ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavamox LC Intramammary suspension for lactating cattle
Amoxicillin, Clavulanic acid and Prednisolone

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 3 g intramammary syringe contains
Active substances:

Amoxicillin (as amoxicillin trihydrate)	200 mg
Clavulanic acid (as potassium clavulanate)	50 mg
Prednisolone	10 mg

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

3 intramammary syringes
12 intramammary syringes
24 intramammary syringes
300 intramammary syringes

5. TARGET SPECIES

Cattle (lactating cows).

6. INDICATION(S)

For use in clinical cases of mastitis including cases associated with infections with the following pathogens:
Staphylococci (including β-lactamase producing strains)
Streptococci (including *S. agalactiae, S. dysgalactiae and S. uberis*)
Escherichia coli (including β-lactamase producing strains).

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intramammary use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Meat and offal: 7 days.
Milk: 84 hours, i.e. 7 milking times with 2 times a day milking or 11 milking times with 3 times a day milking.

9. SPECIAL WARNING

The product should be used for treatment of clinical mastitis only.
The use of the product should preferably be based on susceptibility tests.
Read the package leaflet before use.
User warnings
Penicillins and cephalosporins may occasionally cause severe allergic reactions. See package leaflet for full user warnings.

10. EXPIRY DATE

EXP {month/year}>

11. SPECIAL STORAGE CONDITIONS

Store below 25 °C.
Store in a dry place.

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

Any unused veterinary medicinal products 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. 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 42058/4017

17. MANUFACTURER'S BATCH NUMBER

Batch

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Polyethylene intramammary syringe

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavamox LC Intramammary suspension for lactating cows

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each syringe contains:

Amoxicillin	200 mg
Clavulanic acid	50 mg
Prednisolone	10 mg

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

3 g.

4. ROUTE(S) OF ADMINISTRATION

Intramammary use

5. WITHDRAWAL PERIOD

Meat and offal: 7 days
Milk: 84 hours

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP {month/year}>

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

Clavamox LC, intramammary suspension for lactating 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:
Haupt Pharma Latina, s.r.l.
SS 156 km 47,600
04100 Borgo San Michele (Latina)
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clavamox LC Intramammary suspension for lactating cattle

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Active substances:
Each 3 g intramammary syringe contains::

Amoxicillin (as amoxicillin trihydrate)	200 mg
Clavulanic acid (as potassium clavulanate)	50 mg
Prednisolone	10 mg

White to off-white oily suspension

4. INDICATIONS

For use in clinical cases of mastitis including cases associated with infections with the following pathogens:
Staphylococci (including β-lactamase producing strains)
Streptococci (including *S.agalactiae, S.dysgalactiae and S.uberis*)
Escherichia coli (including β-lactamase producing strains)

5. CONTRAINDICATIONS

Do not use in animals, which are known to be hypersensitive to ß-lactam antibiotics.

6. ADVERSE REACTIONS

None known.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (lactating cows)

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

Intramammary use.
The contents of one intramammary syringe should be infused into each affected quarter via the teat canal, immediately after milking, at 12 hour intervals for three consecutive milkings.
In cases of infections caused by *Staphylococcus aureus*, a longer course of antibacterial therapy may be required. Therefore overall treatment length must be at the veterinarian's discretion but should be long enough to ensure complete resolution of intramammary infection.

9. ADVICE ON CORRECT ADMINISTRATION

Before the infusion is made, the teat end should be cleaned and disinfected.

10. WITHDRAWAL PERIOD

Meat and offal: 7 days
Milk: 84 hours, i.e. 7 milking times with 2 times a day milking or 11 milking times with 3 times a day milking.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25˚C.
Store in a dry place.

Keep out of the sight and reach of children.

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

12. SPECIAL WARNINGS

Do not use in cases associated with *Pseudomonas.*

Special precautions for use in animals
Swab teat end with appropriate disinfectant before treatment.

Recommendations for prudent use
The product should be used for treatment of clinical mastitis only.
Use of the product should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria and take into account official and local antimicrobial policies.
The use of the product should preferably be based on susceptibility tests.

Avoid use of the product in herds where no β-lactamase producing *Staphylococci* strains have been isolated. *Veterinarians should strive to use narrow spectrum antibiotics if possible.*
Inappropriate use of the product may increase the prevalence of bacteria resistant to ß-lactam antibiotics and may decrease the effectiveness of treatment with ß-lactam antibiotics, due to the potential for cross-resistance.

User warnings
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 preparations.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure such as a skin rash, you should seek medical advice and show the doctor this warning. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention.
Wash hands after use.

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

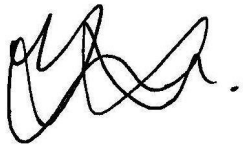
Any unused veterinary medicinal products or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2019

15. OTHER INFORMATION

Pack size: 3, 12, 24 and 300 intramammary syringes. Not all pack sizes may be marketed.
To be supplied by a surgeon or under their direct responsibility



Approved: 13 November 2019