B. PACKAGE LEAFLET

PACKAGE LEAFLET:
Rivalgin 500 mg/ml solution for injection
(BE, BG, CZ, ES, HR, HU, IT, LT, PT)

Rivalgin vet. 500 mg/ml solution for injection
(DK, IS, NO)

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

Rivalgin 500 mg/ml solution for injection
(BE, BG, CZ, ES, HR, HU, IT, LT, PT)

Rivalgin vet. 500 mg/ml solution for injection
(DK, IS, NO)

Metamizole sodium monohydrate

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

1 ml contains:
Active substance:
Metamizole sodium monohydrate 500 mg
(equivalent to metamizole 443.1 mg)

Excipients:
Benzyl alcohol (E1519) 30 mg

Clear, yellowish solution, practically free of particulate matters.

4. INDICATION(S)

Diseases of horses, cattle, pigs and dogs where a positive effect of the central analgesic, spasmolytic, antipyretic or low anti-inflammatory effects of the product can be expected, such as:

General pain relief to suppress nervousness and defensive reactions caused by pain.
Attenuation of pain in colic conditions of varying origins or spastic states of the internal organs in horses and cattle.
Occlusion of the oesophagus with foreign bodies in horses, cattle and pigs.
Feverish illnesses such as severe mastitis, MMA syndrome, swine flu.
Lumbago, tetanus (in combination with tetanus antiserum).
Acute and chronic arthritis, rheumatic states of muscles and joints, nerve inflammation, neuralgia, tendovaginitis.

5. CONTRAINDICATIONS

Do not use in cats.
The product should not be used in animals with haematopoietic disorders.
Do not administer subcutaneously due to possible local irritation.
Do not use in cases of hypersensitivity to the active substance, or to any of the excipients.
Do not use in cases of heart, hepatic or renal failure or gastro-intestinal ulceration.

6. ADVERSE REACTIONS

None known.

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

Horses, cattle, pigs, dogs.

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

Horses: Slow intravenous use.
Cattle, pigs, dogs: Slow intravenous use (in acute conditions) or deep intramuscular use.

Horses: 20-50 mg of metamizole sodium monohydrate/kg BW (4-10 ml of the product/100 kg BW)
Cattle: 20-40 mg of metamizole sodium monohydrate/kg BW (4-8 ml of the product/100 kg BW)
Pigs: 15-50 mg of metamizole sodium monohydrate/kg BW (3-10 ml of the product/100 kg BW)
Dogs: 20-50 mg of metamizole sodium monohydrate/kg BW (0.4-1 ml of the product/10 kg BW)

When used intramuscularly in cattle the maximum volume applied to one site should not exceed 29 ml. In pigs, when administering volumes larger than 20 ml these should be divided between at least two injection sites.

The rubber stopper can be punctured a maximum of 25 times.

9. ADVICE ON CORRECT ADMINISTRATION

Refer to section 8.

10. WITHDRAWAL PERIOD(S)

Horses: Meat and offal (intravenous application): 5 days
Cattle: Meat and offal: 12 days
Milk: 48 hours
Pigs: Meat and offal: 12 days

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

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not refrigerate or freeze.

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.
Shelf life after first opening the container: 28 days

12. SPECIAL WARNING(S)

Special warnings for each target species:
None.

Special precautions for use in animals:
Due to the risk of anaphylactic shock, metamizole-containing solutions should be administered slowly when given intravenously.
Avoid concomitant administration with potentially nephrotoxic drugs.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
People with known hypersensitivity to metamizole should avoid contact with the veterinary medicinal product. Avoid use of the product if you are known to be sensitive to pyrazolones, or to acetylsalicylic acid. Pregnant and breast-feeding women should handle this product with caution.

This product may be irritant to skin and eyes. Avoid contact with the skin and eyes. Wash any splashes from skin and eyes immediately with plenty of water. Seek medical advice if irritation persists.
Metamizole can cause reversible, but potentially serious agranulocytosis. Take care to avoid self-injection. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Wash hands after use.

Pregnancy and lactation:
Can be used during pregnancy and lactation.

Interaction with other medicinal products and other forms of interaction:
Phenobarbital and other barbiturates as well as glutethimide or phenylbutazone can accelerate metamizole excretion due to hepatic microsomal enzyme induction.
Concomitant use of phenothiazine derivatives may lead to severe hypothermia.

Overdose (symptoms, emergency procedures, antidotes):
Effects on the central nervous system such as sedation and convulsions have been reported in all target species at doses from 1,000 to 4,000 mg/kg of bodyweight.
In case of overdose, follow the standard procedures and, if necessary, administer intravenous diazepam to control the seizures.

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

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

15. OTHER INFORMATION

Package sizes: 1 x 100 ml, 5 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.