ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INMUNAIR 17.5 oral suspension for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substances:
Inactivated cells of *Cutibacterium acnes, ATCC 12930* .....0.17 mg
Lipopolysaccharide (LPS) of de *E.coli*, CM 29/495 .....0.05 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	0.1 mg
Povidone	
Potassium dihydrogen phosphate	
Sodium hydroxide	
Water for injections	

Colourless suspension.

3. CLINICAL INFORMATION

3.1 Target species

Chicken

3.2 Indications for use for each target species

To improve the immune status of vaccinated poultry against Marek's disease when applied at three-week interval after vaccination.
To improve the immune status of vaccinated poultry against Infectious Bursitis, because it inrcreases protection index.
To prevent:

- Mortality, clinical symptoms and/or lesions caused by the virus of Marek's disease.
- Lesions and damage of zootechnical parameters produced by the infection of *Mycoplasma gallisepticum*.
- Mortality and damage of zootechnical parameters produced by subgroup J avian Leukosis virus.
- Lesions produced by Infectious Bursitis virus.
- Infections in critical periods of poultry's productive life when they are under stress conditions and are more susceptible to infectious diseases.

3.3 Contraindications

None.

3.4 Special warnings

None.

3.5 Special precautions for use

Special precautions for use in the target species:

Not applicable.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the immediate packaging for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

Can be used during laying.

3.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product. A decision to use this immunological veterinary medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

3.9 Administration routes and dosage

Dose: 0.5-1 ml / 10 Kg b.w. / day for 3 days.

Utilization scheme:
Administration should be determined based on the vaccination program and the specific situation of each farm. It can be generalized in the following cases:
In broilers: administer for 3 days during the first 3 days of life (after vaccination or transport), and can be repeated at 21 days of age (when passive immunity reduces, they are vaccinated, and their diet is changed).
In future layer pullets and future breeder pullets: administer for 3 days during the first 3 days of life (after vaccination or transport), between 10 and 12 weeks (when rearing begins).
Coinciding with the start of laying, the administration can be repeated (for 3 days) between 18 and 23 weeks in laying hens; and in breeder hens.

Administration route: in drinking water use.

Shake before use.

Dilute the product in a quantity of water that can be consumed in less than two hours according to poultry's weight and age. To ensure the consumption of the correct dosage, restrict poultry's drinking water before the administration of the medicated water, assessing the size of the flock to be treated and season when the treatment is administered (less withdrawal time in hottest periods). Return drinking water each day once consumed medicated water during treatment, and in permanent way once finished treatment.
Medicated water should be prepared immediately before use.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse events have been observed after administration of 10 times the maximum dose using the recommended route.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. INMUNOLOGICAL PROPERTIES

4.1 ATCvet code:

ATC vet code: QL03AX

The lipopolysaccharide of *E. coli* activates macrophages, induces the proliferative response of lymphocytes B and their differentiation into antibody-producing plasma cells.

Cutibacterium acnes is able to induce cell immunity, stimulating the production of cytokines.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years
Shelf life after first opening the immediate packaging: 2 hours.

5.3. Special precautions for storage

Store in a refrigerator (2^0 C - 8^0C).
Protect from light.
Do not freeze.

5.4 Nature and composition of immediate packaging

High-density polyethylene vial of 500 ml, closed with chlorobutyl rubber stopper and sealed with aluminum cap.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS CALIER, S.A.

7. MARKETING AUTHORIZATION NUMBER(S)

8. DATE OF FIRST AUTHORISATION

Date of first authorization <{DD/MM/YYYY}>

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

<{MM/YYYY}>

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX III LABELLING AND PACKAGE LEAFLET

COMBINED LABEL AND PACKAGE LEAFLET

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - <u>COMBINED LABEL AND PACKAGE LEAFLET</u>

500 ml vial

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

INMUNAIR 17.5 oral suspension for chicken

2. COMPOSITION

Each ml contains:

Active substances:

Inactivated cells of Propionibacterium *acnes,* ATCC 12930: 0.17 mg

Lipopolysaccharide (LPS) from *E. coli,* CM 29:495: 0.05 mg

Excipients:

Thiomersal: 0.1 mg

Colourless suspension

3. PACKAGE SIZE

500 ml

4. TARGET SPECIES

Chicken.

