

ANNEX II

- A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**
- B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE**
- C. STATEMENT OF THE MRLs**

**A. MANUFACTURER OF THE BIOLOGICAL ACTIVE SUBSTANCES AND
MANUFACTURER RESPONSIBLE FOR BATCH RELEASE**

Name and address of the manufacturers of the biological active substances

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
Amer
17170 Girona
SPAIN

LABORATORIOS HIPRA, S.A.
Paratge Lloret
Carretera de Susqueda
Amer
17170 Girona
SPAIN

LABORATORIOS HIPRA, S.A.
Carretera C-63, Km 48.300 Polígono Industrial El Rieral
Amer
17170 Girona
SPAIN

Name and address of the manufacturer responsible for batch release

LABORATORIOS HIPRA, S.A.
Avda. La Selva 135
Amer
17170 Girona
SPAIN

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

Veterinary medicinal product subject to prescription.

C. STATEMENT OF THE MRLs

The active substances being principles of biological origin intended to produce active immunity are not within the scope of Regulation (EC) No 470/2009.

The excipients (including adjuvants) listed in section 6.1 of the SPC are either allowed substances for which table 1 of the annex to Commission Regulation (EU) No 37/2010 indicates that no MRLs are required or considered as not falling within the scope of Regulation (EC) No 470/2009 when used as in this veterinary medicinal product.

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard boxes

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANT suspension and solvent for oral spray for chickens.

2. STATEMENT OF ACTIVE SUBSTANCES

Each dose (0.007 ml) of undiluted vaccine contains:

<i>Eimeria acervulina</i> , strain 003	332 – 450
<i>Eimeria maxima</i> , strain 013	196 – 265
<i>Eimeria mitis</i> , strain 006	293 – 397
<i>Eimeria praecox</i> , strain 007	293 – 397
<i>Eimeria tenella</i> , strain 004	276 – 374

3. PHARMACEUTICAL FORM

Suspension and solvent for oral spray.

4. PACKAGE SIZE

One vial of 7 ml (1,000 doses) of EVANT and one vial of 50 ml of HIPRAMUNE T (solvent).

One vial of 35 ml (5,000 doses) of EVANT and one vial of 250 ml of HIPRAMUNE T (solvent).

One vial of 70 ml (10,000 doses) of EVANT and one vial of 500 ml of HIPRAMUNE T (solvent).

One vial of 7 ml (1,000 doses) of EVANT and one vial of 50 ml of HIPRACELL (solvent).

One vial of 35 ml (5,000 doses) of EVANT and one vial of 250 ml of HIPRACELL (solvent).

One vial of 70 ml (10,000 doses) of EVANT and one vial of 500 ml of HIPRACELL (solvent).

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
Oral use.
Coarse spray.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once diluted use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

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. 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

Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17533/5004

17. MANUFACTURER'S BATCH NUMBER

Batch {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

EVANT suspension and solvent for oral spray for chickens.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Each dose (0.007 ml) of undiluted vaccine contains:

<i>Eimeria acervulina</i> , strain 003	332 – 450
<i>Eimeria maxima</i> , strain 013	196 – 265
<i>Eimeria mitis</i> , strain 006	293 – 397
<i>Eimeria praecox</i> , strain 007	293 – 397
<i>Eimeria tenella</i> , strain 004	276 – 374

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

1,000 doses
5,000 doses

4. ROUTE(S) OF ADMINISTRATION

To be mixed with HIPRAMUNE T or HIPRACELL (solvent).
Read the package leaflet before use.
Oral use.
Coarse spray

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch {number}

7. EXPIRY DATE

EXP {month/year}
Once diluted use within 10 hours.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

Vaccine vial of 10,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANT suspension and solvent for oral spray for chickens.

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose (0.007 ml) of undiluted vaccine contains:

<i>Eimeria acervulina</i> , strain 003	332 – 450
<i>Eimeria maxima</i> , strain 013	196 – 265
<i>Eimeria mitis</i> , strain 006	293 – 397
<i>Eimeria praecox</i> , strain 007	293 – 397
<i>Eimeria tenella</i> , strain 004	276 – 374

3. PHARMACEUTICAL FORM

Suspension for oral spray.

4. PACKAGE SIZE

10,000 doses

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral use.
Coarse spray.
To be mixed with the HIPRAMUNE T or HIPRACELL (solvent). Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once diluted use within 10 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

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

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

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain

16. MARKETING AUTHORISATION NUMBER(S)

Vm 17533/5004

17. MANUFACTURER’S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING

Solvent vial of 50 ml, 250 ml or 500 ml: Hipramune T

1. NAME OF THE SOLVENT

HIPRAMUNE T solvent for oral spray for chickens

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

50 ml
250 ml
500 ml

3. ROUTE(S) OF ADMINISTRATION

Oral use. Coarse spray.
Read the package leaflet before use.

4. STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

5. BATCH NUMBER

Batch {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

MINIMUM PARTICULARS TO APPEAR ON IMMEDIATE PACKAGING

Solvent vial of 50 ml, 250 ml or 500 ml: Hipracell

1. NAME OF THE SOLVENT

HIPRACELL solvent for oral spray for chickens

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

50 ml
250 ml
500 ml

3. ROUTE(S) OF ADMINISTRATION

Oral use. Coarse spray.
Read the package leaflet before use.

4. STORAGE CONDITIONS

Store and transport refrigerated. Do not freeze.

5. BATCH NUMBER

Batch {number}

6. EXPIRY DATE

EXP {month/year}

7. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:
EVANT suspension and solvent for oral spray for chickens

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

Marketing authorisation holder and manufacturer responsible for batch release:
Laboratorios Hipra SA
Avda La Selva 135
17170 Amer (Girona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANT suspension and solvent for oral spray for chickens.

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

EVANT:

Active substances:

Each dose (0.007 ml) of undiluted vaccine contains:

<i>Eimeria acervulina</i> , strain 003	332 – 450*
<i>Eimeria maxima</i> , strain 013	196 – 265*
<i>Eimeria mitis</i> , strain 006	293 – 397*
<i>Eimeria praecox</i> , strain 007	293 – 397*
<i>Eimeria tenella</i> , 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.

Adjuvant and excipients:

Solvent	HIPRAMUNE T	HIPRACELL
Adjuvant	Montanide IMS	Light mineral oil
Excipients	Brilliant Blue (E133)	
	Red AC (E129)	
	Vanillin	

Suspension: White turbid suspension.
Solvent: Dark brownish solution.

4. INDICATION(S)

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

Onset of immunity: 14 days post-vaccination.

Duration of immunity: 63 days post-vaccination in an environment that permits oocysts recycling.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

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

Chickens.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) 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: 1.5 to 3 bars). Before starting to prepare the spray solution, ensure there is a clean container with sufficient capacity for preparing the diluted vaccine suspension available. Dilute the vaccine with the relevant volumes of the solvent (HIPRAMUNE T or HIPRACELL) and water, as shown in the following table:

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 (HIPRAMUNE T or HIPRACELL). Dilute the contents of the vial with clean, room temperature water into an appropriate container.

Shake the vaccine (EVANT) vial and dilute the contents of it into the solvent and water solution. A purplish suspension is obtained after dilution.

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 into 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 PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Shelf life after dilution according to directions: 10 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:

The vaccine will not protect species other than chickens against coccidiosis and is only effective against the *Eimeria* species indicated. This product is intended for the vaccination of short-lived chickens only. No data is available on protection of longer-lived birds such as future layers/breeders.

Special precautions for use in animals:

Vaccinate healthy chickens only.

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

In order to reduce field infections, it is recommended that all litter should be removed and facilities and related equipment in contact with vaccinated chickens should be cleaned between production cycles.

Lay:

The safety of the veterinary medicinal product has not been established during lay. Do not use in birds in lay or in breeding birds, or within 4 weeks before the start of the laying period.

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

Wash and disinfect hands and equipment after use.

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 the vaccination of chickens with this product otherwise the correct replication of the vaccine oocysts, and consequently the development of a solid immunity, could be hindered. Additionally, the duration of immunity depends on an environment that permits recycling of oocysts, therefore a decision to use any anticoccidial substances in the period after 3 weeks post-vaccination should be made taking into account the potential negative impact on the duration of immunity of this product.

Overdose (symptoms, emergency procedures, antidotes):

After the administration of a severe overdose (10-fold), mild, transient, clinical signs of coccidiosis were commonly observed without any consequences on the final performance.

Major incompatibilities:

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

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

Medicines should not be disposed of via wastewater or household waste. Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

Pack sizes:

Cardboard box with one vial of EVANT containing 7 ml (1,000 doses) and one vial of HIPRAMUNE T containing 50 ml.

Cardboard box with one vial of EVANT containing 35 ml (5,000 doses) and one vial of HIPRAMUNE T containing 250 ml.

Cardboard box with one vial of EVANT containing 70 ml (10,000 doses) and one vial of HIPRAMUNE T containing 500 ml.

Cardboard box with one vial of EVANT containing 7 ml (1,000 doses) and one vial of HIPRACELL containing 50 ml.

Cardboard box with one vial of EVANT containing 35 ml (5,000 doses) and one vial of HIPRACELL containing 250 ml.

Cardboard box with one vial of EVANT containing 70 ml (10,000 doses) and one vial of HIPRACELL containing 500 ml.

Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorization holder.

<p>United Kingdom (Northern Ireland) LABORATORIOS HIPRA, S.A. Tel: +34 972 43 06 60</p>
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