ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVALON suspension and solvent for oral spray for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.007 ml) of undiluted vaccine contains:

Active substances:

Eimeria acervulina, strain 003	332 – 450*
Eimeria brunetti, strain 034	213 – 288*
Eimeria maxima, strain 013	196 – 265*
Eimeria necatrix, strain 033	340 – 460*
Eimeria tenella, strain 004	276 – 374*

* Number of sporulated oocysts derived from precocious attenuated lines of coccidia, according to *in vitro* procedures of the manufacturer at the time of blending.

Adjuvants:
Montanide IMS

Excipients:

Qualitative composition of excipients and other constituents
EVALON (suspension):
Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
HIPRAMUNE T (solvent):
Brilliant Blue (E 133)
Red AC (E 129)
Vanillin
Montanide IMS

Suspension: white turbid suspension.
Solvent: dark brownish solution.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For active immunisation of chicks from 1 day of age to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina*, *Eimeria brunetti, Eimeria maxima, Eimeria necatrix* and *Eimeria tenella*.

Onset of immunity: 3 weeks post-vaccination.
Duration of immunity: 60 weeks post-vaccination in an environment that permits oocysts recycling.

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

The vaccine will not protect species other than chickens against coccidiosis and is only effective against the *Eimeria* species indicated.

It is normal to find vaccinal oocysts in the intestine or litter of vaccinated flocks. Generally, the number is higher the first week post-vaccination and lower once the flock has achieved a proper protection.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Chickens must be strictly floor-reared in the first 3 weeks after vaccination.

It is recommended that litter should be removed and facilities and material cleaned between production cycles to reduce field infections.

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

Wash and disinfect hands and equipment after use.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Chickens:

None.

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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:
The safety of the veterinary medicinal product has not been established during lay. Do not use in birds in lay and within 2 weeks before the onset of the laying period.

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.

No anticoccidial substances or other agents having anticoccidial activity via feed or water should be used for at least 3 weeks following vaccination of the chickens. The correct replication of the vaccine oocysts and consequently, the development of a solid immunity could be hindered. Additionally, the enhancement of protection produced by oocyst re-infections would also be limited.

3.9 Administration routes and dosage

Oral use.
The method of administration is by coarse spray.

Vaccination schedule:
One dose of vaccine (0.007 ml) from 1 day of age.

Administration route:
The method of administration is by coarse spray by using a suitable device (volume delivered: 28 ml / 100 chicks, droplet size: 200 – 250 µm and working pressure: 2 to 3 bars). Before starting the preparation, make certain to have a clean container available with sufficient capacity for preparing the diluted vaccine suspension. Dilute the vaccine with the corresponding volumes:

Doses	Water	Vaccine	Solvent	Total
1 000	223 ml	7 ml	50 ml	280 ml
5 000	1 115 ml	35 ml	250 ml	1 400 ml
10 000	2 230 ml	70 ml	500 ml	2 800 ml

Shake the solvent vial. Dilute the content of the vial with clean room temperature water into an appropriate container.
Shake the vaccine vial and dilute the content into the previous solution.
Fill the reservoir of the spraying device with all the vaccine suspension prepared.
Maintain the diluted vaccine suspension in continuous homogenisation by using a magnetic stirrer while the vaccine is being administered via coarse spray to the chicks.
To improve the uniformity of the vaccination maintain the chicks inside the transportation box for at least 1 hour in order to let them ingest all the vaccine droplets.
After this time, place the chicks carefully in the litter and continue with regular management practices.

The device should be cleaned after each use. See the manufacturer's instructions to ensure proper disinfection and maintenance of the device.

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

Severe overdose (10 - fold) may result in a temporary reduction in daily live weight gain within the first week without any consequences on the final performances.

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. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AN01.

To stimulate active immunity against coccidiosis caused by *Eimeria acervulina*, *Eimeria brunetti, Eimeria maxima, Eimeria necatrix* and *Eimeria tenella.*

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

5.2 Shelf life

EVALON (vaccine):
Shelf life of the veterinary medicinal product as packaged for sale: 10 months.
Shelf life after first opening the immediate packaging: use immediately.
Shelf life after dilution according to directions: 10 hours.

HIPRAMUNE T (solvent):
Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

5.3 Special precautions for storage

Store and transport refrigerated (2 ºC– 8 ºC).
Do not freeze.

