SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC lyophilisate for oculonasal suspension/use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substance:
Live avian pneumovirus, PL21 strain, at least 2.3 log10 CCID50*
* CCID50 = 50% cell culture infective dose.

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension
Pale Pellet

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

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

Onset of immunity: 17 days after vaccination.
Duration of immunity: 3 weeks after vaccination.

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

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only

4.5 Special precautions for use

Special precautions for use in animals:
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 4.5, 4.9, and 6.6.

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.

Special precautions for the protection of the environment:
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

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

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 the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

Laying birds:
Do not use in birds in lay.

4.8 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.

4.9 Amount(s) to be administered and administration route

Broiler chickens:
One dose of vaccine to be administered between 7 and 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.

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 2.5g 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 1-2 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 80-150 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.

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

None known.

4.11 Withdrawal period(s)

Zero days

5. IMMUNOLOGICAL PROPERTIES

Pharmaceutical group: Immunologicals for aves, Live viral vaccines for domestic fowl, avian rhinotracheitis virus
ATCvet code: QI01AD01.

The vaccine stimulates active immunity of broilers chicken against avian pneumovirus infection (Swollen Head Syndrome).
The vaccine stimulates active immunity of breeder and layer pullets against avian pneumovirus infection (Swollen Head Syndrome), when used as a primer before booster vaccination with an inactivated vaccine containing pneumovirus.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Protein hydrolysate
Bovine albumin
Povidone
Sucrose
Mannitol
Monopotassium phosphate
Dipotassium phosphate
Potassium glutamate

6.2 Major incompatibilities

Only disinfectant-free and/or antiseptic-free water should be used for the preparation of vaccine solution. In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf-life after reconstitution according to directions: 2 hours

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C)
Protect from light.
Do not freeze.
After reconstitution, do not store above 25°C.
Broached vials should not be stored

6.5 Nature and composition of immediate packaging

Type of immediate packaging:
Type I glass vial, with butyl elastomer closure and aluminium cap.

Plastic box with 1 or 10 vials of 1,000 doses.

Plastic box of 1 or 10 vials of 2,000 doses.
Plastic box of 1 or 10 vials of 5,000 doses.

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

Medicines should not be disposed of via wastewater.
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

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/5008

9. DATE OF FIRST AUTHORISATION

16 April 1999

10. DATE OF REVISION OF THE TEXT

May 2024

Prohibition of sale, supply and/or use

Not applicable

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Approved: 07 May 2024