Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Nafpenzal DC Intramammary Suspension

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 suspension.
White, to off-white suspension.

4 CLINICAL PARTICULARS

4.1 Target Species

Dry cows

4.2 Indications for use, specifying the target species

To treat existing mastitis at drying off and to provide protection against further infections during the dry period.

Susceptible organisms include: *Staphylococcus aureus, Streptococcus agalactiae, Streptococcus dysgalactiae, Streptococcus uberis* and *Escherichia coli*

4.3 Contraindications

Do not use in cases of hypersensitivity to penicillin, nafcillin or dihydro-streptomycin, or to any of the excipients.
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
Not applicable.

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.

4.6 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).

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 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: 14 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, 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

6.2 Incompatibilities

None known.

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

Do not store above 25 ^{o}C.

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 20 syringes and 20 cleaning towels.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

7 MARKETING AUTHORISATION HOLDER

INTERVET IRELAND Ltd.
Magna Drive
Magna Business Park
Citywest Road
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8 MARKETING AUTHORISATION NUMBER(S)

VPA 10996/074/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 1st October 1987
Date of last renewal: 30th September 2007

10 DATE OF REVISION OF THE TEXT

October 2016