PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cattle
Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZUPREVO 180 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

180 mg/ml of tildipirosin

3. PACKAGE SIZE

20 ml
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: 47 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.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use within 28 days.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.

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

MSD Animal Health UK Ltd.

14. MARKETING AUTHORISATION NUMBER

Vm 01708/5060

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

Accidental injection is dangerous. Do not use in automatically powered syringes which have no additional protection system.

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

Disposal: Read package leaflet.

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

Veterinary medicinal product subject to prescription.

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Cattle
Vial (20 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZUPREVO 180 mg/ml solution for injection for cattle

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

180 mg/ml of tildipirosin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use by:

5. ROUTE(S) OF ADMINISTRATION

SC use.

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Cattle
Vial (100 ml, 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZUPREVO 180 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

180 mg/ml of tildipirosin

3. TARGET SPECIES

Cattle

4. ROUTES OF ADMINISTRATION

Subcutaneous use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:

Meat and offal: 47 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.

6. EXPIRY DATE

Exp. {mm/yyyy}
Once opened use by:

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Keep the vial in the outer carton.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

9. BATCH NUMBER

Lot {number}

10. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
Accidental injection is dangerous.

11. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet.

12. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only. Veterinary medicinal product subject to prescription.
POM-V

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZUPREVO 180 mg/ml solution for injection for cattle

2. COMPOSITION

Active substance:
One ml contains:
Tildipirosin 180 mg

Clear yellowish solution.

3. TARGET SPECIES

Cattle

4. INDICATIONS FOR USE

For the treatment and prevention of bovine respiratory disease (BRD) associated with *Histophilus somni, Mannheimia haemolytica* and *Pasteurella multocida*.
The presence of the disease in the group must be established before the product is used.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to macrolide antibiotics or to any of the excipients.
Do not administer simultaneously with other macrolides or lincosamides (see section “Special warnings”).

6. SPECIAL WARNINGS

Special warnings:
There is cross resistance with other macrolides.

Special precautions for safe use in the target species:
Use of the product should be based on identification and susceptibility testing of the target pathogen(s). If this is not possible, therapy should be based on epidemiological information and knowledge of susceptibility of the target pathogens at farm level, or at local/regional level.
Use of the product should be in accordance with official, national and regional antimicrobial policies.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

People with known hypersensitivity to tildipirosin should avoid contact with the veterinary medicinal product.

Special caution should be taken to avoid accidental self-injection, as toxicology studies in laboratory animals showed cardiovascular effects after intramuscular administration of tildipirosin. In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Do not use in automatically powered syringes which have no additional protection system.

Tildipirosin may cause sensitisation by skin contact. If accidental skin exposure occurs, wash the skin immediately with soap and water. If accidental eye exposure occurs, flush eyes immediately with clean water.
Wash hands after use.

Pregnancy and lactation:

The safety of the veterinary medicinal product has not been established during pregnancy and lactation. However, there was no evidence for any selective developmental or reproductive effects in any of the laboratory studies. Use only according to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:

The product should not be administered with antimicrobials with a similar mode of action such as other macrolides or lincosamides.

Overdose:

Overdoses of 10 times the recommended dose as well as repeated subcutaneous administration of the veterinary medicinal product only led to transient clinical signs attributed to injection site discomfort and injection site swellings associated with pain in calves.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

7. ADVERSE EVENTS

Cattle

Very common (>1 animal / 10 animals treated):
Immediate pain upon injection, Injection site swelling[1], Injection site pain[2], Injection site reaction[3]
Very rare (<1 animal / 10,000 animals treated, including isolated reports):
Anaphylaxis[4]

[1] may be present up to 21 days post treatment
[2] may be present up to 1 day post treatment
[3] pathomorphological, will largely resolve within 35 days
[4] may be fatal

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
Email: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. DOSAGE FOR EACH SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Subcutaneous use.

Administer 4 mg tildipirosin/kg body weight (equivalent to 1 ml/45 kg body weight) once only.

It is recommended to treat animals in the early stages of the disease and to evaluate the response to treatment within 2 to 3 days after injection.
If clinical signs of respiratory disease persist or increase, treatment should be changed using another antibiotic, and continued until clinical signs have resolved.

9. ADVICE ON CORRECT ADMINISTRATION

For treatment of cattle over 450 kg body weight, divide the dose so that no more than 10 ml are injected at one site.

The rubber stopper of the vial may be safely punctured up to 20 times. Otherwise, the use of a multiple-dose syringe is recommended.

To ensure a correct dosage, body weight should be determined as accurately as possible.

10. WITHDRAWAL PERIODS

Meat and offal: 47 days
Not authorised for use in lactating 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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and on the vial after Exp.
Shelf life after first opening the container: 28 days.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.
These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 01708/5060

Box containing 1 vial of 20 ml, 50 ml, 100 ml or 250 ml.Not all

pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

September 2023

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:

MSD Animal Health UK Ltd.
Walton Manor, Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

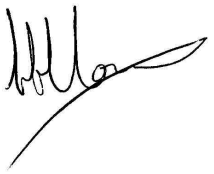
Manufacturer responsible for batch release:
Intervet International GmbH
Feldstrasse 1 a
85716 Unterschleissheim
GERMANY

Contact details to report suspected adverse reactions:
MSD Animal Health UK Ltd.
Tel.: +44 (0)1908 685685

17. OTHER INFORMATION

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.



Approved 08 January 2024