ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g dose unit contains the following:

Active substance:
Cloxacillin as cloxacillin sodium 200 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E 320)	0.558 mg
Castor Oil, Hydrogenated	
Silica, Hydrophobic Colloidal	
Arachis Oil, Refined	

An off-white viscous intramammary suspension

3. CLINICAL INFORMATION

3.1 Target species

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

3.2 Indications for use for each target species

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

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

3.3 Contraindications

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

3.4 Special warnings

For the best results in cattle, the product should be used as early as possible after detection of infection.

In staphylococcal and certain forms of streptococcal mastitis, an adequate duration of treatment is important in achieving both clinical and bacteriological cures.

3.5 Special precautions for use

Special precautions for safe use in the target species:
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 identification and susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) acquired epidemiological information about susceptibility of the target bacteria.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to the cloxacillin and may decrease the effectiveness of the treatment.
The cleaning towel should not be used in presence of teat injuries.
The feeding of waste milk containing residues of antimicrobials to calves should be avoided up to the end of the milk withdrawal period because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria.

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 reaction to these substances may occasionally be serious.

1- People with known hypersensitivity to penicillins or cephalosporins and people who have been advised not to work with such preparations should avoid contact with the veterinary medicinal product.
2- Handle this product with great care to avoid exposure, taking all recommended precautions.
3- If you develop symptoms following exposure, such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
Wash hands after use.

Special precautions for the protection of the environment:
Not applicable.

3.6 Adverse events

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

Very rare (<1 animal /10,000 animals treated, including isolated reports):	Hypersensitivity reaction* (allergic skin reaction*, anaphylaxis*)

*If such a reaction occurs, the current treatment should be stopped immediately and an appropriate symptomatic treatment be initiated.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder <or its local representative> or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Lactation:
The product is indicated for use in the lactating cow and for use in ewes at weaning.

3.8 Interaction with other medicinal products and other forms of interaction

None known.

3.9 Administration routes and dosage

Intramammary use.
Persons administering the veterinary medicinal product should wear appropriate disposable gloves.
The syringe must only be used once. Partly used syringes should be discarded.
Care should be taken to avoid contamination of injector nozzle.

Cows
Dosage
The recommended dose is three infusions per infected quarter - one syringe administered every 48 hours.
Dosing guide
Milk out the affected quarter(s).
Clean and disinfect the teat and teat orifice thoroughly with the cleaning towel provided or surgical spirit after milking; insert the syringe nozzle only the first ~~2~~ 3-4 mm into the teat channel and gently infuse the content of one syringe into each affected quarter applying continuous pressure until the suspension is expressed.
Teats should be dipped with an appropriate teat dip solution after treatment.
The treated quarter(s) may be milked out at the next normal milking time.

Ewes
Dosage
A single infusion should be made into each udder half at weaning.
Administration
It is important that an accurate 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 and teat orifices thoroughly with the cleaning towel provided or surgical spirit. Appose the syringe nozzle to the teat orifice precisely. Gently infuse the content of one syringe into each udder half applying 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.
Teats should be dipped with an appropriate teat dip solution after treatment.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

None known.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Cattle and sheep - meat and offal: 7 days
Cattle - milk: 4 days

Not authorised for use in sheep producing milk for human consumption.

4. PHARMACOLOGICAL INFORMATION

4.1 ATCvet code: QJ51CF02

4.2 Pharmacodynamics

Cloxacillin, a semi-synthetic β-lactam antibiotic, is active against Gram-positive organisms, but 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. It acts through the inhibition of biosynthesis of cell wall.

The resistance situation especially for staphylococci may differ geographically.

4.3 Pharmacokinetics

No data available.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Not applicable.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Low density polyethylene (LDPE) intramammary syringe comprising dual nozzle, barrel and cap.

Pack size:
12 intramammary syringes and cleaning towels per carton.

