CONSUMER PACKAGE INSERT FOR VETERINARY MEDICINAL PRODUCT
The medicine is dispensed with a veterinarian's prescription only
For use in animals only

1. Name of the medicine:
Nafpenzal DC Veterinary
Intramammary Ointment

2. Composition:
Each 3 g syringe contains the following active ingredients:
Procaine benzylpenicillin 300 mg (300,000 I.U.)
Dihydrostreptomycin (as sulphate) 100 mg
Nafcillin (as sodium) 100 mg

A list of the inactive ingredients is detailed in section 13 – "Further information".

3. What the medicine is intended for:
For treatment of cows during the dry period, for mastitis caused by bacteria susceptible to penicillin, streptomycin or nafcillin.

Therapeutic group: A combination of antibacterial agents for intramammary use; combinations of procaine benzylpenicillin with other antibacterial agents.

4. Contraindications:
Do not use in cases of hypersensitivity to penicillin, nafcillin or dihydrostreptomycin, or to the inactive ingredients.
Do not use in lactating cows.

5. Side effects:
In very rare cases (less than one animal in 10,000 animals, including isolated reports), hypersensitivity (allergic) reactions have been observed.

If you have noticed any serious effects or other effects not mentioned in this consumer leaflet, please inform your veterinarian.

Side effects can be reported to the Ministry of Health by clicking on the link "Reporting Side Effects due to Drug Treatment" found on the Ministry of Health homepage (www.health.gov.il), that directs you to the online form for reporting side effects, or by entering the link: **http://sideeffects.health.gov.il**

6. Target animals:

Cows during the dry period

7. Method of administration and dosage:

An ointment for intramammary administration.

The content of one syringe is infused into each quarter of an udder via the teat canal when the cow is dried off at the end of the lactation period.

8. How to use the medicinal product:

Before administration, milk the udder completely dry and thoroughly clean the end of the teat. 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 gently massage the teat to disperse the suspension upwards from the teat into the area of the quarter. Massage each quarter with care.
The syringe may be used only once. Safely dispose of remnants from a used product.
Following treatment, it is advisable to use a teat dip or spray.

9. Withdrawal period:

Meat and offal: Slaughter for food consumption is permitted after a withdrawal period of at least 28 days after the last treatment.
Milk: When treatment to calving interval ≥ 46 days: 48 hours.
When treatment to calving interval < 46 days: 48 days after treatment.

10. Warnings:

- <u>Special warnings relating to the use of the medicine in animals</u>:
  Do not transfer the syringe from one teat to another.

- <u>Special warnings relating to the safety of the person handling the medicinal product</u>:

Penicillin and cephalosporins may cause hypersensitivity reactions (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 sometimes serious.

1. Do not touch the product if you are sensitive to it or if you have been advised not to work with such preparations.
2. Handle this product with great care to avoid exposure, by taking all recommended precautions.
3. If you develop symptoms following exposure, such as a rash, you should seek medical advice and show this warning. Swelling of the face, lips, eyes or breathing difficulties are more serious effects that require urgent medical attention.

4. It is advisable not to touch the active ingredient, and to wear gloves.

- Use during pregnancy or lactation:

May be used during pregnancy. There are no known foetotoxic effects. Do not use in lactating cows.

- Interaction with other medicinal products and other forms of interaction:

Antagonism between Nafpenzal DC Veterinary and another preparation containing bacteriostatic compounds may occur. Resistant bacteria might emerge that shows cross resistance to beta-lactam antibiotics or aminoglycosides.

- Overdose:

Not applicable.

- Incompatibilities:

Unknown.

11. Storage instructions:

- Avoid poisoning! This medicine, and any other medicine, should be kept in a closed place out of the reach and sight of children and/or infants in order to avoid poisoning.
- Do not use the medicine after the expiry date (exp. date) that appears on the package. The expiry date refers to the last day of that month.
- Shelf life after opening: The syringe is intended for immediate single use.
- Storage conditions: Store at a temperature below 25ºC. Do not freeze.

12. Instructions regarding disposal of the medicinal product /remnants of the medicinal product after use:

All remnants of a veterinary medicinal product or waste materials obtained upon use of a veterinary medicinal product should be disposed of as toxic waste, do not throw to sewer.

13. Further information:

- In addition to the active ingredient(s), the medicine also contains: Aluminium Distearate, Liquid Paraffin, Sodium Citrate.

- What the medicine looks like and the package contents:
  A syringe containing a white to off-white ointment.
  A carton box containing a 3 g polyethylene syringe packed in a sachet.
  Cleaning towels are also included in the carton.

- Pack size:

A carton box containing either one or 20 syringes. It is possible that not all pack sizes are marketed.

- Registration holder and its address:
  Intervet Israel Ltd., Neve Ne'eman Industrial Zone, Hod Hasharon 45240.

- Manufacturer and address:
  Intervet International B.V., Wim De Korverstraat 35, Boxmeer, The Netherlands.

- Revised in February 2021 according to MOHs guidelines.

- **Registration number of the medicinal product in the National Drug Registry of the Ministry of Health:** 077-64-91961