

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:

<i>Eimeria acervulina</i> , strain 003	332 – 450 *
<i>Eimeria brunetti</i> , strain 034	213 – 288 *
<i>Eimeria maxima</i> , strain 013	196 – 265 *
<i>Eimeria necatrix</i> , strain 033	340 – 460 *
<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.

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.

DOSEAGE 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 °C - 8 °C). 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 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.

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.

