

**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**

Richter Pharma AG, 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**

Richter Pharma AG, 4600 Wels, Austria

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER’S BATCH NUMBER**

Lot {number}