

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

**Label on carton**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

NaCl Bernburg 9 mg/ml solution for injection/infusion and irrigation solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains: Sodium chloride 9 mg

**3. PACKAGE SIZE**

500 ml  
10 x 500 ml  
20 x 500 ml  
10 x 1000 ml  
5000 ml  
2 x 5000 ml

**4. TARGET SPECIES**

Cattle, horses, sheep, goats, pigs, dogs, cats, rabbits and guinea pigs

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Slow intravenous infusion; intravenous, subcutaneous or intraperitoneal injection; cutaneous use.

**7. WITHDRAWAL PERIODS**

Withdrawal period:  
Cattle, horses, sheep, goats, pigs, rabbits:  
Meat and offal: zero days.  
Milk: zero hours.

**8. EXPIRY DATE**

Exp. {mm/yyyy}

**9. SPECIAL STORAGE PRECAUTIONS**

**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**

Serumwerk Bernburg AG (logo)

**14. MARKETING AUTHORISATION NUMBERS**

**15. BATCH NUMBER**

Lot {number}

**PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Printing on bags or bottles**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

NaCl Bernburg 9 mg/ml solution for injection/infusion and irrigation solution

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each ml contains: Sodium chloride 9 mg

**3. TARGET SPECIES**

Cattle, horses, sheep, goats, pigs, dogs, cats, rabbits and guinea pigs

**4. ROUTES OF ADMINISTRATION**

Slow intravenous infusion; intravenous, subcutaneous or intraperitoneal injection; cutaneous use.  
Read the package leaflet before use.

**5. WITHDRAWAL PERIODS**

Withdrawal period:  
Cattle, horses, sheep, goats, pigs, rabbits:  
Meat and offal: zero days.  
Milk: zero hours.

**6. EXPIRY DATE**

Exp. {mm/yyyy}

**7. SPECIAL STORAGE PRECAUTIONS**

**8. NAME OF THE MARKETING AUTHORISATION HOLDER**

Serumwerk Bernburg AG (logo)

**9. BATCH NUMBER**

Lot {number}

500 ml  
1000 ml  
5000 ml