A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box (100 ml / 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DORAXX 100 mg/ml solution for injection for cattle, pigs and sheep
tulathromycin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Tulathromycin 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle, pigs and sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: For subcutaneous use.
Pigs and sheep: For intramuscular use.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle (meat and offal): 22 days.
Pigs (meat and offal): 13 days.
Sheep (meat and offal): 16 days.

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 28 days
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC 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

DOPHARMA RESEARCH B.V.
Zalmweg 24
4941 VX Raamsdonksveer
NETHERLANDS

16. MARKETING AUTHORISATION NUMBER(S)

<To be completed in accordance to National Authorisation after conclusion of the DC/MR phase>.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial (100 ml / 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DORAXX 100 mg/ml solution for injection for cattle, pigs and sheep
tulathromycin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains:

Active substance:
Tulathromycin 100 mg

3. PHARMACEUTICAL FORM

Solution for injection

4. PACKAGE SIZE

100ml
250 ml

5. TARGET SPECIES

Cattle, pigs and sheep

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Cattle: SC.
Pigs and sheep: IM.

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Cattle (meat and offal): 22 days.
Pigs (meat and offal): 13 days.
Sheep (meat and offal): 16 days.

Not authorised for use in animals producing milk for human consumption. Do not use in pregnant animals, which are intended to produce milk for human consumption, within 2 months of expected parturition.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened, use within 28 days
Once opened use by…

11. SPECIAL STORAGE CONDITIONS

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

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 reach and sight of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

DOPHARMA RESEARCH B.V.
Zalmweg 24
4941 VX Raamsdonksveer
NETHERLANDS

16. MARKETING AUTHORISATION NUMBER(S)

<To be completed in accordance to National Authorisation after conclusion of the DC/MR phase>.

17. MANUFACTURER'S BATCH NUMBER

Batch {number}