Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nafpenzal DC Veterinary

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 3 g syringe contains:

Active substances:

Procaine benzylpenicillin	300 mg
Dihydrostreptomycin (as the sulfate)	100 mg
Nafcillin (as the sodium salt)	100 mg

For the full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Intramammary ointment.
White, to off-white ointment.

4 CLINICAL PARTICULARS

4.1 Target Species

Dry cows

4.2 Indications for use, specifying the target species

Treatment of mastitis in cows during the dry period caused by penicillin, nafcillin and streptomycin sensitive microorganisms.

4.3 Contraindications

Do not use in cases of hypersensitivity to penicillin, nafcillin or dihydro-streptomycin, or to any of the excipients listed in section 6.1.
Do not use in lactating animals.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

Special precautions for use in animals
Do not transfer the syringe from one teat to another.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillin and cephalosporins may cause hypersensitivity (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillin may lead to cross reactions to cephalosporins and *vice versa*. Allergic reactions to these substances are occasionally serious.

1. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
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, 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.
4. It is recommended to avoid contact with the active ingredient and to use gloves.

4.6 Adverse reactions (frequency and seriousness)

Allergic reactions have been observed in very rare cases.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

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

https://sideeffects.health.gov.il

4.7 Use during pregnancy, lactation or lay

Pregnancy: The product is used during pregnancy. There are no known foetotoxic effects.

Lactation: Do not use in lactating animals.

4.8 Interaction with other medicinal products and other forms of interaction

Antagonism between Nafpenzal DC Veterinary and preparations containing bacteriostatic compounds may occur. Resistant bacteria might emerge that show a cross resistance to other beta-lactam antibiotics or aminoglycosides.

4.9 Amounts to be administered and administration route

Intramammary use.

Infuse the contents of one syringe into each quarter via the teat canal when the cow is dried off at the end of each lactation.

Before use, milk the udder completely dry and clean the end of the teat thoroughly.
Break off the tip of the cap (for partial insertion) or remove the cap from the end of the syringe (for full insertion).
Insert the nozzle carefully into the teat opening.

Squeeze the complete contents of the syringe slowly into the teat and massage gently to disperse the suspension upwards into the quarter. Massage the quarter with care.
The syringe may be used only once. Part used syringes must be discarded safely.
Following infusion it is advisable to use a teat dip or spray.

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

Not applicable.

4.11 Withdrawal Period(s)

Meat and offal: 28 days.
Milk: Treatment to calving interval ≥ 46 days: 48 hours.
Treatment to calving interval < 46 days: 48 days after treatment.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Combination of antibacterials for intramammary use; procaine benzylpenicillin combinations with other antibacterials.
ATCvet code: QJ51RC23.

5.1 Pharmacodynamic properties

Penicillin is a beta-lactam antibiotic which has bactericidal activity against mainly Gram-positive bacteria and some Gram-negative aerobes. It is sensitive to beta-lactamase (penicillinase) inactivation.
Nafcillin is a penicillinase resistant, semisynthetic penicillin.
Dihydrostreptomycin is an aminoglycoside antibiotic which has bactericidal activity against primarily aerobic, Gram-negative bacteria.
Synergism between penicillin and dihydrostreptomycin combined produces a greater activity than the use of either drug by itself, and these in further combination with nafcillin ensure a spectrum of activity against a wide range of bacteria including penicillin-resistant staphylococci.

5.2 Pharmacokinetic properties

After intramammary administration of Nafpenzal DC Veterinary, systemic absorption is limited in cattle. Efficient levels of antibiotics remained in udder secreta up to 4 weeks for nafcillin, up to 8 weeks for benzylpenicillin and up to 13 weeks for dihydrostreptomycin.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Aluminium stearate
Liquid paraffin
Sodium citrate

6.2 Incompatibilities

None known.

6.3 Shelf-life

The expiry date of the product is indicated on the packaging materials.

Shelf life after opening: The syringes are intended for immediate use after opening and may be used only once.

6.4 Special precautions for storage

Store below 25 ^{o}C.
Do not freeze.

6.5 Nature and composition of immediate packaging

Each 3 g syringe is made of low density polyethylene. The syringes are packed in a sachet.
The sachet is packed in a carton. Cleaning towels packed in a sachet are also included in the carton.
Packs of 1 syringe or 20 syringes and 20 cleaning towels.
Not all pack sizes may be marketed.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of as toxic waste, do not throw to sewer.

7. MANUFACTURER
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