

**IRISH MEDICINES BOARD ACT 1995, as amended**

**European Communities (Animal Remedies) (No. 2) Regulations 2007**

VPA: **10857/035/001**  
Case No: 7006308

The Irish Medicines Board in exercise of the powers conferred on it by Animal Remedies (No. 2) Regulations (S.I. No. 786 of 2007) hereby grants to:

**Merial Animal Health Limited**

**Sandringham House, Sandringham Avenue, Harlow Business Park, Harlow, Essex CM19 5TG, United Kingdom**

an authorisation, subject to the provisions of the said Regulations and the general conditions of the attached authorisation, in respect of the Veterinary Medicinal Product:

**Nemovac**

The particulars of which are set out in the attached Schedule. The authorisation is also subject to any special conditions as may be specified in the Schedule.

The authorisation,unless revoked, shall continue in force from **17/12/2009**.

Signed on behalf of the Irish Medicines Board

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A person authorised in that behalf by the said Board.

(NOTE: This authorisation replaces any previous authorisation in respect of this product which is now null and void.)

## Part II

### Summary of Product Characteristics

#### 1 NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

#### 2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

**Active substance:**

Live pneumovirus, PL21 strain, at least  $2.3 \log_{10} \text{CCID}_{50}$

$\text{CCID}_{50}$  = 50% cell culture infective dose.

For a full list of excipients, see section 6.1.

#### 3 PHARMACEUTICAL FORM

Lyophilisate for suspension

#### 4 CLINICAL PARTICULARS

##### 4.1 Target Species

Broiler chickens between 7 and 14 days.

Breeder and layer pullets from 14 weeks of age.

##### 4.2 Indications for use, specifying the target species

For broiler chickens:

For active immunisation of chickens to reduce upper respiratory signs associated with avian pneumovirus infection (Swollen Head Syndrome).

Immunity has been demonstrated 17 days after vaccination and has been shown to persist for a further three weeks.

For breeder and layer pullets:

Priming for active immunisation of pullets 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

Do not vaccinate unhealthy birds.

Do not use in chickens in lay.

#### **4.4 Special warnings for each 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 4.3, 4.5, 4.9, and 6.6.

The safety studies were carried out by oculo-nasal and oral administration and no side effects were observed. 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.

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals**

None.

##### **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.

#### **4.6 Adverse reactions (frequency and seriousness)**

None known.

In layer and breeder pullets, refer to the SPC of the inactivated booster vaccine.

#### **4.7 Use during pregnancy, lactation or lay**

Do not use in chickens 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 a decision to use this vaccine before or after any other veterinary medicinal product needs to be made on a case by case basis.

## 4.9 Amounts to be administered and administration route

### 4.9.1 Posology

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.

### 4.9.2 Method and route of 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 2.5g 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.

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

None known.

## 4.11 Withdrawal Period(s)

Zero days.

## 5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

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.

ATCvet code: QI01AD01.

## 6 PHARMACEUTICAL PARTICULARS

### 6.1 List of excipients

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

### 6.2 Incompatibilities

Only disinfectant-free and/or antiseptic-free water should be used for the preparation of vaccine solution.  
As no information is available, do not mix with other 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 at 2-8°C in the outer container (also during transport), protected from light.  
After reconstitution, store at 25°C.  
Do not freeze.  
Part used vials should not be stored

### 6.5 Nature and composition of immediate packaging

1,000-dose (type I glass) bottle, with butyl elastomer closure and aluminium cap.  
1,000-dose (type I glass) bottle, with butyl elastomer closure and aluminium cap, box of 10 bottles.  
2,000-dose (type I glass) bottle, with butyl elastomer closure and aluminium cap.  
2,000-dose (type I glass) bottle, with butyl elastomer closure and aluminium cap, box of 10 bottles.  
5,000-dose (type I glass) bottle, with butyl elastomer closure and aluminium cap.  
5,000-dose (type I glass) bottle, with butyl elastomer closure and aluminium cap, box of 10 bottles.

Not all pack sizes may be marketed.

### 6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Empty containers or contaminated equipment should be disposed of safely by boiling, incineration or immersion in appropriate disinfectant approved for use by the competent authorities.

## 7 MARKETING AUTHORISATION HOLDER

Merial Animal Health Ltd  
PO Box 327, Sandringham House  
Harlow Business Park, Harlow  
Essex CM19 5TG  
United Kingdom

**8 MARKETING AUTHORISATION NUMBER(S)**

VPA 10857/035/001

**9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

17th December 2009

**10 DATE OF REVISION OF THE TEXT**