PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nafpenzal Dry Cow

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each 3 g syringe contains:

Active substances:

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

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

3 g syringe.

Packs of 20 and 120 syringes.

5. TARGET SPECIES

Cattle (dry cows)

6. INDICATION(S)

For dry cow therapy (treatment of existing subclinical infections and the prevention of new infections which might occur during the dry period, caused by bacteria sensitive to penicillin, streptomycin or nafcillin

7. METHOD AND ROUTE(S) OF ADMINISTRATION

The contents of one syringe are infused 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.

After breaking off the tip of the cap (for partial insertion) or removing 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.

8. WITHDRAWAL PERIOD

Meat and offal: 28 days.

Milk: Treatment to calving interval ≥ 46 days: 36 hours.

Treatment to calving interval < 46 days: 46 days plus 36 hours after last treatment.

9. SPECIAL WARNING(S), IF NECESSARY

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

To the user:

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. Wash hands after use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Keep the container in the outer carton.

Do not store above 25 °C.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4624

17. MANUFACTURER'S BATCH NUMBER

BN:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nafpenzal Dry Cow

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 3 g syringe contains:

Active substances:

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

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

3g

4. ROUTE(S) OF ADMINISTRATION

Intramammary suspension

5. WITHDRAWAL PERIOD

Meat and offal: 28 days.

Milk: Treatment to calving interval ≥ 46 days: 36 hours.

Treatment to calving interval < 46 days: 46 days plus 36 hours after last treatment.

6. BATCH NUMBER

BN:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MSD Animal Health UK Ltd.

Walton Manor

Walton

Milton Keynes

MK7 7AJ

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Nafpenzal Dry Cow

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Each 3 g syringe contains:

Active substances:

Procaine benzylpenicillin 300 mg

Dihydrostreptomycin(as the sulphate) 100 mg

Aluminium stearate

Liquid paraffin

4. PHARMACEUTICAL FORM

Intramammary suspension

5. PACKAGE SIZE

3g syringe

Packs of 20 and 120 syringes

6. INDICATION(S)

For dry cow therapy (treatment of existing subclinical infections and the prevention of new infections which might occur during the dry period, caused by bacteria sensitive to penicillin, streptomycin or nafcillin

7. CONTRAINDICATIONS

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

Do not use in lactating animals.

8. ADVERSE REACTIONS

Occasional allergies to penicillin have been observed, but these are uncommon.

9. TARGET SPECIES

Cattle (dry cows)

10. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

The contents of one syringe are infused 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.

After breaking off the tip of the cap (for partial insertion) or removing 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

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

Meat and offal: 28 days.

Milk: Treatment to calving interval ≥ 46 days: 36 hours.

Treatment to calving interval < 46 days: 46 days plus 36 hours after last treatment.

13. SPECIAL STORAGE PRECAUTIONS

Keep the container in the outer carton.

Do not store above 25 °C.

14. SPECIAL WARNING(S)

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

To the user:

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.

5. Do not handle this product if you know you are sensitised or if you have been advised not to work with such preparations.
6. Handle this product with great care to avoid exposure, taking all recommended precautions.
7. 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.
8. Wash hands after use.

15. EXPIRY DATE

EXP:

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

November 2020

18. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

POM-V

19. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

20. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4624

21. MANUFACTURER'S BATCH NUMBER

BN:

<22. OTHER INFORMATION>

Approved 17 November 2020