

## **A. LABELLING**

## **PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE**

**Bags of 400 g and 1 kg.**

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

Rhemox 500 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [AT, BE, BG, CY, CZ, DE, EL, ES, HU, IE, IT, PT, RO, SI, SK, UK]

Rhemox 500 mg/g powder for use in drinking water for pigs, chickens, ducks and turkeys [PL]

Rhemox 435.6 mg/g powder for use in drinking water for pigs, chicken broilers, duck broilers and turkeys for meat production [FR]

Amoxicillin trihydrate

### **2. STATEMENT OF ACTIVE SUBSTANCES**

Each gram contains:

Amoxicillin trihydrate                      500 mg

(Equivalent to 435.6 mg Amoxicillin)

“Only for France:”

Amoxicillin (as trihydrate)                      435.6 mg

(Equivalent to 500 mg of Amoxicillin trihydrate)

**3. PHARMACEUTICAL FORM**

Powder for use in drinking water.

**4. PACKAGE SIZE**

400 g

1 kg

**5. TARGET SPECIES**

Pigs

Chicken (broiler), duck (duck broiler) and turkey (turkey for meat production)

**6. INDICATION(S)****7. METHOD AND ROUTE(S) OF ADMINISTRATION**

For administration in drinking water.

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period(s):

Meat and offal: Pigs: 6 days.

Chickens: 1 day.

Turkeys: 5 days

Ducks: 9 days.

Not authorised for use in birds producing eggs for human consumption and within 4 weeks before onset of the laying period.

<b>9. SPECIAL WARNING(S), IF NECESSARY</b>
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Read the package leaflet before use.

<b>10. EXPIRY DATE</b>
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EXP {month/year}

Shelf-life after first opening the container: 3 months.

Shelf life after reconstitution in water according to directions: 16 hours.

Once opened, use by...

<b>11. SPECIAL STORAGE CONDITIONS</b>
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**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.

Administration by a veterinary surgeon, or under their direct responsibility.

**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**

Industrial Veterinaria, S.A.

Esmeralda, 19

08950 Esplugues de Llobregat

(Barcelona) Spain

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

<b>17. MANUFACTURER'S BATCH NUMBER</b>
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Batch {number}