

**ANNEX I**  
**SUMMARY OF PRODUCT CHARACTERISTICS**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

AVISHIELD ND B1 + IB H120

Lyophilisate for oculonasal suspension/use in drinking water for chickens

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

### Active substances:

Live, lentogenic virus of Newcastle disease, strain Hitchner B1  $10^{6.0}$  to  $10^{7.0}$  TCID<sub>50</sub>\*

Attenuated live virus of avian infectious bronchitis, strain H-120, Massachusetts serotype  $10^{3.5}$  to  $10^{4.5}$  EID<sub>50</sub>\*\*

\*TCID<sub>50</sub> = 50% Tissue Culture Infective Dose

\*\*EID<sub>50</sub> = 50% Embryo Infective Dose

### Excipients:

For the full list of excipients, see section 6.1.

## 3. PHARMACEUTICAL FORM

Lyophilisate for oculonasal suspension/use in drinking water

Cream coloured lyophilisate

## 4. CLINICAL PARTICULARS

### 4.1 Target species

Chickens

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

For active immunisation of chickens (broilers and future layers/breeders) in order to reduce:

- detrimental effect resulting from the infection by avian infectious bronchitis virus, serotype Massachusetts on the ciliary activity, which may be manifested in respiratory clinical signs
- clinical signs and mortality due to infection with Newcastle disease virus .

Onset of immunity: 3 weeks post vaccination.

Duration of immunity: 5 weeks post vaccination

### 4.3 Contraindications

None.

### 4.4 Special warnings for each target species

Vaccinate healthy animals only.

Maternally Derived Antibodies (MDA) can interfere with the development of active immunity. In flocks where high levels of MDAs are expected, vaccination programme should be planned accordingly.

## **4.5 Special precautions for use**

### Special precautions for use in animals

Vaccinated chickens may excrete the vaccine viruses for a minimum of 10 days following vaccination. To reduce spread all the birds in the flock should be vaccinated at the same time. Duration of the spreading was not monitored longer than 10 days and during this time, the contact of immunosuppressed and unvaccinated chickens and to other bird species, if any are close by, with vaccinated chickens should be avoided.

It is possible that the vaccine viruses can be spread to non-target susceptible species, so appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species as much as possible.

### Special precautions to be taken by the person administering the veterinary medicinal product to animals

Care should be taken when handling and administering the vaccine.

Newcastle disease virus can cause a mild transient conjunctivitis in the person administering the vaccine.

Personal protective equipment consisting of well-fitting masks and eye protection to European standards should be worn when handling the veterinary medicinal product. Personnel involved in attending vaccinated chickens should follow general hygiene principles (washing/disinfecting hands, changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials litter from recently vaccinated chickens.

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

Tracheal rales for 3-13 days post vaccination occurred very commonly in the safety studies. These resolve spontaneously and do not need treatment.

A reduced weight gain until 14 days post vaccination was observed very commonly in the safety studies.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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

### Laying birds:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

## **4.8 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.

## **4.9 Amounts to be administered and administration route**

Coarse spray and oculonasal route: from one day of age

Drinking water administration: from 7 days of age

The method of application depends on the epizootiological situation, age category and number of animals.

### *Spray administration*

It is recommended to resuspend 1000 doses of the vaccine in 150 - 300 ml of distilled water.

The number of doses diluted corresponds to the number of birds in a flock.

The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds, and will vary according to the age of the birds being vaccinated and the management system.

The reconstituted vaccine suspension should be spread evenly over the correct number of chickens, at a distance of 30 – 40 cm using a coarse spray (targeted average droplet size of 150 - 170 microns), preferably when the chickens are sitting together in dim light. The spray apparatus should be free from sediments, corrosion and traces of disinfectants and ideally should be used for vaccination purposes only.

### *Oculo-nasal administration*

Each 1000 doses of the vaccine are suspended in 100 ml of distilled water.

A dose of reconstituted vaccine is 0.1 ml, i.e. two drops, irrespective of poultry age, weight and type. Instil one drop into the eye and one drop into the nostril.

