PARTICULARS TO APPEAR ON THE BOX

BOX – OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oriverm 10 mg/mL solution for injection for cattle, sheep and pigs Ivermectin

2. STATEMENT OF ACTIVE SUBSTANCES

Each mL contains 10 mg Ivermectin

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

50 mL 100 mL

5. TARGET SPECIES

Cattle, sheep and pigs.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Subcutaneous use. Single-use only. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal periods:

Cattle:

Meat and offal: 49 days.

Milk: Do not use in cattle producing milk for human consumption.

Sheep:

Meat and offal: 28 days.

Milk: Do not use in sheep producing milk for human consumption.

Pigs:

Meat and offal: 28 days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

Special precautions for use in animals:

Care should be taken to avoid the following practices because they increase the risk of development of resistance and could ultimately result in ineffective therapy:

- Too frequent and repeated use of anthelmintics from the same class, over an extended period of time.
- Underdosing, which may be due to underestimation of body weight, misadministration of the product, or lack of calibration of the dosing device (if any).

To ensure administration of a correct dose, bodyweight should be determined as accurately as possible; accuracy of the dosing device should be checked.

10. EXPIRY DATE

EXP.: {month/year}

Shelf life after first opening the immediate packaging: 28 days.

11. SPECIAL STORAGE CONDITIONS

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

EXTREMELY DANGEROUS FOR FISH AND AQUATIC LIFE. Do not contaminate surface waters or ditches with this product or used container. 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

actrevo GmbH Neuer Wall 54 22307 Hamburg Germany

Logo of distributor

ORION PHARMA

16. MARKETING AUTHORISATION NUMBER(S)

XXXXXX

17. MANUFACTURER'S BATCH NUMBER

Batch:{number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

50 mL GLASS VIAL – IMMEDIATE PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oriverm 10 mg/mL solution for injection for cattle, sheep and pigs Ivermectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substance: Ivermectin 10 mg/mL

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 mL solution

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Single-use only.

5. WITHDRAWAL PERIOD(S)

Withdrawal Periods:

Cattle:

Meat and offal: 49 days.

Milk: Do not use in cattle producing milk for human consumption.

Sheep:

Meat and offal: 28 days.

Milk: Do not use in sheep producing milk for human consumption

Pigs:

Meat and offal: 28 days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP.: {month/year}

Once opened use within 28 days.

Once broached use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

100 mL GLASS VIAL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Oriverm 10 mg/mL solution for injection for cattle, sheep and pigs Ivermectin

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substance: Ivermectin 10 mg/mL

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

100 mL solution

4. ROUTE(S) OF ADMINISTRATION

Subcutaneous use.

Single-use only.

5. WITHDRAWAL PERIOD(S)

Withdrawal Periods:

Cattle:

Meat and offal: 49 days.

Milk: Do not use in cattle producing milk for human consumption.

Sheep:

Meat and offal: 28 days.

Milk: Do not use in sheep producing milk for human consumption.

Pigs:

Meat and offal: 28 days.

6. BATCH NUMBER

Batch: {number}

7. EXPIRY DATE

EXP.: {month/year}

Once opened use within 28 days.

Once broached use by:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.