Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Albiotic 330 mg/100 mg Intramammary Solution

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 10 ml syringe contains:

Active substances

Lincomycin		
(as Lincomycin Hydrochloride)	330	mg
Neomycin		
(as Neomycin Sulphate)	100	mg

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Intramammary solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Lactating cow.

4.2 Indications for use, specifying the target species

For the treatment of mastitis in lactating cattle. The product is effective against Staphylococcus species (both penicillinase and non-penicillinase producers) including *Staphylococcus aureus,* Streptococcus species including *Streptococcus agalactiae, Streptococcus dysgalactiae* and *Streptococcus uberis,* and coliform bacteria including *Escherichia coli*.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals

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.

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

Avoid contact with the solution. Wash hands and any exposed skin immediately.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

No restrictions.

4.8 Interaction with other medicinal products and other forms of interactions

This product should not be used concomitantly with macrolides e.g. erythromycins, because lincomycin and the macrolides antagonise each other at the site of action, the 50S ribosomal sub-unit.

4.9 Amounts to be administered and administration route

Dosage

Infuse one syringe (10 ml product) into each affected quarter. Repeat this treatment immediately after each of the next two 12 hourly milkings, to give a total of three infusions per infected quarter. The syringe should only be used once.

Administration

By intramammary infusion only, taking aseptic precautions.

Where necessary, wash teats or whole udder thoroughly with warm water containing a suitable dairy disinfectant and dry them thoroughly. Milk out the udder completely. Disinfect teat end with a pad of alcohol or other suitable disinfectant.Use a separate pad for each teat. Remove cap from plastic tip. Choose the desired insertion length (full or partial) and insert the tip into the teat canal. Push plunger to dispense entire contents and massage the quarter to distribute the product into the milk cistern. Following infusion, it is advisable to dip all teats in an approved teat dip.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

The product is well tolerated. In the event of accidental overdose, it is unlikely that any local or systemic adverse effects will occur in the animal, however, any signs of adverse effect should be immediately reported to the veterinarian concerned.

4.11 Withdrawal period(s)

Milk
Milk should not be taken for human consumption during treatment.
The milk discard time should be 60 hours after last treatment i.e. milk can be taken for human consumption at the 6th milking (72 hours after last treatment).

Meat
Animals must not be slaughtered for human consumption during treatment.Treated animals must not be slaughtered for human consumption within 48 hours following last treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Phamacotherapeutic group: Antibacterial for intramammary use, lincomycin, with other antibacterials.
ATCvet code: QJ51RF03

5.1 Pharmacodynamic properties

Lincomycin is a lincosaminide antibiotic derived from *Streptomyces lincolnensis*. It possesses specific activity against gram-positive bacteria, particularly Staphylococcus species and Streptococcus species and has little or no activity against gram-negative bacteria such as *E.coli* (except anaerobes). Lincomycin has good activity against mycoplasma.Lincomycin binds to the 50S sub-unit of the bacterial ribosome, thereby inhibiting protein synthesis of the cell.It is generally regarded as a bacteriostatic compound.

Neomycin is an aminoglycoside antibiotic derived from *Streptomyces fradiae*. It has a broad spectrum of activity against both gram-positive bacteria, including Staphylococcus species and Streptococcus species, and gram-negative bacteria, including *Escherichia coli*. It is more active against Staphylococcus species than against Streptococcus species.
Neomycin binds to the 30S sub-unit of the bacterial ribosome resulting in a malconformation of binding ribosomal protein due to errors in reading the amino acid coding of the mRNA.Neomycin thus compromises translation and hence bacterial protein synthesis. At high concentrations, the aminoglycosides have also been shown to damage the cellular membrane of bacteria and hence are generally regarded as possessing both bacteriostatic and bactericidal properties.
In vitro studies have demonstrated that lincomycin and neomycin in combination have bactericidal activity against *Staphylococcus aureus* and *Escherichia coli* and bacteriostatic activity against streptococci. The combination has also demonstrated synergy against *Staphylococcus aureus*.
Lincomycin, neomycin and the combination have been shown to be active against both penicillinase and non-penicillinase producing staphylococci.

5.2 Pharmacokinetic particulars

After recommending infusion of the product, the following mean concentrations of lincomycin and neomycin were measured in individual treated quarters:

Antibiotic	Concentrations (microgram/ml) / Time after first infusion			
	12 hours[1]	24 hours[2]	36 hours	48 hours
Lincomycin	52.7	53.5	56.9	4.6
Neomycin	22.2	29.7	28.0	4.9

[1]immediately before second infusion.
[2]immediately before third (last) infusion.
Antibiotic levels in milk above the MIC-values for target pathogens are sustained for the full dosage period and for at least 12 hours thereafter.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium Edetate
Sodium Hydroxide
Hydrochloric Acid
Water for injection

6.2 Major incompatibilities

None known.

6.3 Shelf-life

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

6.4 Special precautions for storage

Do not store above 30°C.
Protect from freezing.
Protect from light.

6.5 Nature and composition of immediate packaging

Sterile aqueous solution in 10 ml high density polyethylene syringes with a fixed cannula (plastets), packaged as 1 to 100 plastets in an outer cardboard box also containing alcohol pads for teat disinfection. Cap LDPE, brombutyl rubber stopper.

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

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Huvepharma NV
Uitbreidingstraat 80
2600 Antwerpen
Belgium

8 MARKETING AUTHORISATION NUMBER(S)

VPA10782/028/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 26 July 1999
Date of last renewal: 25 July 2009

10 DATE OF REVISION OF THE TEXT

May 2019