For chickens aged from 1 to 14 days of smaller breeds, 4 drops of 25 µl should be used. Administer one drop in each eye (0.05 ml altogether) and then one drop in each nostril (0.05 ml altogether).

### *Drinking water administration*

Suspend the vaccine in cool and clean water without traces of chlorine, other disinfectants or impurities in a number of doses corresponding to the number of birds to be vaccinated.

The vaccine should be suspended immediately before use.

Measure the correct volume of water for the number of birds to be vaccinated. The volume of water for reconstitution depends on the age of the birds, breed, management practice and weather conditions. In order to determine the quantity of water in which vaccine will be suspended, measure the volume of water consumed within a two hours period one day before vaccination.

If this approach is not possible, an orientational method for chickens in a younger category (until third week of life), is to multiply the number of birds in the thousands with the day of life (e.g. 1 thousand of chickens in the 7th day of life = 1 x 7 = 7 L). The vaccine should be dissolved in the amount of water which will be drunk within 1.5 - 2.0 hours (taking into account the different types of drinking systems for poultry). In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to immunisation (depending on the air temperature). Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat. The drinking system should be clean, without traces of chlorine, other disinfectants or impurities.

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

After the administration of a 10 fold dose, no adverse reactions other than those described in section 4.6 were observed.

## **4.11 Withdrawal period(s)**

Zero days.

## **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: Immunologicals for aves, domestic fowl, live viral vaccines, Newcastle disease virus/paramyxovirus vaccine + avian infectious bronchitis virus vaccine

ATC vet code: QI01AD11

To stimulate active immunity against strains of Avian Infectious Bronchitis virus belonging to Massachusetts serotype and the Newcastle disease virus.

## **6. PHARMACEUTICAL PARTICULARS**

### **6.1 List of excipients**

Povidone K-25  
Bacto-peptone  
Monosodium glutamate  
Potassium dihydrogen phosphate  
Potassium hydroxide  
Dextran 40 000  
Sucrose

### **6.2 Major incompatibilities**

Do not mix with any other veterinary medicinal product.

### **6.3 Shelf life**

Shelf life of the veterinary medicinal product as packaged for sale: 18 month

Shelf life after reconstitution according to directions: 3 hours

### **6.4. Special precautions for storage**

Store and transport refrigerated (2 °C – 8 °C).

Protect from light.

Do not freeze.

### **6.5 Nature and composition of immediate packaging**

The vaccine is filled into colourless glass vials (type I), which are closed with rubber stoppers (brombutyl) and sealed with aluminium caps.

Carton with 10 vials, each containing 1000 doses of vaccine.

Carton with 10 vials, each containing 2500 doses of vaccine.

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**

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**

Genera Inc.  
Svetonedeljska cesta 2, Kalinovica,  
10436 Rakov Potok  
Croatia  
Tel: +385 1 33 88 888  
Fax: +385 1 33 88 886  
E-mail: [info.hr@dechra.com](mailto:info.hr@dechra.com)

## **8. MARKETING AUTHORISATION NUMBER(S)**

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

**10. DATE OF REVISION OF THE TEXT**

04/2018

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**ANNEX III**  
**LABELLING AND PACKAGE LEAFLET**

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**  
**{carton }**

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AVISHIELD ND B1 + IB H120, lyophilisate for oculonasal suspension/use in drinking water for chickens

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose contains:

Live, lentogenic virus of Newcastle disease, strain Hitchner B1  $10^{6.0}$  to  $10^{7.0}$  TCID<sub>50</sub>

Attenuated live virus of avian infectious bronchitis,  $10^{3.5}$  to  $10^{4.5}$  EID<sub>50</sub>  
strain H-120, Massachusetts serotype

**3. PHARMACEUTICAL FORM**

Lyophilisate for oculonasal suspension/use in drinking water

**4. PACKAGE SIZE**

10 x 1000 doses

10 x 2500 doses

**5. TARGET SPECIES**

Chickens

**6. INDICATION(S)**

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

For oculonasal, spray or drinking water administration

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period: zero days

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

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP

Once reconstituted use within 3 hours.