5.4 Nature and composition of immediate packaging

EVALON (vaccine):
10 ml, 50 ml or 100 ml type I colourless glass vials containing 7 ml, 35 ml or 70 ml of suspension (1 000, 5 000 and 10 000 doses) closed with type I polymeric elastomer closures and aluminium caps.

HIPRAMUNE T (solvent):
Polypropylene (PP) vials containing 50 ml, 250 ml and 500 ml of solvent closed with type I polymeric elastomer closures and aluminium caps.

Pack sizes:
Cardboard box with one vial of 1 000 doses (7 ml) and one vial with 50 ml of solvent.
Cardboard box with one vial of 5 000 doses (35 ml) and one vial with 250 ml of solvent.
Cardboard box with one vial of 10 000 doses (70 ml) and one vial with 500 ml of solvent.

Not all pack sizes may be marketed.

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 HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/194/001–003

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 18/04/2016

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

{DD/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 II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVALON suspension and solvent for oral spray for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.007 ml) of undiluted vaccine contains the following number of sporulated oocysts:

Eimeria acervulina, strain 003	332 – 450
Eimeria brunetti, strain 034	213 – 288
Eimeria maxima, strain 013	196 – 265
Eimeria necatrix, strain 033	340 – 460
Eimeria tenella, strain 004	276 – 374

3. PACKAGE SIZE

One vial of 1 000 doses and one vial with 50 ml of HIPRAMUNE T (solvent).
One vial of 5 000 doses and one vial with 250 ml of HIPRAMUNE T (solvent).
One vial of 10 000 doses and one vial with 500 ml of HIPRAMUNE T (solvent).

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use.
Coarse spray.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp {mm/yyyy}
Once diluted use within 10 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/16/194/001 (1 000 doses)
EU/2/16/194/002 (5 000 doses)
EU/2/16/194/003 (10 000 doses)

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vaccine vial of 1 000 or 5 000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVALON

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each dose (0.007 ml) of undiluted vaccine contains the following number of sporulated oocysts:

Eimeria acervulina, strain 003	332 – 450
Eimeria brunetti, strain 034	213 – 288
Eimeria maxima, strain 013	196 – 265
Eimeria necatrix, strain 033	340 – 460
Eimeria tenella, strain 004	276 – 374

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 10 hours.

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

1,000 doses
5,000 doses

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vaccine vial of 10 000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVALON suspension for oral spray for chickens

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.007 ml) of undiluted vaccine contains the following number of sporulated oocysts:

Eimeria acervulina, strain 003	332 – 450
Eimeria brunetti, strain 034	213 – 288
Eimeria maxima, strain 013	196 – 265
Eimeria necatrix, strain 033	340 – 460
Eimeria tenella, strain 004	276 – 374

3. TARGET SPECIES

Chickens.

4. ROUTES OF ADMINISTRATION

Oral use.
Coarse spray.
To be mixed with the solvent.
Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

6. EXPIRY DATE

Exp. {mm/yyyy}

Once diluted use within 10 hours.

7. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

9. BATCH NUMBER

Lot {number}

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

10 000 doses

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING (LABEL) OF THE SOLVENT

Solvent vial of 50 ml, 250 ml or 500 ml

1. NAME OF THE SOLVENT

HIPRAMUNE T solvent for oral spray for chickens

2. TARGET SPECIES

Chickens.

3. ROUTES OF ADMINISTRATION

Read package leaflet before use.

4. EXPIRY DATE

Exp. {mm/yyyy}

5. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. BATCH NUMBER

Lot {number}

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

50 ml
250 ml
500 ml

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

EVALON suspension and solvent for oral spray for chickens

2. Composition

Active substances:
Each dose (0.007 ml) of undiluted vaccine contains

Eimeria acervulina, strain 003	332 – 450 *
Eimeria brunetti, strain 034	213 – 288 *
Eimeria maxima, strain 013	196 – 265 *
Eimeria necatrix, strain 033	340 – 460 *
Eimeria tenella, strain 004	276 – 374 *

* Number of sporulated oocysts derived from precocious attenuated lines of coccidia, according to *in vitro* procedures of the manufacturer at the time of blending.

Suspension: white turbid suspension.
Solvent: dark brownish solution.

3. Target species

Chickens.

