RESPIVAC® aMPV

Lyophilisate for oculonasal suspension/use in drinking water for chickens

Name of the veterinary medicinal product
RESPIVAC aMPV lyophilisate for oculonasal suspension/use in drinking water for chickens.
Composition
Each dose contains:
Active substance:
Avian metapneumovirus subtype B, strain 1062, live $10^{1.8}$ – $10^{5.4}$ $CCID_{50}$*/dose.
*$CCID_{50}$: 50% Cell Culture Infective Dose.
White freeze-dried lyophilisate.
Target species: Chickens.
Indications for use
Active immunisation of chickens to reduce the detrimental effect caused by virulent avian metapneumovirus on the ciliary activity, which may be manifested in respiratory clinical signs.
Onset of immunity: 3 weeks post vaccination. Duration of immunity: 9 weeks post vaccination.
Contraindications: None.
Special warnings
Special warnings: Vaccinate healthy animals only.
Special precautions for safe use in the target species: Vaccinated chickens may excrete the vaccine strain at least 21 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated chickens and turkeys with vaccinated chickens should be avoided. Naïve chickens and turkeys in contact with vaccinated chickens have not shown clinical signs under experimental conditions. Appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species.
Special precautions to be taken by the person administering the veterinary medicinal product to animals: Personal protective equipment consisting of gloves should be worn when handling the veterinary medicinal product. For spray administration it is recommended to wear a protective face shield. The vaccine strain can be found in the environment for at least 21 days. Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated chickens.
Laying birds: The safety of RESPIVAC aMPV has been demonstrated during lay.
Interaction with other medicinal products and other forms of interaction: No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. A decision to use this vaccine before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.
Overdose: No adverse reactions have been observed after the administration of a 10-fold maximum dose of the vaccine.
Major incompatibilities: Do not mix with any other veterinary medicinal product.
Adverse events
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.
Dosage for each species, routes and method of administration
Oculonasal use (by coarse spray administration) or use in drinking water.
Vaccination schedule
One dose of vaccine should be applied by oculonasal use (by coarse spray administration) or via drinking water. Spray can be used from 1 day of age and drinking water from 7 days of age.
For prolonged immunity, chickens can be vaccinated every 9 weeks. The veterinarian should determine the optimum vaccination schedule according to the local epidemiological situation.
Advice on correct administration
Vaccine preparation
Use clean vaccination equipment.
Calculate the number of vials of vaccine required and the volume of water needed to vaccinate all the birds.
For spray administration the recommended volume of water for one dose of vaccine is between 0.14 and 1 ml.
For use in drinking water, the adequate volume is that which can be ingested within 2 hours at most, keeping in mind the age of the birds. If in doubt, measure water intake the day before administering the vaccine.
The final volume of vaccine needed will depend on the number of birds to be vaccinated.
Fill half of the calculated volume of clean, fresh, antiseptic and disinfectant free water (or a lower volume when using half is not feasible) into a clean container in which the vaccine vials can be submerged.

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The size of the container and the volume of water initially used should be appropriate to achieve a complete reconstitution of all vials that are required for vaccination. Remove the caps from each of the vaccine vials, submerge each one individually and remove the stopper. Shake gently until the lyophilisate is completely dissolved and dilute the resulting suspension. Once empty, the vials should be rinsed a couple of times to ensure the complete reconstitution of the vaccine.
The reconstituted vaccine is a clear, colourless suspension.
Application via oculonasal use (by coarse spray method):
Turn off ventilation during vaccination and up to 15 minutes after vaccination.
The spray applicator should be free from sediments and corrosion traces or disinfectants.
For the adjustment up to the final calculated volume, transfer the reconstituted vaccine into a container containing the remaining volume of water needed for preparation of the vaccine suspension. Fill the spray applicator with the vaccine suspension. Make sure that birds are uniformly distributed during spraying.
The vaccine should be sprayed evenly over the appropriate number of chickens at a distance of 30 - 40 cm. Vaccination is recommended assuring a droplet size of ≥ 120 µm.
Application via drinking water:
Water should be withheld for 1 - 2 hours prior vaccination, depending on the environmental conditions, to increase the thirst of the birds to ensure that all reconstituted vaccine is consumed within 2 hours.
Confirm that all elements for the drinking equipment are thoroughly clean and free of any trace of antiseptics or disinfectants.
For the adjustment up to the final calculated volume, transfer the reconstituted vaccine into a container containing the remaining volume of water needed for preparation of the vaccine suspension. Transfer the vaccine suspension to the drinking equipment.
Withdrawal periods: 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. Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 2 hours.
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.
Classification of veterinary medicinal products: Veterinary medicinal product subject to prescription.
Marketing authorisation numbers and pack sizes
Marketing authorisation numbers: EU/2/24/314/001-008.
Pack sizes:
Cardboard box with 1 lyophilisate vial containing 1 000 doses.
Cardboard box with 1 lyophilisate vial containing 2 000 doses.
Cardboard box with 1 lyophilisate vial containing 5 000 doses.
Cardboard box with 1 lyophilisate vial containing 10 000 doses.
Cardboard box with 10 lyophilisate vials containing 1 000 doses.
Cardboard box with 10 lyophilisate vials containing 2 000 doses.
Cardboard box with 10 lyophilisate vials containing 5 000 doses.
Cardboard box with 10 lyophilisate vials containing 10 000 doses.
Not all pack sizes may be marketed.
Date on which the package leaflet was last revised
07/2024. Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).
Contact details
Marketing authorisation holder, 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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