A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box containing one 50/100/250 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ADVOCIN 180, 180 mg/ml, Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Danofloxacin 180 mg/ml
(Equivalent to 228.4 mg/ml Danofloxacin mesylate)

Excipients:
Phenol 2.5 mg/ml
Monothioglycerol 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

50ml
100 ml
250 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For subcutaneous or intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 8 days
Milk: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use within 28 days

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.
Do not freeze.

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

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.

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(S)

Vm 42058/5107

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vial label (100/250 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ADVOCIN 180, 180 mg/ml, Solution for Injection for Cattle

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Active substance:
Danofloxacin 180 mg/ml
(Equivalent to 228.4 mg/ml Danofloxacin mesylate).

Excipients:
Phenol 2.5 mg/ml
Monothioglycerol 5 mg/ml

3. PHARMACEUTICAL FORM

Solution for Injection.

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Cattle

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

SC/IV.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Meat and offal: 8 days
Milk: 4 days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}

Once broached use by…

11. SPECIAL STORAGE CONDITIONS

Store in the original package in order to protect from light.
Do not freeze.

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

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.

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(S)

Vm 42058/5107

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

VIAL label (50 ml)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

ADVOCIN 180, 180 mg/ml, Solution for Injection for Cattle

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Danofloxacin 180 mg/ml
(Equivalent to 228.4 mg/ml Danofloxacin mesylate).

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

50 ml

4. ROUTE(S) OF ADMINISTRATION

SC/IV.

5. WITHDRAWAL PERIOD(S)

Meat and offal:	8 days
Milk:	4 days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP {month/year}
Once opened use within:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
ADVOCIN 180, 180 mg/ml, Solution for Injection for Cattle

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

Marketing authorisation holder:

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

Manufacturer responsible for batch release:

Zoetis Manufacturing & Research Spain, S.L.
Ctra. de Camprodon s/n°, Finca La Riba
Vall de Bianya
17813 Gerona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

ADVOCIN 180, 180 mg/ml, Solution for Injection for Cattle.

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

1ml contains:

Active substance:
Danofloxacin 180 mg
(Equivalent to 228.4 mg Danofloxacin mesylate)

Excipients:
Phenol 2.5 mg
Monothioglycerol 5 mg

4. INDICATION(S)

In cattle: Treatment of bovine respiratory disease caused by *Mannheimia haemolytica*, *Pasteurella multocida* and *Histophilus somni* sensitive to danofloxacin. For the treatment of acute bovine mastitis caused by *Escherichia coli* sensitive to danofloxacin. In neo-natal calves: Treatment of enteric infections caused by *Escherichia coli* sensitive to danofloxacin.

5. CONTRAINDICATIONS

Do not use in cases of hypersensitivity to the active substance, to other (fluoro)quinolones or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases in sensitive animals, immediate or delayed anaphylactic shock may occur after the injection.
Subcutaneous injection of the product induces a moderate inflammatory response in the tissue around the injection site. The resultant lesions may persist for up to 30 days.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

7. TARGET SPECIES

Cattle.

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

6 mg/kg body weight (1 ml/30 kg body weight) as a single injection by the subcutaneous or intravenous route.

If clinical signs of respiratory or enteric disease persist 48 hours after the first injection, an additional dose at 6 mg/kg body weight may be administered.

It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 48 hours.

For the treatment of acute bovine mastitis, the product should be administered at 6 mg/kg body weight (1 ml/30 kg body weight) as a single injection by the subcutaneous or intravenous route. The clinical signs should be monitored carefully and supportive therapy should be given as appropriate. If clinical signs of acute bovine mastitis persist 36-48 hours after the first injection, the antibiotic treatment strategy should be reviewed. It is recommended to treat animals in the early stages of disease and to evaluate the response to treatment within 36-48 hours.

To ensure a correct dosage body weight should be determined as accurately as possible to avoid underdosing.

9. ADVICE ON CORRECT ADMINISTRATION

For treatment of cattle weighing more than 450 kg, divide the subcutaneous dose so that no more than 15 ml are injected at one site.

When dosing a large number of animals from a single vial, the use of an automatic syringe is recommended to avoid excessive broaching of the rubber stopper.

10. WITHDRAWAL PERIOD(S)

Meat and offal: 8 days
Milk: 4 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store in the original packaging in order to protect from light.
Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

Shelf life after first opening the container: 28 days.

12. SPECIAL WARNING(S)

Special warnings for each target species:
The safety of the product has not been assessed in breeding bulls.

Special precautions for use in animals

Use of fluoroquinolones should be based on susceptibility testing and take into account official and local antimicrobial use policies. It is prudent to reserve fluoroquinolones for the treatment of clinical conditions which have responded poorly, or are expected to respond poorly, to other classes of antimicrobials. Efficacy against gram positive strains has not been established.

For fluoroquinolones as a class, over-dosage at multiples of the recommended dose has been shown to induce erosion of articular cartilage. Care should be taken to dose accurately and the product should be used with caution in animals with joint disease or cartilage growth disorders.

Use of product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to fluoroquinolones and may decrease the

effectiveness of treatment with other quinolones due to the potential for cross resistance. Do not use in cases where the pathogen involved is resistant to other fluoroquinolones (due to the potential for cross resistance).

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

Persons with known hypersensitivity to (fluoro)quinolones should avoid contact with the product.
Care should be taken to avoid accidental self-injection, it can induce a slight irritation.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.
In case of contact with skin or eyes, rinse with plenty of water.

Wash hands after use.
Do not eat, drink or smoke during application.

Pregnancy:

Studies in laboratory animals have shown adverse effects on reproduction. At high doses in rats (100 to 200 mg/kg/day), increase in foetal delayed ossification and in dilatation of the cerebral ventricles were observed. Dams given high dose produced fewer live pups per litter and pup weight and survival were adversely affected. The safety of the product has not been established during pregnancy in cows. The use of the product is not recommended during pregnancy.

Interaction with other medicinal products and other forms of interaction:

When fluoroquinolones have been combined with bacteriostatic antimicrobials, such as tetracyclines and macrolides or phenicols, an antagonism was demonstrated *in vitro*.

Overdose (symptoms, emergency procedures, antidotes):

At doses of three times the therapeutic dose (18 mg/kg bw), erythema of the nasal and ocular mucosae was induced and food intake was reduced. At even higher doses and prolonged exposure, there was damage to the cartilage in the joints and some animals displayed paresis, ataxia or nystagmus.

Incompatibilities:

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

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

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

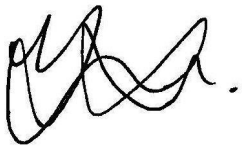
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

January 2023

15. OTHER INFORMATION

Supplied in boxes containing one vial of 50 ml, 100 ml or 250 ml. Not all pack sizes may be marketed.



Approved: 17 January 2023