PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Pigs
Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZUPREVO 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

40 mg/ml of tildipirosin

3. PACKAGE SIZE

20 ml
50 ml
100 ml
250 ml

4. TARGET SPECIES

Pigs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramuscular use.

7. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days

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 01708/5061

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

POM-V Veterinary medicinal product subject to prescription.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Pigs
Vial (100 ml, 250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZUPREVO 40 mg/ml solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

40 mg/ml of tildipirosin

3. TARGET SPECIES

Pigs

4. ROUTES OF ADMINISTRATION

Intramuscular use.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period:
Meat and offal: 9 days.

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.

POM-V Veterinary medicinal product subject to prescription.

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Pigs
Vial (20 ml, 50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZUPREVO 40 mg/ml solution for injection for pigs

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

40 mg/ml of tildipirosin

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

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

5. ROUTE(S) OF ADMINISTRATION

IM use.

6. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ZUPREVO 40 mg/ml solution for injection for pigs

2. COMPOSITION

Active substance:
One ml contains:
Tildipirosin 40 mg

Clear yellowish solution.

3. TARGET SPECIES

Pigs

4. INDICATIONS FOR USE

Treatment and metaphylaxis of swine respiratory disease (SRD) associated with *Actinobacillus pleuropneumoniae*, *Bordetella bronchiseptica, Glaesserella parasuis* 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 intravenously.
Do not administer simultaneously with other macrolides or lincosamides (see section “Special warnings”).

6. SPECIAL WARNINGS

Special warnings:
In line with responsible use principles, metaphylactic use of the veterinary medicinal product is only indicated in severe outbreaks of SRD caused by the indicated pathogens. Metaphylaxis implies that clinically healthy animals in close contact with diseased animals are administered the product at the same time as the treatment of the clinically diseased animals, to reduce the risk for development of clinical signs.

The efficacy of metaphylactic use of the veterinary medicinal product was demonstrated in a placebo controlled multi-centre field study, when outbreak of

clinical disease was confirmed (i.e. animals in at least 30% of the pens sharing the same airspace showed clinical signs of SRD, including at least 10% animals per pen within 1 day; or 20% within 2 days or 30% within 3 days). Following metaphylactic use, approximately 86% of the healthy animals remained free of clinical signs of disease (as compared to approximately 65% of animals in the untreated control group).

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.

Administer strictly intramuscularly. Special attention should be paid to using the appropriate injection site and to use the appropriate needle size and length (adjusted to the size and weight of animal) according to good veterinary practice.

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 or 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:

In piglets, intramuscular administration of tildipirosin (on three occasions in intervals of 4 days) at 8, 12 and 20 mg/kg bodyweight (2, 3 and 5 times the recommended clinical dose), resulted in transient slightly subdued behaviour in one piglet each from the 8 and 12 mg/kg bodyweight group and 2 piglets from the 20 mg/kg bodyweight group following the first or second injection. Muscle tremors to the hind legs were observed following the first treatment in one pig each from the 12 and 20 mg/kg bodyweight group.

At 20 mg/kg bodyweight one of eight animals showed transient generalised body tremors with inability to stand after the first administration and the animal showed transient unsteadiness on its feet after the third administration. Another animal developed treatment related shock after the first administration and was euthanised on welfare grounds. Mortality was observed at doses of 25 mg/kg body weight and higher.

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

Pigs

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

[1] may be present up to 6 days post treatment
[2] pathomorphological, resolved completely within 21 days
[3] may be fatal
[4] has been observed in piglets and is transient

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

Intramuscular use.

Administer 4 mg tildipirosin/kg body weight (equivalent to 1 ml/10 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 48 hours after injection. If clinical signs of respiratory disease persist or increase, or if relapse occurs, treatment should be changed using another antibiotic, and continued until clinical signs have resolved.

9. ADVICE ON CORRECT ADMINISTRATION

Administer strictly intramuscularly.

Special attention should be paid to using the appropriate injection site and to use the appropriate needle size and length (adjusted to the size and weight of animal) according to Good Veterinary Practice.

The recommended injection site is the location just behind the ear at the highest point of the base of the ear, at the transition from bald to hairy skin.
Injection should be given in a horizontal direction and a 90° angle to the body axis.

Recommended needle size and diameter per production stage

	Needle length (cm)	Needle diameter (mm)
Piglet, newborn	1.0	1.2
Piglet, 3 - 4 weeks	1.5 - 2.0	1.4
Growing	2.0 - 2.5	1.5
Growing-finishing	3.5	1.6
Finishing/sows/boars	4.0	2.0

The injection volume should not exceed 5 ml per injection 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: 9 days.

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 01708/5061

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

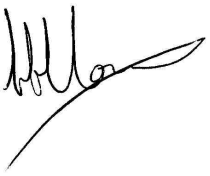
Contact details to report suspected adverse reactions:

MSD Animal Health UK Ltd
Walton Manor,Walton
Milton Keynes
Buckinghamshire
MK7 7AJ
Tel.: +44 (0)1908 685685

17. OTHER INFORMATION

For animal treatment only.

POM-V Veterinary medicinal product subject to prescription.



Approved 08 January 2024