PARTICULARS TO APPEAR ON THE OUTER PACKAGE (Cardboard box)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rifen 100 mg/ml solution for injection

Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:
Ketoprofen 100 mg

3. PACKAGE SIZE

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

4. TARGET SPECIES

Horses, cattle, pigs

5. INDICATIONS

-

6. ROUTES OF ADMINISTRATION

Horses: i.v./ Cattle: i.v., deep i.m./ Pigs: deep i.m.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal:

Horses:	1 day	
Cattle:	i.v.	1 day
	i.m.	3 days
Pigs:	4 days	

Milk (cattle): Zero hours

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

8. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

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.

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 57446/5000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Rifen 100 mg/ml solution for injection

Ketoprofen

2. STATEMENT OF ACTIVE SUBSTANCES

Ketoprofen 100 mg/ml

3. TARGET SPECIES

Horses, cattle, pigs

4. ROUTES OF ADMINISTRATION

Horses: i.v./ Cattle: i.v., deep i.m./ Pigs: deep i.m.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal:

Horses:	1 day	
Cattle:	i.v.	1 day
	i.m.	3 days
Pigs:	4 days	

Milk (cattle): Zero hours

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

6. EXPIRY DATE

Exp. {mm/yyyy}

Once broached, use within 28 days by ……..

7. SPECIAL STORAGE PRECAUTIONS

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

8. NAME OF THE MARKETING AUTHORISATION HOLDER

VetViva Richter GmbH

9. BATCH NUMBER

Lot {number}

50 ml
100 ml

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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

2. Composition

Each ml contains:

Active substance:
Ketoprofen 100 mg

Excipients:
Benzyl alcohol (E1519) 10 mg

Clear, colourless to brownish-yellowish solution for injection.

3. Target species

Horses, cattle, pigs

4. Indications for use

Horses

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. Special warnings

Special warnings:

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.

Special precautions for safe use in the target species:

Avoid intra-arterial injection. Do not exceed recommended dose or period of treatment. Special care should be taken when administering the veterinary medicinal 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 section “Pregnancy and lactation” regarding the use of the veterinary medicinal 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.

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.

Pregnancy and lactation:

Pregnancy: The safety of ketoprofen has been investigated in pregnant laboratory animals and cattle and no adverse effects were noted. The veterinary medicinal product can be used in pregnant cows.
In absence of studies on pigs use only according to the benefit-risk assessment by the responsible veterinarian. Do not use in pregnant mares.
Lactation: Can be used in lactating cows.

Interaction with other medicinal products and other forms of interaction:
The veterinary medicinal 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:
Overdose with NSAIDs can lead to gastrointestinal 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) for three days or at the recommended dose (3 mg/kg) 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. If overdose symptoms are observed, symptomatic treatment should be initiated. The occurrence of ulcers is dose dependent to a limited extent.

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

7. Adverse events

Horses, cattle, pigs:
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Hypersensitivity reaction, Anaphylaxis[1].

Undetermined frequency (cannot be estimated from the available data):
Gastrointestinal irritation[2], Gastric ulceration[2], Small intestine ulcer[2]; Renal disorder[2]; Injection site irritation[3]; Inappetence[4].

[1] Anaphylaxis may be life-threatening and should be treated symptomatically.
[2] Due to the mechanism of action of NSAIDs (inhibition of prostaglandin synthesis).
[3] Transient, caused by intramuscular injections.
[4] Only in pigs, due to repeated administration, reversible.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at https://www.gov.uk/report-veterinary-medicine-problem.

8. Dosage for each species, routes and method of administration

Horses: Intravenous use (i.v.)
Cattle: Intravenous or intramuscular use (i.v. or i.m.)
Pigs: Intramuscular use (i.m.)

To ensure a correct dosage, body weight should be determined as accurately as possible.

Horses:
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 section 'Special warnings'.

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 veterinary medicinal 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 i.m. 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 veterinary medicinal 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).

9. Advice on correct administration

See section "Special warnings".

10. Withdrawal periods

Meat and offal:
Horses: 1 day (24 hours)
Cattle: i.v. 1 day (24 hours)
i.m. 3 days (72 hours)
Pigs: 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 this veterinary medicinal product after the expiry date which is stated on the label and carton after “Exp.”.. The expiry date refers to the last day of that month.
After first opening the container do not store above 25 °C.
Shelf-life after first opening the immediate packaging: 28 days.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 57446/5000

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

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the ‘Product Information Database’ on www.gov.uk.

16. Contact details

Marketing authorisation holder, manufacturer responsible for batch release and contact details to report suspected adverse reactions:
VetViva Richter GmbH, Durisolstrasse 14, 4600 Wels, Austria
adverse.events@vetviva.com
Tel: +43 664 8455326

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

17. Other information

POM-V	Veterinary medicinal product subject to prescription

Gavin Hall
Approved: 23 October 2025