5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

7. MARKETING AUTHORISATION NUMBER(S)

To be completed nationally

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: {DD/MM/YYYY}
To be completed nationally

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

MM/YYYY

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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 200 mg intramammary suspension for cattle and sheep [PL]
Orbenin Lattazione 200 mg intramammary suspension for cattle and sheep [IT]
Cloxacillin

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

12 syringes

4. TARGET SPECIES

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

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Intramammary use.

7. WITHDRAWAL PERIODS

Cattle and sheep – meat and offal: 7 days
Cattle - milk: 4 days
Not authorised for use in sheep producing milk for human consumption

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

To be completed nationally

14. MARKETING AUTHORISATION NUMBERS

To be completed nationally

15. BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

3g syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

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Orbelux LA 200 mg intramammary suspension for cattle and sheep [PL]
Orbenin Lattazione 200 mg intramammary suspension for cattle and sheep [IT]
Cloxacillin

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

200 mg cloxacillin

3. BATCH NUMBER

Lot

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

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. Composition

Each 3 g intramammary syringe contains:

Active substance:
Cloxacillin as cloxacillin sodium 200 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Butylhydroxyanisole (E 320)	0.558 mg
Castor Oil, Hydrogenated	
Silica, Hydrophobic Colloidal	
Arachis Oil, Refined	

An off-white viscous intramammary suspension.

3. Target species

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

4. Indications for use

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

Sheep (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.
Do not use in ewes with clinical mastitis.

6. Special warnings

Special warnings:
For the best results in cattle, the product should be used as early as possible after detection 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 safe use in the target species:
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 identification and susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) acquired 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.
The cleaning towel should not be used in presence of teat injuries.
The feeding of waste milk containing residues of antimicrobials to calves should be avoided up to the end of the milk withdrawal period because it could select antimicrobial-resistant bacteria within the intestinal microbiota of the calf and increase the faecal shedding of these bacteria

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.
People with known hypersensitivity to penicillins or cephalosporins and people who have been advised not to work with such preparations should avoid contact with the veterinary medicinal product.
Handle this product with great care to avoid exposure, taking all recommended precautions.
If you develop symptoms following exposure such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing, are more serious symptoms and require urgent medical attention. Wash hands after use.

Lactation:
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.

Overdose:
None known.

Major incompatibilities:
Not applicable.

7. Adverse events

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

Very rare (<1 animal /10,000 animals treated, including	Hypersensitivity reaction* (allergic skin reaction*, anaphylaxis*)

isolated reports):	

* If such a reaction occurs, the current treatment should be stopped immediately and an appropriate symptomatic treatment be initiated.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder <or the local representative of the marketing authorisation holder> using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes and method of administration

Intramammary use.

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

Persons administering the veterinary medicinal product should wear appropriate disposable gloves.
The syringe must only be used once. Partly used syringes should be discarded.
Care should be taken to avoid contamination of injector nozzle.

Cows
Milk out the affected quarter(s).
Clean and disinfect the teat and teat orifice thoroughly with the cleaning towel provided or surgical spirit after milking. Insert the syringe nozzle only the first 3-4mm into the teat channel and gently infuse the content of one syringe into each affected quarter applying continuous pressure until the suspension is expressed.
Teats should be dipped with an appropriate teat dip solution after treatment.

The treated quarter(s) may be milked out at the next normal milking time.

Ewes
It is important that an accurate 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 and teat orifices thoroughly with the cleaning towel provided or surgical spirit. Appose the syringe nozzle to the teat orifice precisely. Gently infuse the contents of one syringe into each udder half applying 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.
Teats should be dipped with an appropriate teat dip solution after treatment.

10. Withdrawal periods

Cattle and sheep - meat and offal: 7 days
Cattle - milk: 4 days
Not authorised for use in sheep producing milk for human consumption.

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 precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

To be completed nationally

Pack size:
12 intramammary syringes and cleaning towels per carton.

15. Date on which the package leaflet was last revised

MM/YYYY
Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. Contact details

Marketing authorisation holder< and contact details to report suspected adverse reactions>:
To be completed nationally

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

<Local representative <and contact details to report suspected adverse reactions>:*
To be completed nationally (if needed)*

17. 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 completed nationally