**11. SPECIAL STORAGE CONDITIONS**

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

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

Dispose of waste material in accordance with local requirements.

**13. THE WORDS “FOR ANIMAL TREATMENT ONLY” AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE**

For animal treatment only. To be supplied only on veterinary prescription.  
Administration by a veterinary surgeon or under their direct responsibility.

**14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

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

Genera Inc.  
Svetonedeljska cesta 2, Kalinovica,  
10436 Rakov Potok  
Croatia

**16. MARKETING AUTHORISATION NUMBER(S)**

**17. MANUFACTURER'S BATCH NUMBER**

Lot

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

{label}

**1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AVISHIELD ND B1 + IB H120, lyophilisate for ocular nasal suspension/use in drinking water for chickens

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

Each dose contains:

Live, lentogenic virus of Newcastle disease, strain Hitchner B1  $10^{6.0}$  to  $10^{7.0}$  TCID<sub>50</sub>

Attenuated live virus of avian infectious bronchitis,  $10^{3.5}$  to  $10^{4.5}$  EID<sub>50</sub>  
strain H-120, Massachusetts serotype

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

1000 doses

2500 doses

**4. ROUTE(S) OF ADMINISTRATION**

Ocular nasal, spray, drinking water

**5. WITHDRAWAL PERIOD(S)**

Withdrawal period: 0 d

**6. BATCH NUMBER**

Lot

**7. EXPIRY DATE**

EXP

Once reconstituted use within 3 h

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

For animal treatment only

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**AVISHIELD ND B1 + IB H120**  
Lyophilisate for ocularnasal suspension/use in drinking water, for chickens

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

Marketing authorisation holder and manufacturer responsible for batch release:

Genera Inc.  
Svetonedeljska cesta 2, Kalinovica,  
10436 Rakov Potok  
Croatia

**2. NAME OF THE VETERINARY MEDICINAL PRODUCT**

AVISHIELD ND B1 + IB H120, lyophilisate for ocularnasal suspension/use in drinking water for chickens

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

Each dose contains:

Live, lentogenic virus of Newcastle disease, strain Hitchner B1  $10^{6.0}$  to  $10^{7.0}$  TCID<sub>50</sub>\*

Attenuated live virus of avian infectious bronchitis,  $10^{3.5}$  to  $10^{4.5}$  EID<sub>50</sub>\*\*  
strain H-120, Massachusetts serotype

\*TCID<sub>50</sub> = 50% Tissue Culture Infective Dose

\*\*EID<sub>50</sub> = 50% Embryo Infective Dose

Cream coloured lyophilisate.

**4. INDICATION(S)**

For active immunisation of chickens (broilers and future layers/breeders) in order to reduce:

- detrimental effect resulting from the infection by avian infectious bronchitis virus, serotype Massachusetts on the ciliary activity, which may be manifested in respiratory clinical signs .
- clinical signs and mortality due to infection with Newcastle disease virus.

Onset of immunity: 3 weeks post vaccination.

Duration of immunity: 5 weeks post vaccination

**5. CONTRAINDICATIONS**

None.

**6. ADVERSE REACTIONS**

Tracheal rales for 3-13 days post vaccination occurred very commonly in the safety studies. These resolve spontaneously and do not need treatment.

A reduced weight gain until 14 days post vaccination was observed very commonly in the safety studies.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated )
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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 inform your veterinary surgeon.

## **7. TARGET SPECIES**

Chickens

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

Vaccination:

Coarse spray and oculonasal route: from one day of age

Drinking water administration: from 7 days of age

The method of application depends on the epizootiological situation, age category and number of animals.

### *Spray administration*

It is recommended to resuspend 1000 doses of the vaccine in 150 - 300 ml of distilled water.

The number of doses diluted corresponds to the number of birds in a flock.

The volume of water for reconstitution should be sufficient to ensure an even distribution when sprayed onto the birds, and will vary according to the age of the birds being vaccinated and the management system.

