PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ADVOCIN™ 2.5% Solution for Injection
Danofloxacin mesylate

2. STATEMENT OF ACTIVE SUBSTANCE

Each ml contains 25 mg of danofloxacin as danofloxacin mesylate and 2.5 mg phenol and 5.0 mg monothioglycerol

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, pigs (as icons)

6. INDICATION(S)

Read package leaflet for full indications.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer by intramuscular or intravenous (cattle only) injection at the dosage rate of 1.25 mg danofloxacin/kg bodyweight (1 ml/20 kg bodyweight). Three treatments should be given at 24 hour intervals.

Read package leaflet for complete information.

8. WITHDRAWAL PERIOD

Cattle: meat: 5 days. Milk: 48 hours

Pigs: meat: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Wash hands after use.

10. EXPIRY DATE

EXP:

Following withdrawal of the first dose, use the product within 28 days. Discard unused material after this time.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

For animal treatment only.

POM-V

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

Zoetis UK Limited
1st Floor Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ADVOCIN™ 2.5% Solution for Injection
Danofloxacin mesylate

2. STATEMENT OF ACTIVE SUBSTANCE

Each ml contains 25 mg of danofloxacin as danofloxacin mesylate and 2.5 mg phenol and 5.0 mg monothioglycerol

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Cattle, pigs (as icons)

6. INDICATION(S)

Read package leaflet for full indications.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Administer by intramuscular or intravenous (cattle only) injection at the dosage rate of 1.25 mg danofloxacin/kg bodyweight (1 ml/20 kg bodyweight). Three treatments should be given at 24 hour intervals.

Read package leaflet for complete information.

8. WITHDRAWAL PERIOD

Cattle: meat: 5 days. Milk: 48 hours

Pigs: meat: 3 days.

9. SPECIAL WARNING(S), IF NECESSARY

Wash hands after use.

10. EXPIRY DATE

EXP:

Following withdrawal of the first dose, use the product within 28 days. Discard unused material after this time.

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

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

For animal treatment only.

POM-V

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

MA Holder:
Zoetis UK Limited
1st Floor Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4001

17. MANUFACTURER'S BATCH NUMBER

Batch:

PACKAGE LEAFLET FOR:

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MA Holder:
Zoetis UK Limited
1st Floor Birchwood Building
Springfield Drive
Leatherhead
Surrey, KT22 7LP

Manufacturer responsible for batch release:
Fareva Amboise
Zone Industrielle
29 route des industries
37530 Poce-Sur-Cisse
France

Zoetis Manufacturing & Research Spain S.L.
Carretera Camprodón s/n "La Riba"
17813 Vall de Bianya, Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ADVOCIN™ 2.5% Solution for Injection
Danofloxacin mesylate

3. STATEMENT OF THE ACTIVE SUBSTANCE (S) AND OTHER INGREDIENTS

ADVOCIN injectable solution is a clear, sterile, aqueous injectable formulation of danofloxacin mesylate that contains 25 mg danofloxacin per ml. The product is ready for immediate administration. Each ml contains 2.5 mg phenol as preservative and 5.0 mg monothioglycerol as an antioxidant.

4. INDICATION(S)

Cattle: The treatment of bovine respiratory disease caused by *Mannheimia haemolytica* and *Pasteurella multocida* and enteric infections caused by *Escherichia coli* and *Salmonella* spp., in cattle (including dairy cows).

Pigs: The treatment of respiratory disease caused by *Pasteurella multocida* and *Actinobacillus pleuropneumoniae* in pigs, and the treatment of enteric disease caused by *Escherichia coli* in pigs.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

7. TARGET SPECIES

Cattle and pigs.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Cattle: Administer ADVOCIN injectable solution by the intramuscular or intravenous routes at a dosage rate of 1.25 mg danofloxacin/kg bodyweight (1 ml/20 kg body weight). Three treatments should be given at 24 hour intervals. Treatment may be extended up to an additional two days for animals that have not fully recovered after the initial three treatments.

Pigs: Administer ADVOCIN injectable solution by intramuscular injection at a dosage rate of 1.25 mg danofloxacin/kg bodyweight (1ml/20kg bodyweight). Three treatments should be given at 24 hour intervals.

9. ADVICE ON CORRECT ADMINISTRATION

For treatment of cattle weighing more than 400 kg, divide the intramuscular dose so that no more than 20 ml are injected per site.

For treatment of pigs weighing more than 100 kg, divide the dose so that no more than 5 ml are injected per site.

Seek veterinary advice regarding use of appropriately sized needles and syringes when dosing animals of low bodyweight e.g. piglets less than 2 kg. An appropriately graduated syringe must be used to allow accurate administration of the required dose volume. This is particularly important when injecting small volumes.

When dosing a large number of animals from a single bottle, the use of an aspirating needle is recommended to avoid excessive broaching of the stopper.

10. WITHDRAWAL PERIOD(S)

Cattle: meat: 5 days. Milk: 48 hours

Pigs: meat: 3 days.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 30°C.

Following withdrawal of the first dose, use the product within 4 weeks. Discard unused material after this time.

Avoid the introduction of contamination during use. Should any apparent growth or discolouration occur, the product should be discarded immediately.

12. SPECIAL WARNING(S)

Wash hands after use.

Keep out of the sight and reach of children. For animal treatment only.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

March 2020

15. OTHER INFORMATION

The effects of danofloxacin on reproductive performance and on pregnancy in pigs have not been assessed.

No interactions with other products have been noted.

Overdosage of cattle by up to 25 times the recommended dose produces only mild signs of intolerance, including head tremors, ataxia and mild depression. No treatment related effects have been seen on gestation, parturition or calf viability.

Overdosing of pigs by ten times the recommended dose showed only minor adverse clinical reactions including transient reduction in mobility. Three times the recommended dose given on three consecutive days to neonatal pigs produced no adverse clinical effects.

No antidote is recommended.

ADVOCIN has demonstrated in vitro and in vivo activity against *M.haemolytica* and *P.multocida*, *E.coli*, *Salmonella* spp. and *A.pleuropneumoniae*, the major pathogenic bacteria associated with bovine and porcine respiratory and enteric diseases.

The in vitro MIC_{90} *Mycoplasma hyopneumoniae* is reported to be 0.06 µg/ml, and for *M.bovis* 0.5 µg/ml.

ADVOCIN is rapidly absorbed from the site of injection and reaches a high concentration in lung and gastrointestinal tissue. Within one hour following initial

treatment, drug levels in the lung and gastrointestinal tissues of cattle are up to four-fold those found in the plasma, and in pigs, up to three-fold those in plasma in lung tissue and up to eight-fold in gastrointestinal tissue.

ADVOCIN exerts its activity by inhibiting the bacterial DNA gyrase enzyme which is involved in bacterial DNA replication. Inhibition of DNA gyrase is lethal to bacteria.

Official and local antimicrobial policies should be taken into account when the product is used.

Fluoroquinolones should be reserved for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials.

Whenever possible, fluoroquinolones should only be used based on susceptibility testing.

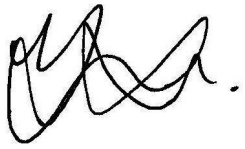
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the fluoroquinolones and may decrease the effectiveness of treatment with other quinolones due to the potential for cross resistance.

Multidose glass vials containing 50 ml, 100 ml and 250 ml. Not all pack sizes may be marketed.

Vm 42058/4001

POM-V

To be supplied only on veterinary prescription.



Approved: 01 April 2020