

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. 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

2. STATEMENT OF ACTIVE SUBSTANCES

Metamizole sodium monohydrate 500 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

1 x 100 ml
5 x 100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Horses: Slow intravenous use.
Cattle, pigs, dogs: Slow intravenous or deep intramuscular use.

8. WITHDRAWAL PERIOD(S)Withdrawal periods:

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.

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

Do not refrigerate or freeze.

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, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)

17. MANUFACTURER’S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING

100 ml clear glass vial with bromobutyl rubber stopper and alu caps

1. 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

2. STATEMENT OF ACTIVE SUBSTANCES

Metamizole sodium monohydrate 500 mg/ml

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Horses, cattle, pigs, dogs

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

Horses: slow IV.

Cattle, pigs, dogs: slow IV or deep IM.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Horses: Meat and offal (IV): 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.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once broached, use by ...

11. SPECIAL STORAGE CONDITIONS

Do not refrigerate or freeze.

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

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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, 4600 Wels, Austria

16. MARKETING AUTHORISATION NUMBER(S)**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}