EVALON®

Suspension and solvent for oral spray for chickens

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, S.A.
Avda. la Selva 135
17170 Amer (Girona)
SPAIN

STATEMENT OF THE ACTIVE SUBSTANCE(S):
EVALON
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.

HIPRAMUNE T (solvent)

INDICATION(S):
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.

CONTRAINDICATIONS: None.

ADVERSE REACTIONS:
None.
If you notice any serious effects or other effects not mentioned in this package leaflet, please inform your veterinary surgeon.

TARGET SPECIES: Chickens.

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.

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.

WITHDRAWAL PERIOD: Zero days.

SPECIAL STORAGE PRECAUTIONS:
Keep out of the sight and reach of children.
Store and transport refrigerated (2 ºC - 8 ºC). Do not freeze.
Shelf life of Evalon 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.
Shelf life of HIPRAMUNE T as packaged for sale: 2 years.
Do not use this veterinary medicinal product after the expiry date which is stated on the carton and the label.

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. 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 use in animals
Chickens must be strictly floor-reared in the first 3weeks after vaccination.
Vaccinate healthy chickens only. 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.

Lay
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 (symptoms, emergency procedures, 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.

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

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.

DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED:
Detailed information on this product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

OTHER INFORMATION:
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.

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

LABORATORIOS HIPRA, S.A. Avda. la Selva, 135 . 17170 Amer (Girona) Spain
Tel. (34) 972 43 06 60. Fax (34) 972 43 06 61. hipra@hipra.com

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

Evalon:
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.

HIPRAMUNE T (solvent):
Adjuvant:
Montanide IMS
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 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.

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.

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.

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.

Vaccinate healthy chickens only.

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.

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 and within 2 weeks before the onset 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 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.

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 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.

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

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.

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 brunetti, Eimeria maxima, Eimeria necatrix* and *Eimeria tenella.*

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Evalon (vaccine)
Phosphate buffered solution (PBS):
- Potassium chloride
- Disodium phosphate dodecahydrate
- Potassium dihydrogen phosphate

- Sodium chloride

HIPRAMUNE T (solvent)
- Brilliant blue (E 133)
- Red AC (E 129)
- Vanillin
- Montanide IMS

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

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.

6.4. Special precautions for storage

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

6.5 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.

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 product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.
Avda. la Selva, 135

17170 Amer (Girona)
SPAIN
Tel.: +34 972 430660
Fax: +34 972 430661
E-mail: hipra@hipra.com

8. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/194/001–003

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 18/04/2016

10 DATE OF REVISION OF THE TEXT

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

ANNEX II

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

B. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE

C. STATEMENT OF THE MRLs

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

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

Name and address of the manufacturer of the biological active substances

Laboratorios Hipra, S.A.
Avda. La Selva 135, Amer, 17170 Gerona, Spain

Laboratorios Hipra, S.A.
Crta. de Susqueda, Amer, 17170 Gerona, Spain

Laboratorios Hipra, S.A.
Carretera C-63, km 48.300,
Polígono Industrial El Rieral
Amer, 17170 Gerona, Spain

Name and address of the manufacturer responsible for batch release

Laboratorios Hipra, S.A.
Avda. La Selva 135, Amer, 17170 Gerona, 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.

D. OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

The MAH shall complete, within the stated timeframe, the following measures:

Description	Due date
Alignment of the manufacturers' specifications for the plastic containers with the applicant's internal specifications for the plastic containers, ensuring Ph. Eur. compliance. A copy of example certificates of analysis should be provided to confirm compliance.	Within 6 months of Commission Decision.
Alignment of the supplier's specifications for Foetal Bovine Serum (FBS) with the applicant's internal specifications for FBS, ensuring Ph. Eur. compliance. A copy of example certificates of analysis should be provided to confirm compliance.	Within 6 months of Commission Decision.

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:

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. PHARMACEUTICAL FORM

Suspension and solvent for oral spray.

4. 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).

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

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

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read 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, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/194/001
EU/2/16/194/002
EU/2/16/194/003

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

Evalon suspension for oral spray for chickens.

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

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

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

1,000 doses
5,000 doses

4. ROUTE(S) OF ADMINISTRATION

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

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

Evalon suspension for oral spray for chickens.

2. STATEMENT OF 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

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 solvent. Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read 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, S.A.
Avda. la Selva, 135
17170 Amer (Girona)
SPAIN

16. MARKETING AUTHORISATION NUMBER(S)

EU/2/16/194/003

17. MANUFACTURER'S BATCH NUMBER

Batch {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Solvent vial of 50 ml, 250 ml or 500 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HIPRAMUNE T, solvent for Evalon

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

50 ml
250 ml
500 ml

3. ROUTE(S) OF ADMINISTRATION

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:
Evalon 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, S.A.
Avda. la Selva 135
17170 Amer (Girona)
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Evalon suspension and solvent for oral spray for chickens.

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

Evalon
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.

HIPRAMUNE T (solvent)
Adjuvant:
Montanide IMS
Excipients:
Brilliant Blue (E133)
Red AC (E129)
Vanillin

4. INDICATION(S)

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. ADVERSE REACTIONS

None.
If you notice any serious effects or other effects not mentioned in this package leaflet, 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: 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	1115 ml	35 ml	250 ml	1400 ml
10,000	2230 ml	70 ml	500 ml	2800 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 PERIOD(S)

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.
Shelf life of Evalon 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.
Shelf life of HIPRAMUNE T as packaged for sale: 2 years.
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.
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 use in animals:
Chickens must be strictly floor-reared in the first 3weeks after vaccination.
Vaccinate healthy chickens only.
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.

Lay:
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 (symptoms, emergency procedures, 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.

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

Detailed information on this veterinary medicinal product is available on the website of the European Medicines Agency (http://www.ema.europa.eu/).

15. OTHER INFORMATION

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.

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

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