PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Outer label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kloxerate Gold DC

Intramammary suspension.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

20 (100) x 5.4g syringes each containing:

Cloxacillin (as Benzathine salt) 600 mg

Ampicillin (as Trihydrate) 300 mg

In a long acting base.

Ampicillin and cloxacillin are semi-synthetic penicillins derived from 6-aminopenicillianic acid.

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

20 x 5.4 g syringes
100 x 5.4 g syringes

5. TARGET SPECIES

Cattle

6. INDICATION(S)

For use: See package leaflet.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Drying Off Therapy: After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one syringe into each quarter via the teat canal.

When infusing heifers it is important that the syringe nozzle is not introduced into the teat. The recommended procedure is as follows:

The animal(s) should be properly restrained. Each teat should be cleaned and disinfected and then the teat orifice located and the nozzle of the syringe placed against it but not inserted. When the syringe plunger is thoroughly depressed the antibiotic passes easily through the teat into the udder.

8. WITHDRAWAL PERIOD

Do not use on cows which have a short dry period.

Not intended for use within 49 days of calving. Should a cow calve earlier than 49 days after the last treatment, milk for human consumption may only be taken from 49 days plus 156 hours after the last treatment.

Cattle must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

In cows suffering from hypocalcaemia it may be necessary to withhold milk for a longer period. In such cases milk should be withheld until the levels of antibiotics are below the maximum accepted residue levels, i.e. 0.03 mcg/ml for cloxacillin and 0.004 mcg/ml for ampicillin.

9. SPECIAL WARNING(S), IF NECESSARY

Kloxerate Gold DC must not be used in the treatment of lactating cows.

When infusing heifers, protective gloves should always be worn in order to avoid skin contact with the product.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this product if you know you are sensitised or if you have been advised not to work with such presentations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

Should symptoms develop following exposure such as skin rash, medical advice should be sought. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use

10. EXPIRY DATE

Exp:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

The syringe may only be used once.

Part used syringes must be discarded.

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

Dispose of any unused product or waste containers in accordance with guidance from your local waste regulation authority.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

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 reach and sight 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 42058/4201

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kloxerate Gold DC

Intramammary suspension.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

5.4 g syringe containing, in a long acting base:

Cloxacillin (as Benzathine salt) 600mg

Ampicillin (as the Trihydrate) 300mg

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

5.4 g

4. ROUTE(S) OF ADMINISTRATION

For use: See package leaflet.

5. WITHDRAWAL PERIOD

Do not use in cows which have a short dry period.

Milk may only be taken for human consumption from 49 days plus 156 hours after treatment.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp.:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

Protective gloves should always be worn when infusing heifers. Penicillins and cephalosporins may occasionally cause allergic reactions. Read package leaflet for details.

Do not store above 25°C. The syringe may only be used once. Part used syringes must be discarded. Keep out of reach and sight of children. Keep syringe in outer carton.

POM–V To be supplied only on veterinary prescription

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

Vm 42058/4201

PACKAGE LEAFLET FOR: Kloxerate Gold DC

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Kloxerate Gold DC

Intramammary suspension.

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

Kloxerate Gold DC is an off-white stable intramammary suspension prepared under sterile conditions.

Each single 5.4g syringe contains:

Cloxacillin (as Benzathine salt) 600mg

Ampicillin (as the Trihydrate) 300mg

Ampicillin and Cloxacillin are semi-synthetic penicillins derived from 6-amino-penicillianic acid

4. INDICATION(S)

Kloxerate Gold DC is formulated for use in the dairy cow at the point of drying off, immediately after the last milking of the lactation, in order to treat existing mastitis caused by organisms sensitive to cloxacillin and ampicillin and to provide protection against further infections during the dry period.

Kloxerate Gold DC is indicated for use against both Gram-positive and Gram-negative organisms which are associated with mastitis and susceptible to cloxacillin and ampicillin therapy, including *Streptococcus agalactiae* and other *Streptococcus* species, penicillin resistant and sensitive Staphylococci, *Arcanobacterium* species, *Escherichia coli* and other susceptible Gram-negative bacteria.

Cloxacillin benzathine and ampicillin trihydrate are presented in a long-acting base which is non-irritant to udder tissues and maintains effective antibacterial levels in the dry cow udder for up to 10 weeks.

5. CONTRAINDICATIONS

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cattle

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

Drying Off Therapy: For intramammary use. After the final milking of a lactation, clean and disinfect the teats and introduce the contents of one tube into each quarter via the teat canal.

9. ADVICE ON CORRECT ADMINISTRATION

When infusing heifers it is important that the syringe nozzle is not introduced into the teat. The recommended procedure is as follows:

The animal(s) should be properly restrained. Each teat should be cleaned and disinfected and then the teat orifice located and the nozzle of the syringe placed against it but NOT inserted. When the syringe plunger is steadily depressed the antibiotic will pass easily through the teat into the udder.

10. WITHDRAWAL PERIOD(S)

Do not use in cows which have a short dry period.

Not intended for use within 49 days of calving.

Milk for human consumption may only be taken from 156 hours after calving. Should a cow calve earlier than 49 days after the last treatment, milk for human consumption may only be taken from 49 days plus 156 hours after the last treatment. Should a cow calve earlier than 49 days after treatment consult your veterinary surgeon.

In cows suffering from hypocalcaemia it may be necessary to withhold milk for a longer period than that stated above. In such cases milk should be withheld until the levels of antibiotics are below the maximum accepted residue levels, i.e. 0.03 mcg/ml for cloxacillin and 0.004 mcg/ml for ampicillin.

Animals must not be slaughtered for human consumption during treatment. Cattle may be slaughtered for human consumption only after 28 days from the last treatment.

The product must not be used in the treatment of lactating cows. Should this occur milk should be discarded for 28 days, following which time milk should be tested until antibiotic can no longer be detected.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25^{o}C. Keep out of the reach and sight of children

The syringe may only be used once.

Part-used syringes must be discarded.

12. SPECIAL WARNING(S)

When infusing heifers, protective gloves should always be worn in order to avoid skin contact with the product.

Penicillins and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious. Do not handle this product if you know you are sensitised or if you have been advised not to work with such presentations.

Handle this product with great care to avoid exposure, taking all recommended precautions.

Should symptoms develop following exposure such as skin rash, medical advice should be sought. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.

Wash hands after use

For animal treatment only

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

Dispose of any unused product or waste containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2020

15. OTHER INFORMATION

POM–V To be supplied only on veterinary prescription

Vm 42058/4201

Package quantities: Cartons of 20 or 100 syringes. Not all pack sizes may be marketed.

Approved 04 September 2020