LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1 or 10 vials of 1,000, 2,000 or 5,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC lyophilisate for suspension

2. STATEMENT OF ACTIVE SUBSTANCES

Per dose:
Live avian pneumovirus, PL21 strain ≥ 2.3 $\log_{10}$ $CCID_{50*}$
* $CCID_{50}$ = 50% cell culture infective dose.

3. PACKAGE SIZE

10 x 1,000 doses
10 x 2,000 doses
10 x 5,000 doses
1 x 1,000 doses
1 x 2,000 doses
1 x 5,000 doses

4. TARGET SPECIES

Chickens

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral route (broiler, pullet)/spray route (pullet).

7. WITHDRAWAL PERIODS

Withdrawal period: zero days.

8. EXPIRY DATE

Exp.{dd/mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

After reconstitution, do not store above 25 °C.
Broached vials should not be stored.

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 SIGHTAND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

14. MARKETING AUTHORISATION NUMBERS

Vm 08327/3006

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Vial of 1,000, 2,000 or 5,000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1,000 doses
2,000 doses
5,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {dd/mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

NEMOVAC lyophilisate for oculonasal suspension/use in drinking water

2. Composition

Each dose of reconstituted vaccine contains:

Active substance:
Live avian pneumovirus, PL21 strain, at least 2.3 $\log_{10}$ $CCID_{50*}$
* $CCID_{50}$ = 50% cell culture infective dose

Pale pellet

3. Target species

Chickens

4. Indications for use

For broiler chickens:
For active immunisation of chickens from 7 to 14 days of age to reduce upper respiratory signs associated with avian pneumovirus infection (Swollen Head Syndrome).

Onset of immunity: 17 days after vaccination.
Duration of immunity: 5 weeks after vaccination.

For breeder and layer pullets:
For active immunisation of pullets from 14 weeks of age to reduce respiratory signs associated with avian pneumovirus infection before booster vaccination with an inactivated vaccine containing avian pneumovirus.
For onset of immunity and duration of immunity of full schedule, see leaflet of the inactivated booster vaccine.

5. Contraindications

None

6. Special warnings

Vaccinate healthy animals only.

Special precautions for safe use in the target species:
The product is a live vaccine and is excreted from vaccinated birds and so spreads to unvaccinated chickens and turkeys. Reversion to virulence trials carried out in the laboratory have shown that the strain does not revert to virulence neither in chickens nor in turkeys.
However, precautionary measures have to be followed in order to diminish the spread, see “Advice on correct administration” and “Special precautions for disposal”.

It is advised not to vaccinate in the presence of other sensitive species (guinea fowl, pheasant), taking into account the spread of the vaccine strain and the lack of safety data for these species.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Care should be taken during reconstitution and administration of the vaccine.
Wash hands and wear disposable gloves during reconstitution and administration of the vaccine.
Hands should be washed and disinfected after vaccinating.

Laying birds:
Do not use in birds in lay.

Interaction with other medicinal products and other forms of interaction:
Safety and efficacy data are available which demonstrate that the simultaneous use of the vaccine and Infectious Bursal Disease, Infectious Bronchitis and Newcastle Disease vaccines may slightly decrease or transiently delay the humoral response of animals to NEMOVAC. The simultaneous use of the vaccine and Infectious Bronchitis vaccine may decrease and/or delay the Infectious Bronchitis seroconversion. Therefore, no other vaccine should be used simultaneously with the product.

Major incompatibilities:
Only disinfectant-free and/or antiseptic-free water should be used for the preparation of vaccine solution.
Do not mix with other veterinary medicinal products.

7. Adverse events

None known.
In layer and breeder pullets, refer to the package leaflet of the inactivated booster vaccine.

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, the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system via your national reporting system: {national system}.

8. Dosage for each species, routes and method of administration

Broiler chickens:
One dose of vaccine to be administered from 7 to 14 days of age when levels of maternally derived antibodies are low, or at 14 days of age when levels of maternally derived antibodies are likely to be high.

Breeder/layer pullets:
One dose of vaccine to be administered at 14 weeks of age before booster vaccination with inactivated vaccine prior to the onset of lay.

9. Advice on correct administration

Apply the usual aseptic precautions to all administration procedures.
Calculate the number of vials of vaccine required to vaccinate all the birds. Treat all water to come into contact with the vaccine with skimmed milk powder at a rate of 2.5 g per litre (use only clean, antiseptic and disinfectant free drinking water).
Half fill a plastic (non-metallic) container in which a vaccine vial can be submerged with the clean treated drinking water.
Remove the metal caps from each of the vaccine bottles, submerge each one individually and remove the rubber cap. Rinse the bottle, remove the cap and bottle and discard appropriately.
Repeat for each bottle.

Administration by oral route (broilers and pullets)
For 1,000 birds, reconstitute the freeze-dried pellet corresponding to 1,000 doses in a small quantity of non-chlorinated drinking water and subsequently dilute it into a volume of non-chlorinated drinking water to be consumed within 1 to 2 hours. Birds may have drinking water withdrawn for 1 to 2 hours before administering vaccine.

Administration by spray route (pullets)
For 1,000 birds, reconstitute the freeze-dried pellet corresponding to 1,000 doses into 1 ml of non-chlorinated water and subsequently dilute it into the volume of non-chlorinated water according to the type of sprayer used (pressure-sprayer or sprayer with rotary cone, for further information on sprayer equipment, contact the manufacturer).
Spray the vaccine solution above the birds using a sprayer capable of producing droplets with a mean diameter of 80 to 150 µm.
For proper vaccine distribution, make sure that birds are evenly distributed during spraying.
The ventilation system of the poultry house should be inoperative during the spray administration.

The reconstituted product appears as a pale suspension.

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.
After reconstitution, do not store above 25 °C.
Shelf-life after reconstitution according to directions: 2 hours.
Broached vials should not be stored.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp.

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

Plastic box with 1 or 10 vials of 1,000 doses.
Plastic box with 1 or 10 vials of 2,000 doses.
Plastic box with 1 or 10 vials of 5,000 doses.
Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

November 2023

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:
Boehringer Ingelheim Animal Health UK Ltd, Bracknell, RG12 8YS, UK

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire de Porte des Alpes
99 rue de l'aviation
69800 Saint-Priest, France

Local representatives and contact details to report suspected adverse reactions:

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