ANNEX I

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIVAC aMPV lyophilisate for oculonasal suspension/use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE 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

Excipients:

Qualitative composition of excipients and other constituents
Dextran 70
Sucrose
Gelatine
NZ Amine
Sorbitol
Potassium dihydrogen phosphate
Dipotassium phosphate

White freeze-dried lyophilisate

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

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

3.3 Contraindications

None.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

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 at least for 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.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

None.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Laying birds:

The safety of RESPIVAC aMPV has been demonstrated during lay.

3.8 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.

3.9 Administration routes and dosage

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.

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. 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.

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

No adverse reactions have been observed after the administration of a 10-fold maximum dose of the vaccine.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance.

Any person intending to manufacture, import, possess, distribute, sell, supply and use this veterinary medicinal product must first consult the relevant Member State's competent authority on the current vaccination policies, as these activities may be prohibited in a Member State on the whole or part of its territory pursuant to national legislation.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD01

The vaccine contains the avian metapneumovirus subtype B, strain 1062, live. Upon administration, the vaccine induces active immunity in chickens against avian metapneumovirus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

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

5.4 Nature and composition of immediate packaging

Type I glass vials of 10 ml containing 1 000 doses, 2 000 doses, 5 000 doses, or 10 000 doses of lyophilisate closed with Type I bromobutyl stoppers and sealed with aluminium caps.

Package 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.

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

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 national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

7. MARKETING AUTHORISATION NUMBER(S)

EU/2/24/314/001-008

8. DATE OF FIRST AUTHORISATION

Date of first authorisation: 30/05/2024

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

ANNEX II

OTHER CONDITIONS AND REQUIREMENTS OF THE MARKETING AUTHORISATION

None

ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIVAC aMPV lyophilisate for oculonasal suspension/use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

Avian metapneumovirus subtype B, strain, 1062, live $10^{1.8} – 10^{5.4}$ $CCID_{50}$*/dose
*$CCID_{50}$: 50% Cell Culture Infective Dose

3. PACKAGE SIZE

1 000 doses.
2 000 doses.
5 000 doses.
10 000 doses.
10 x 1 000 doses.
10 x 2 000 doses.
10 x 5 000 doses.
10 x 10 000 doses.

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oculonasal use (by spray) or in drinking water use.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not freeze.
Protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

LABORATORIOS HIPRA, S.A.

14. MARKETING AUTHORISATION NUMBERS

EU/2/24/314/001-008

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Lyophilisate vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

RESPIVAC aMPV

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Avian metapneumovirus subtype B, strain 1062, live $10^{1.8} – 10^{5.4}$ $CCID_{50}$*/dose
*$CCID_{50}$: 50% Cell Culture Infective Dose

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

Once reconstituted use within 2 hours.

5. PACKAGE SIZE

1 000 doses.
2 000 doses.
5 000 doses.
10 000 doses.

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

RESPIVAC aMPV lyophilisate for oculonasal suspension/use in drinking water for chickens

2. 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

3. Target species

Chickens.

4. 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

5. Contraindications

None.

6. 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.

7. 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: {national system details}.

8. 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.

9. 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. 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.

10. Withdrawal periods

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.
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.

12. 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.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. 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.

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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.

15. Date on which the package leaflet was last revised

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

16. 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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