ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box with 24 syringes
Cardboard box with 60 syringes
Cardboard box with 120 syringes
Cardboard box with 24 syringes + 24 cleaning wipes
Cardboard box with 60 syringes + 60 cleaning wipes
Cardboard box with 120 syringes + 120 cleaning wipes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROSEAL 2.6 g intramammary suspension for dry cows (AT, BE, CZ, DE, DK, EE, EL, ES, IE, LU, NL, HU, PL, PT, SK, NI).
FATROSEAL intramammary suspension for dry cows (FR).
Bismuth subnitrate, heavy

2. STATEMENT OF ACTIVE SUBSTANCES

Each 4 g intramammary syringe contains:
Active substance: Bismuth subnitrate, heavy 2.6 g (equivalent to Bismuth, heavy 1.858 g).

3. PHARMACEUTICAL FORM

Intramammary suspension

4. PACKAGE SIZE

24 x 4 g
60 x 4 g
120 x 4 g

5. TARGET SPECIES

Cattle (dairy cows at drying-off)

6. INDICATION(S)

For OTC products:
The product is indicated for the prevention of new intramammary infections throughout the dry period. In cows considered likely to be free of sub-clinical mastitis, the product can be used alone in dry cow management and mastitis control.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For intramammary use only.
Read the package leaflet before use.

Infuse the contents of one intramammary syringe of the product into each udder quarter immediately after the last milking of the lactation at drying off. Do not massage the teat or udder after infusion of the product because it is important that the sealant stays in the teat itself and does not enter the udder.

Care must be taken not to introduce pathogens into the teat in order to reduce the risk of post-infusion mastitis.

Under cold conditions the product may be warmed to room temperature in a warm environment, to aid syringeability.

8. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: Zero days.
Milk: Zero hours.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.
Do not use the product alone in cows with sub-clinical mastitis at drying off (for more info see "Special warnings" in the package leaflet).
Do not use in cows with clinical mastitis at drying off.
Do not use in lactating cows.
Do not administer any other intramammary product following administration of the product. In cows that may have sub-clinical mastitis, the product may be used following administration of a suitable dry cow antibiotic treatment to the infected quarter.

To reduce the risk of contamination, do not immerse the syringe in water.
Use the syringe only once.
Bismuth salts have been associated with hypersensitivity reactions.
People with known hypersensitivity (allergy) to bismuth salts should avoid contact with the veterinary medicinal product.
This product may cause skin and eye irritation. Avoid contact with skin or eyes.
Should skin or eye contact occur, wash the affected area thoroughly with water. If irritation persists, seek medical advice and show this label to the physician.

If provided, the cleaning wipes may cause skin and eye irritation in some people due to the presence of isopropyl alcohol and chlorhexidine digluconate. Avoid contact with skin or eyes.

Wash hands after use.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

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

Disposal: read the package leaflet.

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

For animal treatment only.
To be completed nationally.

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

LABORATORIOS SUPPORT PHARMA S.L.
General Álvarez de Castro, 39 - 28010 Madrid, Spain

16. MARKETING AUTHORISATION NUMBERS

To be completed nationally

17. MANUFACTURER'S BATCH NUMBER

LOT. {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
4 g intramammary syringe label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

FATROSEAL 2.6 g intramammary suspension for dry cows (AT, BE, CZ, DE, DK, EE, EL, ES, IE, LU, NL, HU, PL, PT, SK, NI).
FATROSEAL intramammary suspension for dry cows (FR).
Bismuth subnitrate, heavy

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Bismuth subnitrate, heavy 2.6 g

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

4 g

4. ROUTE(S) OF ADMINISTRATION

Intramammary use.

5. WITHDRAWAL PERIOD(S)

Withdrawal period:
Meat and offal: Zero days.
Milk: Zero hours.

6. BATCH NUMBER

LOT. {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.