PARTICULARS TO APPEAR ON THE ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbolan Lactating 200 mg intramammary suspension for cattle and sheep [UK]
Orbenin Lactation 200 mg intramammary suspension for cattle and sheep [NL]
Orbenin LA 200 mg intramammary suspension for lactating cattle and sheep [DE, ES, PT]
Orbelux LA 200mg intramammary suspension for cattle and sheep [PL]
Orbenin Lattazione 200 mg intramammary suspension for cattle and sheep [IT]

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

200mg cloxacillin (as cloxacillin sodium) per 3 g syringe

3. PHARMACEUTICAL FORM

Intramammary suspension.

4. PACKAGE SIZE

12 syringes

5. TARGET SPECIES

Cattle (lactating cows) and sheep (sheep for meat production).

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramammary use.
Read the package leaflet before use.
Individual syringes must only be used once.

8. WITHDRAWAL PERIOD

Cattle - milk: 96 hours
Not authorised for use in sheep producing milk for human consumption

Cattle and sheep - meat and offal: 7 days

9. SPECIAL WARNING(S), IF NECESSARY

Penicillins and cephalosporins may occasionally cause severe allergic reactions.
See package leaflet for full user warnings.
Read the package leaflet before use.

10. EXPIRY DATE

EXP

11. SPECIAL STORAGE CONDITIONS

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

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

Dispose of waste material 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(S)

Vm 42058/4188

17. MANUFACTURER'S BATCH NUMBER*]*

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

3g syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbolan Lactating 200 mg intramammary suspension for cattle and sheep [UK]
Orbenin Lactation 200 mg intramammary suspension for cattle and sheep [NL]
Orbenin LA 200 mg intramammary suspension for lactating cattle and sheep [DE, ES, PT]
Orbelux LA 200mg intramammary suspension for cattle and sheep [PL]
Orbenin Lattazione 200 mg intramammary suspension for cattle and sheep [IT]

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

200mg cloxacillin

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

3 g

4. ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

5. WITHDRAWAL PERIOD

Cattle - milk: 96 hours
Not authorised for use in sheep producing milk for human consumption
Cattle and sheep - meat and offal: 7 days

6. BATCH NUMBER

Lot

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET FOR:

Orbolan Lactating 200 mg intramammary suspension for cattle and sheep [UK]
Orbenin Lactation 200 mg intramammary suspension for cattle and sheep [NL]
Orbenin LA 200 mg intramammary suspension for lactating cattle and sheep [DE, ES, PT]
Orbelux LA 200mg intramammary suspension for cattle and sheep [PL]
Orbenin Lattazione 200 mg intramammary suspension for cattle and sheep [IT]

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.,
S.S.n. 156 dei Monti Lepini Km 47,600,
04100 Borgo San Michele - Latina
Italy

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Orbolan Lactating 200 mg intramammary suspension for cattle and sheep [UK]
Orbenin Lactation 200 mg intramammary suspension for cattle and sheep [NL]
Orbenin LA 200 mg intramammary suspension for lactating cattle and sheep [DE]
Orbenin Lattazione 200 mg intramammary suspension for cattle and sheep [IT]
Cloxacillin

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

Each 3 g intramammary syringe contains:

Active substance:	
Cloxacillin as cloxacillin sodium	200 mg
Excipient:	
Butylhydroxyanisole (E 320)	0.558 mg

An off-white viscous suspension.

4. INDICATION(S)

Lactating cows
For the treatment of mastitis associated with staphylococcal and streptococcal species sensitive to cloxacillin.

Ewes
For the treatment of subclinical infections of the udder during the dry period, associated with staphylococcal species and *Trueperella pyogenes* sensitive to cloxacillin.

5. CONTRAINDICATIONS

Do not use in animals with known hypersensitivity to cloxacillin, other β-lactam antibiotics or to any of the excipients.

6. ADVERSE REACTIONS

In very rare cases ß-lactam antibiotics may cause hypersensitivity reactions (allergic skin reactions, anaphylaxis). If such a reaction occurs, the current treatment should be stopped immediately and an appropriate symptomatic treatment be initiated.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Cattle (lactating cows) and sheep (sheep for meat production).

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

Cows
Dosage: A course of three infusions per infected quarter - one syringe given every 48 hours.
Ewes
Dosage: A single infusion should be made into each udder half at weaning.

9. ADVICE ON CORRECT ADMINISTRATION

For intramammary use

Cows
Administration: Clean and disinfect the teat with the cleaning towel provided or surgical spirit after milking. Insert nozzle into the teat and apply gentle and continuous pressure until the suspension is expressed. The treated quarter(s) may be milked out at the next normal milking time.
Ewes

Administration: It is important that a simple hygienic procedure is followed. One operator should turn up and hold each ewe whilst a second person carries out the infusion technique. Clean and disinfect each teat end thoroughly with the cleaning towel provided or surgical spirit. Appose the syringe nozzle to the teat orifice and apply gentle, continuous pressure to express the suspension in the udder. Actual cannulation of the teat orifice is neither necessary nor desirable. Use a fresh syringe for each udder half to avoid the possibility of cross contamination during infusion.

10. WITHDRAWAL PERIOD

Cattle - milk: 96 hours
Not authorised for use in sheep producing milk for human consumption
Cattle and sheep - meat and offal: 7 days

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25 °C
Store in a dry place.
Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton. The expiry date refers to the last day of that month.

12. SPECIAL WARNING(S)

Special warnings for each target species
For the best results in cattle, the product should be used at the earliest signs of infection.
In staphylococcal and certain forms of streptococcal mastitis, an adequate duration of treatment is important in achieving both clinical and bacteriological cures.

Special precautions for use in animals:
Individual syringes must only be used once.
Official, national and regional antimicrobial policies should be taken into account when the
product is used.
Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Use of the product deviating from the instructions given may increase the prevalence of bacteria resistant to the cloxacillin and may decrease the effectiveness of the treatment.

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

Overdose:
None known.

Use during pregnancy, lactation or lay:
The product is indicated for use in the lactating cow and for use in ewes at weaning.

Interaction with other medicinal products and other forms of interaction:
None known.

Incompatibilities:
Not applicable.

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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

The product is not destroyed by staphylococcal penicillinase. It is therefore active against penicillin resistant staphylococci which are an important cause of mastitis. The antibiotic is bactericidal at the concentrations produced in the udder.

To be supplied only on veterinary prescription.
Supplied in cartons of 12 syringes and cleaning towels.

Approved: