

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

EVANT suspension and solvent for oral spray for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose (0.007 ml) of undiluted vaccine contains:

EVANT:

Active substances:

<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	

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension and solvent for oral spray.

Suspension: White turbid suspension.

Solvent: Dark brownish solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

4.4 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.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

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.

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

Wash and disinfect hands and equipment after use.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or 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.

4.8 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 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.

4.9 Amounts to be administered and administration route

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:

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 (HIPRAMUNE T or HIPRACELL) vial. Dilute the content 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.

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

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.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunological for Aves, live parasitic vaccines for domestic fowl.

ATCvet code: QI01AN01.

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

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

EVANT (vaccine):

Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Polysorbate 80
Purified water

HIPRAMUNE T (solvent):

Brilliant blue (E 133)
Red AC (E 129)
Vanillin
Montanide IMS

HIPRACELL (solvent):

Brilliant blue (E 133)
Red AC (E 129)
Vanillin
Light mineral oil
Polysorbate 80
Sorbitan mono-oleato
Potassium chloride
Disodium phosphate dodecahydrate
Potassium dihydrogen phosphate
Sodium chloride
Water for injections

6.2 Major incompatibilities

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

6.3 Shelf life

EVANT:

Shelf life of the veterinary medicinal product as packaged for sale: 10 months.
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.

HIPRACELL (solvent):

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

EVANT:

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 and HIPRACELL (solvents):

Polypropylene vials containing 50 ml, 250 ml or 500 ml of solvent closed with type I polymeric elastomer closures and aluminium caps.

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.

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

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 17533/5004

9. DATE OF FIRST AUTHORISATION

05 February 2019

10. DATE OF REVISION OF THE TEXT

May 2023

Approved 15 May 2023

