastrointestinal ulceration, loss of proteins, hepatic and renal impairment. Early signs of toxicity include loss of appetite and pasty faeces or diarrhoea. If overdose symptoms are observed, 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.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician. People with known hypersensitivity to ketoprofen or benzyl alcohol should avoid contact with the veterinary medicinal product.
Avoid splashes on the skin and eyes. Rinse thoroughly with water should this occur. If irritation persists seek medical advice. Wash hands after use.

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

June 2023

15. OTHER INFORMATION

Ketoprofen is a non-steroidal anti-inflammatory drug. In addition to the anti-inflammatory effect, it also exerts an anti-pyretic and analgesic effect. Ketoprofen is rapidly absorbed after intramuscular administration. Maximum plasma concentration is reached within 30 to 60 minutes. 80 % of the dose administered are eliminated within 12 hours.

Package sizes: 50 ml, 100 ml, 10 x 50 ml, 10 x 100 ml
Not all pack sizes may be marketed.

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

Approved 15 June 2023