A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARDBOARD BOX FOR 50 ml, 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Draxxin Plus 100 mg/ml + 120 mg/ml solution for injection
(AT, BE, BG, CY, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK)

Draxxin KP 100 mg/ml + 120 mg/ml solution for injection
(FR)

2. STATEMENT OF ACTIVE SUBSTANCES

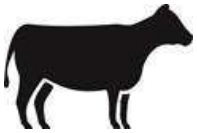
Tulathromycin 100 mg/ml
Ketoprofen 120 mg/ml

3. PACKAGE SIZE

50 ml
100 ml
250 ml

4. TARGET SPECIES

Cattle



5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Subcutaneous use.

7. WITHDRAWAL PERIODS

Withdrawal period**:**
Meat and offal: 50 days
Milk: Not authorised for use in cattle 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.

8. EXPIRY DATE

Exp. {mm/yyyy}
Shelf life after first broaching the container: 56 days.
Once broached, use by:

9. SPECIAL STORAGE CONDITIONS

Do not freeze.

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

{Name or company name or logo name of the marketing authorisation holder} *To be completed nationally.*

14. MARKETING AUTHORISATION NUMBERS

Number allocated by the Member State. To be completed in accordance with national requirements.

15. BATCH NUMBER

Lot {number}:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

VIAL LABEL FOR 100 ml and 250 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Draxxin Plus 100 mg/ml + 120 mg/ml solution for injection
(AT, BE, BG, CY, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK)

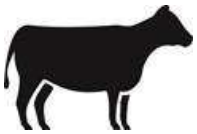
Draxxin KP 100 mg/ml + 120 mg/ml solution for injection
(FR)

2. STATEMENT OF ACTIVE SUBSTANCES

Tulathromycin 100 mg/ml
Ketoprofen 120 mg/ml

3. TARGET SPECIES

Cattle.



4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 50 days
Milk: Not authorised for use in cattle 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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once broached, use within 56 days, by:

7. SPECIAL STORAGE PRECAUTIONS

Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

{Name or company name or logo name of the marketing authorisation holder}*To be completed nationally.*

9. BATCH NUMBER

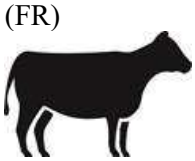
Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL LABEL FOR 50 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Draxxin Plus
(AT, BE, BG, CY, CZ, DE, EE, EL, ES, HR, HU, IE, IT, LT, LU, LV, NL, PL, PT, RO, SI, SK, UK)
Draxxin KP
(FR)



2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Tulathromycin 100 mg/ml
Ketoprofen 120 mg/ml

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP. {mm/yyyy}
Once broached, use within 56 days, by: