This leaflet format was determined by the Ministry of Health and the content thereof was checked and approved in June 2019

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

SYNULOX LACTATING COW (LC) VETERINARY

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients:

One syringe (3 g) contains:

Amoxicillin trihydrate equivalent to amoxicillin	200 mg
Potassium clavulanate equivalent to clavulanic acid	50 mg
Prednisolone	10 mg

For a full list of excipients see section 6.1.

3. PHARMACEUTICAL FORM

Intramammary suspension for infusion.
White to off-white oily suspension.

4. CLINICAL PARTICULARS

4.1. Target species

Cattle (lactating cows).

4.2. Indications for use, specifying the target species

For the treatment of bovine mastitis in lactating cows. It has a broad spectrum of bactericidal activity against bacteria isolated from the bovine udder which are sensitive to SYNULOX.

4.3. Contraindications

Do not use in animals which are known to be hypersensitive to β-lactamase antibiotics.

4.4. Special warnings for each target species

Do not use in cases associated with *Pseudomonas*.

4.5. Special precautions for use

i) 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.

ii) 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.

4.6. Adverse reactions (frequency and seriousness)

None known.

Reporting suspected adverse reactions after authorization of the medicinal product is important. It allows continued monitoring of the benefit/risk balance of the medicinal product. Any suspected adverse events should be reported to the Ministry of Health according to the National Regulation by using an online form (http://forms.gov.il/globaldata/getsequence/getsequence.aspx?formType=AdversEffectMedic@moh.health.gov.il).

4.7. Use during pregnancy, lactation or lay

No special precautions.

4.8. Interaction with other medicinal products and other forms of interaction

None known.

4.9. Amounts to be administered and administration route

Before the infusion is made, the teat end should be cleaned and disinfected. The contents of one 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.

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

No adverse reactions are to be expected from an accidental overdose.

4.11. Withdrawal periods

Meat and offal: 7 days.
Milk: 84 hours. With cows milked twice daily, milk for human consumption may only be taken from the 7th milking after the last treatment. Where any other milking routine is followed, milk may be taken for human consumption only after the same period from the last treatment (e.g. with 3 times a day milking, milk may be taken for human consumption at the 11th milking).

5. PHARMACOLOGICAL PROPERTIES

Amoxicillin is a broad spectrum bactericidal β-lactam antibiotic. Clavulanic acid inactivates β-lactamases. This combination is effective against β-lactamase producing organisms.

Prednisolone is an anti-inflammatory corticosteroid.

In vitro, clavulanic acid and amoxicillin in combination are active against a wide range of clinically important bacteria including the following organisms which are commonly associated with bovine mastitis:
Staphylococci (including β-lactamase producing strains)
Streptococci (including *S. agalactiae*, *S. dysgalactiae* and *S. uberis*)
Arcanobacteria (including *A. pyogenes*)
Escherichia coli (including β-lactamase producing strains)

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

Liquid Paraffin Light
White Soft Paraffin
Calcium Sodium Aluminosilicate
Emulsifying Wax

6.2. Incompatibilities

None known.

6.3. Shelf life

Do not use the veterinary medicinal product after the expiry date (exp. Date) mentioned on the package. The expiry date refers to the last day of that month.

6.4. Special precautions for storage

Keep out of the reach of children.
Store below 25°C.

6.5. Nature and composition of immediate packaging

Low density polyethylene syringes packed in cartons containing 24 or 12 (4.5 ml) syringes. Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products, if appropriate

This product is for single use only.

Any unused veterinary medicinal product or waste materials from such veterinary medicinal products should be disposed of as a toxic waste. Do not dispose of in the sewage system.

7. MARKETING AUTHORISATION HOLDER

Zoetis Israel Holding B.V. 5 Atir Yeda Street, Kfar Saba, Israel

8. MARKETING AUTHORISATION NUMBER(S)

084-06-92252-00

9. MANUFACTURER

Haupt Pharma Latina S.R.L, Italy, S.S. 156 KM, 04010 BORGO SAN MICHELE, LATINA, ITALY

10. VETERINARY USE

The veterinary medicine is dispensed with a veterinarian’s prescription only