Part IB 2 Labelling and Package Leaflet

{Proposed QRD Label Text}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON/CONTAINER (24s)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Multishield DC Intramammary Suspension for Cows

Neomycin Sulphate
Penethamate Hydriode
Procaine Benzylpenicillin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Presentation:

Each 4.5g intramammary syringe contains:
Neomycin70 000 IU (100 mg Neomycin Sulphate), Penethamate 77.2 mg (100 mg Penethamate Hydriodide), Benzylpenicillin 227.2 mg (400 mg Procaine Benzylpenicillin) in an oily base.

3. PHARMACEUTICAL FORM

(stated in the product name)

4. PACKAGE SIZE

24 syringes

5. TARGET SPECIES

Cows (at dry off)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal Periods:
Meat and Offal: 28 days.
Milk: 96 hours post calving in cows with a dry period of more than 50 days.
50 days + 96 hours after treatment from cows with a dry period of 50 days or less.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate or freeze.
For single use only.

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

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only.

POM-V To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4005

17. MANUFACTURER'S BATCH NUMBER

Batch:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

BUCKET (120s) TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Multishield DC Intramammary Suspension for Cows

Neomycin Sulphate
Penethamate Hydriode
Procaine Benzylpenicillin

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Presentation:

Each 4.5g intramammary syringe contains:

Neomycin	70 000 IU
(corresponding to Neomycin Sulphate	100 mg)
Penethamate	77.2 mg
(corresponding to Penethamate Hydriodide	100 mg)
Benzylpenicillin	227.2 mg
(corresponding to Procaine Benzylpenicillin	400 mg)

in an oily base.

3. PHARMACEUTICAL FORM

(stated in the product name)

4. PACKAGE SIZE

120 syringes

5. TARGET SPECIES

Cows (at dry off)

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Single intramammary administration.
The contents of one syringe should be infused into each quarter via the teat canal immediately after the final milking of a lactation.

8. WITHDRAWAL PERIOD(S)

Withdrawal Periods:
Meat and Offal: 28 days
Milk: 96 hours post calving in cows with a dry period of more than 50 days.
50 days + 96 hours after treatment from cows with a dry period of 50 days or less.

9. SPECIAL WARNING(S), IF NECESSARY

Do not use in the lactating cow.

Do not use in animals which are known to be hypersensitive to β-lactam antibiotics, cephalosporin antibiotics, neomycin or other aminoglycoside antibiotics or to any of the excipients.
Do not use in cows with clinical mastitis.
Read the package leaflet before use.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Do not refrigerate or freeze.
For single use only.

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

Read the package leaflet before use.

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

For animal treatment only.

POM-V To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

16. MARKETING AUTHORISATION NUMBER

Vm 50146/4005

17. MANUFACTURER'S BATCH NUMBER

Batch:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

SYRINGE LABEL TEXT

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Multishield DC Intramammary Suspension for Cows

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each 4.5g intramammary syringe contains: Neomcyin 70 000 IU (100 mg Neomycin Sulphate),
Penethamate 77.2 mg (100 mg Penethamate Hydriodide), Benzylpenicillin 227.2 mg (400 mg Procaine Benzylpenicillin).

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

4. ROUTE(S) OF ADMINISTRATION

For intramammary use.

5. WITHDRAWAL PERIOD(S)

Withdrawal periods:
Milk: 50 days + 96 hours
Meat and Offal: 28 days

6. BATCH NUMBER

Batch

7. EXPIRY DATE

EXP:

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

POM-V

MA Number: 50146/4005

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

PACKAGE LEAFLET FOR: Multishield DC Intramammary Suspension

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

Bimeda Animal Health Limited
2 / 3 / 4 Airton Close
Tallaght
Dublin 24
Ireland

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Multishield DC Intramammary Suspension for Cows

Neomycin Sulphate
Penethamate Hydriode
Procaine Benzylpenicillin

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

Smooth off-white oily suspension.