5. INDICATIONS FOR USE

Indications for use

To improve the immune status of vaccinated poultry against Marek's disease when applied at three-week interval after vaccination.

To improve the immune status of vaccinated poultry against Infectious Bursitis, because it inrcreases protection index.

To prevent:

- Mortality, clinical symptoms and/or lesions caused by the virus of Marek's disease.
- Lesions and damage of zootechnical parameters produced by the infection of Mycoplasma gallisepticum.
- Mortality and damage of zootechnical parameters produced by subgroup J avian Leukosis virus.
- Lesions produced by Infectious Bursitis virus.
- Infections in critical periods of poultry's productive life when they are under stress conditions and are more susceptible to infectious diseases.

6. CONTRAINDICATIONS

Contraindications

None.

7. SPECIAL WARNINGS

Special warnings

None.

Special precautions for safe use in the target species:

Not applicable.

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

Not applicable.

Special precautions for the protection of the environment:

Not applicable.

Laying birds:

Can be used during laying.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this immunological veterinary medicinal product when used with any other veterinary medicinal product. A decision to use this immunological veterinary medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case-by-case basis.

Overdose:

No adverse events have been observed after administration of 10 times the maximum dose using the recommended route.

Special restrictions for use and special conditions for use:

Veterinary medicinal product subject to prescription.

Major incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

8. ADVERSE EVENTS

Adverse events

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed on this label, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details on this label, or via your national reporting system:

9. DOSAGE FOR EACH TARGET SPECIES, ROUTES AND METHOD OF ADMINISTRATION

Dosage for each species, routes and method of administration

Dose: 0.5-1 ml/10 Kg b.w./day for 3 days.

Utilization scheme:

Administration should be determined based on the vaccination program and the specific situation of each farm. It can be generalized in the following cases:

In broilers: administer for 3 days during the first 3 days of life (after vaccination or transport), and can be repeated at 21 days of age (when passive immunity reduces, they are vaccinated, and their diet is changed).

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Coinciding with the start of laying, the administration can be repeated (for 3 days) between 18 and 23 weeks in laying hens; and in breeder hens.

Administration route: in drinking water use.

10. ADVICE ON CORRECT ADMINISTRATION

Advice on correct administration

Shake before use.

Dilute the product in a quantity of water that can be consumed in less than two hours according to poultry's weight and age. To ensure the consumption of the correct dosage, restrict poultry's drinking water before the administration of the medicated water, assessing the size of the flock to be treated and season when the treatment is administered (less withdrawal time in hottest periods). Return drinking water each day once consumed medicated water during treatment, and in permanent way once finished treatment.

Medicated water should be prepared immediately before use.

11. WITHDRAWAL PERIODS

Withdrawal periods: Zero days.

12. SPECIAL STORAGE PRECAUTIONS

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2^0 C - 8^0C).

Protect from light.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.

13. SPECIAL PRECAUTIONS FOR DISPOSAL

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Classification of veterinary medicinal products
Veterinary medicinal product subject to prescription

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Pack sizes
500 ml vial

16. DATE ON WHICH THE LABEL WAS LAST REVISED

Date on which the label was last revised

MM/YYYY

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

17. CONTACT DETAILS

Contact details

Marketing authorisation holder and contact details to report suspected adverse events
CALIER PORTUGAL, S.A.
Centro Empresarial Sintra-Estoril II, Rua Pé de Mouro, Edifício C Estrada de Albarraque
2710 - 335 Sintra
Telf: +351 219248140
Email: farmacovigilancia@calier.pt

Manufacturer responsible for batch release:
LABORATORIOS CALIER, S.A.
C/Barcelonés, 26 (Plá de Ramassar)
LES FRANQUESES DEL VALLES,
08520 (Barcelona)
ESPAÑA

For any information about this veterinary medicinal product, please contact the marketing authorisation holder.

18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only

20. EXPIRY DATE

Exp {mm/yyyy}

Shelf life after first opening the immediate packaging: 2 hours.

21. BATCH NUMBER

Lot { number}