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### *Oculo-nasal administration*

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A dose of reconstituted vaccine is 0.1 ml, i.e. two drops, irrespective of poultry age, weight and type.

Instil one drop into the eye and one drop into the nostril.

For chickens aged from 1 to 14 days of smaller breeds, 4 drops of 25 µl should be used. Administer one drop in each eye (0.05 ml altogether) and then one drop in each nostril (0.05 ml altogether).

### *Drinking water administration*

Suspend the vaccine in cool and clean water without traces of chlorine, other disinfectants or impurities in a number of doses corresponding to the number of birds to be vaccinated.

The vaccine should be suspended immediately before use.

Measure the correct volume of water for the number of birds to be vaccinated. The volume of water for reconstitution depends on the age of the birds, breed, management practice and weather conditions. In order to determine the quantity of water in which vaccine will be suspended, measure the volume of water consumed within a two hours period one day before vaccination.

If this approach is not possible, an orientational method for chickens in a younger category (until third week of life), is to multiply the number of birds in the thousands with the day of life (e.g. 1 thousand of chickens in the 7th day of life =  $1 \times 7 = 7$  L). The vaccine should be dissolved in the amount of water which will be drunk within 1.5 - 2.0 hours (taking into account the different types of drinking systems for poultry). In order to make the birds thirsty, withdraw the supply of drinking water up to 2 hours prior to immunisation (depending on the air temperature). Always make sure that there is food available when vaccinating. Birds will not drink if they have no food to eat. The drinking system should be clean, without traces of chlorine, other disinfectants or impurities.

## **9. ADVICE ON CORRECT ADMINISTRATION**

All the birds in the flock should be vaccinated at the same time.

## **10. WITHDRAWAL PERIOD(S)**

Zero days.

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store and transport refrigerated (2 °C – 8 °C).

Protect from light.

Do not freeze.

Do not use this veterinary medicinal product after the expiry date which is stated on the label and carton.

Shelf life after reconstitution: 3 hours

## **12. SPECIAL WARNING(S)**

Special warnings for each target species:

Vaccinate healthy animals only.

Maternally Derived Antibodies (MDA) can interfere with the development of active immunity. In flocks where high levels of MDAs are expected, vaccination programme should be planned accordingly.

Special precautions for use in animals:

Vaccinated chickens may excrete the vaccine viruses for a minimum of 10 days following vaccination. To reduce spread all the birds in the flock should be vaccinated at the same time. Duration of the spreading was not monitored longer than 10 days and during this time, the contact of immunosuppressed and unvaccinated chickens and to other bird species, if any are close by, with vaccinated chickens should be avoided.

It is possible that the vaccine viruses can be spread to non-target susceptible species, so appropriate veterinary and husbandry measures should be taken to avoid spread of the vaccine strain to susceptible species as much as possible.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Care should be taken when handling and administering the vaccine.

Newcastle disease virus can cause a mild transient conjunctivitis in the person administering the vaccine.

Personal protective equipment consisting of well-fitting masks and eye protection to European standards should be worn when handling the veterinary medicinal product. Personnel involved in attending vaccinated chickens should follow general hygiene principles (washing/disinfecting hands,

changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials litter from recently vaccinated chickens.

Lay:

Do not use in birds in lay and within 4 weeks before the start of the laying period.

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 (symptoms, emergency procedures, antidotes):

After the administration of a 10 fold dose, no adverse reactions other than those described in section "Adverse reaction" were observed.

Incompatibilities:

Do not mix with any other veterinary medicinal product.

**13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

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

**15. OTHER INFORMATION**

The vaccine stimulates active immunity against strains of Avian Infectious Bronchitis virus belonging to Massachusetts serotype and the Newcastle disease virus.

For animal treatment only. To be supplied only on veterinary prescription  
Administration by a veterinary surgeon or under their direct responsibility

Carton with 10 vials of 1000 doses of vaccine.  
Carton with 10 vials of 2500 doses of vaccine.  
Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.