Each 4.5 g intramammary syringe contains:

Neomycin	70 000 IU
(corresponding to Neomycin Sulphate	100 mg)
Penethamate	77.2 mg
(corresponding to Penethamate Hydriodide	100 mg)
Benzylpenicillin	227.2 mg
(corresponding to Procaine Benzylpenicillin	400 mg)

4. INDICATION(S)

In cows at drying off: Treatment of subclinical mastitis caused by bovine mastitis microorganismssusceptible to the combination of active substances, penicillin and neomycin, and as part of strategy for the prevention of new infections occurring during the dry period.

5. CONTRAINDICATIONS

Do not use in lactating cows.
Do not use in cases of hypersensitivity to β-lactam antibiotics, cephalosporin antibiotics, neomycin or other aminoglycoside antibiotics or to any of the excipients.

Do not use in cows with clinical mastitis.

6. ADVERSE REACTIONS

Allergic reactions (allergic skin reactions, anaphylaxis)
Penicillins may cause hypersensitivity following administration. Allergic reactions to these substances may occasionally be serious.

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

If adverse reactions occur, the current treatment should be withdrawn and symptomatic treatment should be initiated.
If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Cows (at dry off).

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

100 mg of neomycin sulphate, 100 mg of Penethamate Hydriodide and 400 mg of Procaine Benzylpenicillin into each quarter.

Intramammary use
The contents of one syringe should be infused into each quarter via the teat canal immediately after the final milking of a lactation.

9. ADVICE ON CORRECT ADMINISTRATION

Before instillation, the udder should be milked out completely. The teat and its orifice should be thoroughly cleaned and disinfected with a cleaning towel. Care should be taken to avoid contamination of the injector nozzle. Gently insert the content of one syringe into each quarter. Disperse the product by gentle massage of the teat and udder. The syringe must only be used once.

10. WITHDRAWAL PERIOD(S)

Meat and Offal: 28 days.
Milk: 96 hours post calving in cows with a dry period of more than 50 days.
50 days plus 96 hours after treatment from cows with a dry period of 50 days or less.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Do not refrigerate or freeze.

For single use only.
Do not use this veterinary medicinal product after the expiry date which is stated on the syringe, carton and bucket labels after 'EXP'.
The expiry date refers to the last day of that month.

12. SPECIAL WARNINGS

Special precautions for use in animals

Use of the product should be based on susceptibility testing of the bacteria isolated from the animal. If this is not possible, therapy should be based on local (regional, farm level) epidemiological information about susceptibility of the target bacteria.
Official, national and regional antimicrobial policies should be taken into account when the product is used.

The therapeutic efficacy of the product is only established against pathogens that aresusceptible to the active substances.
Serious acute mastitis [potentially lethal] due to pathogens like *Pseudomonas aeruginosa*, can occur after drying off despite preventive treatment. Good aseptic practices should be thoroughly respected in order to reduce that risk; cows should be housed in a hygienic paddock far from the milking parlour and regularly checked several days after drying off.
Use of the product deviating from the instructions given in the SPC may increase the prevalence of bacteria resistant to benzylpenicillin and may decrease the effectiveness of treatment with other beta lactam antimicrobials (penicillins and cephalosporins) due to the potential for cross-resistance.

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

Skin sensitisation may occur in persons handling this product, contact with the skin should be avoided.

Penicillins and cephalosporins may cause sensitisation following injection, inhalation, ingestion or skin contact.

Sensitivity to penicillins may lead to cross sensitivity to cephalosporins and vice versa. Allergic reactions to these substances may occasionally be serious.

Do not handle this product if you know that you are sensitised or if you have been advised not to work with such preparations.

If you develop symptoms such as a skin rash following exposure, seek medical advice and show this warning to the doctor. Swelling of the face, lips or eyes, or difficulty with breathing are more serious symptoms and require urgent medical attention.

Use during pregnancy and lactation

The product is not recommended for use in lactating cows, except at the drying off stage

Interaction with other medicinal products and other forms of interactions

No data available.

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

Overdosing may invalidate the stated milk and meat withdrawal times.

Incompatabilities

Not applicable

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY.

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2019

15. OTHER INFORMATION

Legal category:	POM-V Prescription only medicine
Package quantities:	Cartons of 24 syringes. Buckets of 120 syringes. Not all pack sizes may be marketed.
Marketing authorisation number:	Vm 50146/4005

Approved 2 September 2019