# LABELLING AND PACKAGE LEAFLET

# A. LABELLING

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of one 1,000-dose bottle

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

## 3. PHARMACEUTICAL FORM

Lyophilisate for suspension

## 4. PACKAGE SIZE

**1 000 doses**

## 5. TARGET SPECIES

Chickens

## 6. INDICATION(S)

Active immunisation against avian pneumovirus infection

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route (broiler, pullet)/spray route (pullet)
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

**Withdrawal period:** zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not use in chickens in lay.

## 10. EXPIRY DATE

EXP:
Use within 2 hours after reconstitution

## 11. SPECIAL STORAGE CONDITIONS

Store at 2-8°C, protected from light.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

## 14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

## 16. MARKETING AUTHORISATION NUMBER

Vm 08327/4156

VPA10454/070/001

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of ten 1,000-dose bottles

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

## 3. PHARMACEUTICAL FORM

Lyophilisate for suspension

## 4. PACKAGE SIZE

**10x1 000 doses**

## 5. TARGET SPECIES

Chickens

## 6. INDICATION(S)

Active immunisation against avian pneumovirus infection

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route (broiler, pullet)/spray route (pullet)
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

**Withdrawal period:** zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not use in chickens in lay.

## 10. EXPIRY DATE

EXP:
Use within 2 hours after reconstitution

## 11. SPECIAL STORAGE CONDITIONS

Store at 2-8°C, protected from light.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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VPA10454/070/001

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of one 2,000-dose bottle

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

## 3. PHARMACEUTICAL FORM

Lyophilisate for suspension

## 4. PACKAGE SIZE

**2 000 doses**

## 5. TARGET SPECIES

Chickens

## 6. INDICATION(S)

Active immunisation against avian pneumovirus infection

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route (broiler, pullet)/ spray route (pullet)
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

**Withdrawal period:** zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not use in chickens in lay.

## 10. EXPIRY DATE

EXP:
Use within 2 hours after reconstitution

## 11. SPECIAL STORAGE CONDITIONS

Store at 2-8°C, protected from light.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

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## 17. MANUFACTURER'S BATCH NUMBER

Batch:

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of ten 2,000-dose bottles

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

## 3. PHARMACEUTICAL FORM

Lyophilisate for suspension

## 4. PACKAGE SIZE

**10x2 000 doses**

## 5. TARGET SPECIES

Chickens

## 6. INDICATION(S)

Active immunisation against avian pneumovirus infection

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route (broiler, pullet)/spray route (pullet)
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

**Withdrawal period:** zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not use in chickens in lay.

## 10. EXPIRY DATE

EXP:
Use within 2 hours after reconstitution

## 11. SPECIAL STORAGE CONDITIONS

Store at 2-8°C, protected from light.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

## 14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

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Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

## 16. MARKETING AUTHORISATION NUMBER

Vm 08327/4156

VPA10454/070/001

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of one 5,000-dose bottle

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

## 3. PHARMACEUTICAL FORM

Lyophilisate for suspension

## 4. PACKAGE SIZE

**5 000 doses**

## 5. TARGET SPECIES

Chickens

## 6. INDICATION(S)

Active immunisation against avian pneumovirus infection

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route (broiler, pullet)/spray route (pullet)
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

**Withdrawal period:** zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not use in chickens in lay.

## 10. EXPIRY DATE

EXP:
Use within 2 hours after reconstitution

## 11. SPECIAL STORAGE CONDITIONS

Store at 2-8°C, protected from light.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

## 14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

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## 16. MARKETING AUTHORISATION NUMBER

Vm 08327/4156

VPA10454/070/001

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

## PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Box of ten 5,000-dose bottles

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

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

## 3. PHARMACEUTICAL FORM

Lyophilisate for suspension

## 4. PACKAGE SIZE

**10x5 000 doses**

## 5. TARGET SPECIES

Chickens

## 6. INDICATION(S)

Active immunisation against avian pneumovirus infection

## 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral route (broiler, pullet)/spray route (pullet)
Read the package leaflet before use.

## 8. WITHDRAWAL PERIOD

**Withdrawal period:** zero days.

## 9. SPECIAL WARNING(S), IF NECESSARY

Do not use in chickens in lay.

## 10. EXPIRY DATE

EXP:
Use within 2 hours after reconstitution

## 11. SPECIAL STORAGE CONDITIONS

Store at 2-8°C, protected from light.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only

## 14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

## 16. MARKETING AUTHORISATION NUMBER

Vm 08327/4156

VPA10454/070/001

## 17. MANUFACTURER'S BATCH NUMBER

Batch:

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

1,000-dose bottle

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

**1 000 doses**

## 4. ROUTE(S) OF ADMINISTRATION

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

## 5. WITHDRAWAL PERIOD

## 6. BATCH NUMBER

Batch:

## 7. EXPIRY DATE

EXP:

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Chickens
Read the package leaflet before use.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

2,000-dose bottle

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

**2 000 doses**

## 4. ROUTE(S) OF ADMINISTRATION

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

## 5. WITHDRAWAL PERIOD

## 6. BATCH NUMBER

Batch:

## 7. EXPIRY DATE

EXP:

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Chickens
Read the package leaflet before use.

**MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS**

5,000-dose bottle

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC

## 2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

## 3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

**5 000 doses**

## 4. ROUTE(S) OF ADMINISTRATION

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

## 5. WITHDRAWAL PERIOD

## 6. BATCH NUMBER

Batch:

## 7. EXPIRY DATE

EXP:

## 8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

Chickens
Read the package leaflet before use.

# B. PACKAGE LEAFLET

# PACKAGE LEAFLET
# NEMOVAC

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer for the batch release:
Boehringer Ingelheim Animal Health France SCS
Laboratoire Portes des Alpes
Rue de l'Aviation
69800 Saint Priest
France

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

NEMOVAC, lyophilisate for suspension

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

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

## 4. INDICATION(S)

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:
For active immunisation of pullets 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

Do not vaccinate unhealthy birds.
Do not use in chickens in lay.

## 6. ADVERSE REACTIONS

None known.
In layer and breeder pullets, refer to the SPC of the inactivated booster vaccine.
If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

## 7. TARGET SPECIES

Broiler chickens between 7 and 14 days.
Breeder and layer pullets from 14 weeks of age.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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.

## 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 2.5g 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.

<u>Administration by oral route (broilers and pullets)</u>
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.

<u>Administration by spray route (pullets)</u>
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.

## 10. WITHDRAWAL PERIOD

Zero days.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.
Store at 2-8°C in the outer container (also during transport), protected from light.
Do not freeze.
Part used vials should not be stored.
Shelf-life for reconstituted vaccine: 2 hours at a temperature of 25°C.

## 12. SPECIAL WARNING(S)

- 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 “Contraindications”, “Advice on correct administration” and “Special precautions for the disposal of unused product or waste materials if any”.
- 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.
- 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.
- Do not use in chickens in lay.
- The laboratory studies have shown 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 vaccines may be given concomitantly with the product.
- 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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

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.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2020

## 15. OTHER INFORMATION

**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.

Box of one 1,000-dose bottle.
Box of ten 1,000-dose bottles.
Box of one 2,000-dose bottle.
Box of ten 2,000-dose bottles.
Box of one 5,000-dose bottle.
Box of ten 5,000-dose bottles.
Not all pack sizes may be marketed.

Approved 27 May 2020