4. Indications for use

For active immunisation of chicks from 1 day of age to reduce clinical signs (diarrhoea), intestinal lesions and oocysts output associated with coccidiosis caused by *Eimeria acervulina*, *Eimeria brunetti, Eimeria maxima, Eimeria necatrix* and *Eimeria tenella*.

Onset of immunity: 3 weeks post-vaccination.

Duration of immunity: 60 weeks post-vaccination in an environment that permits oocysts recycling.

5. Contraindications

None.

6. Special warnings

Special warnings:
Vaccinate healthy animals only.
The vaccine will not protect species other than chickens against coccidiosis and is only effective against the *Eimeria* species indicated.
It is normal to find vaccinal oocysts in the intestine or litter of vaccinated flocks. Generally the number is higher the first weeks post-vaccination and lower once the flock has achieved a proper protection.

Special precautions for safe use in the target species:
Chickens must be strictly floor-reared in the first 3weeks after vaccination.
It is recommended that litter should be removed and facilities and material cleaned between production cycles to reduce field infections.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Wash and disinfect hands and equipment after use.

Laying birds:
The safety of the veterinary medicinal product has not been established during lay. Do not use in birds in lay and within 2 weeks before the onset of the laying period.

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

No anticoccidial substances or other agents having anticoccidial activity via feed or water should be used for at least 3 weeks following vaccination of the chickens. The correct replication of the vaccine oocysts and consequently, the development of a solid immunity could be hindered. Additionally, the enhancement of protection produced by oocyst re-infections would also be limited.

Overdose:
Severe overdose (10 - fold) may result in a temporary reduction in daily live weight gain within the first week without any consequences on the final performances.

Major incompatibilities:
Do not mix with any other veterinary medicinal product, except the solvent supplied for use with the veterinary medicinal product.

7. Adverse events

Chickens:
None.

Reporting adverse events is important. It allows continuous safety monitoring of a product. 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 contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system: {national system details}.

8. Dosage for each species, routes and method of administration

One dose of vaccine (0.007 ml) from 1 day of age.
Oral use.
The method of administration is by coarse spray.

9. Advice on correct administration

The method of administration is by coarse spray by using a suitable device (volume delivered: 28 ml/100 chicks, droplet size: 200–250 µm and working pressure: 2 to 3 bars). Before starting the preparation, make certain to have a clean container available with sufficient capacity for preparing the diluted vaccine suspension. Dilute the vaccine with the corresponding volumes:

DOSES	WATER	VACCINE	SOLVENT	TOTAL
1 000	223 ml	7 ml	50 ml	280 ml
5 000	1 115 ml	35 ml	250 ml	1 400 ml
10 000	2 230 ml	70 ml	500 ml	2 800 ml

Shake the solvent vial. Dilute the contents of the vial with clean room temperature water into an appropriate container.

Shake the vaccine vial and dilute the content into the previous solution.

Fill the reservoir of the spraying device with all the vaccine suspension prepared.

Maintain the diluted vaccine suspension in continuous homogenisation by using a magnetic stirrer while the vaccine is being administered via coarse spray to the chicks.

To improve the uniformity of the vaccination maintain the chicks inside the transportation box for at least 1 hour in order to let them ingest all the vaccine droplets.

After this time, place the chicks carefully in the litter and continue with regular management practices.

The device should be cleaned after each use. See the manufacturer's instructions to ensure proper disinfection and maintenance of the device.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.

Store and transport refrigerated (2 ºC - 8 ºC).
Do not freeze.

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

Shelf life after first opening the immediate packaging: use immediately.
Shelf life after dilution according to directions: 10 hours.

12. 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 applicable national collection systems. These measures should help to protect the environment.

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

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Marketing authorisation numbers: EU/2/16/194/001–003

Pack sizes
Cardboard box with one vial of 1 000 doses (7 ml) and one vial with 50 ml of solvent.
Cardboard box with one vial of 5 000 doses (35 ml) and one vial with 250 ml of solvent.
Cardboard box with one vial of 10 000 doses (70 ml) and one vial with 500 ml of solvent.

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

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

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

LABORATORIOS HIPRA, S.A.
Avda. la Selva 135
17170 Amer (Girona) SPAIN
TEL:+34 972 43 06 60

Local representatives and contact details to report suspected adverse reactions:
For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

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