

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

## **A. LABELLING**

**PARTICULARS TO APPEAR ON THE OUTER PACKAGE**

Cardboard boxes

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

HATCHPAK IB H120 NEO effervescent tablet for ocular suspension

**2. STATEMENT OF ACTIVE SUBSTANCES**

Each dose contains:

Live Infectious Bronchitis virus, H120 strain: 3.7 to 4.7 log<sub>10</sub> EID<sub>50</sub>

**3. PACKAGE SIZE**

1 blister of 10 tablets of 1000 doses (10 x 1,000 doses)  
10 blisters of 10 tablets of 1000 doses (100 x 1,000 doses)  
1 blister of 10 tablets of 2000 doses (10 x 2,000 doses)  
10 blisters of 10 tablets of 2000 doses (100 x 2,000 doses)

**4. TARGET SPECIES**

One-day-old chickens.

**5. INDICATIONS**

**6. ROUTES OF ADMINISTRATION**

Ocular use.

**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 keep unused tablets removed from the blister.  
Keep the blisters in the outer carton.

**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 SIGHT AND REACH OF CHILDREN”**

Keep out of the sight and reach of children.

**13. NAME OF THE MARKETING AUTHORISATION HOLDER**

Boehringer Ingelheim Animal Health UK Ltd

Manufactured using technology under license from Phibro Animal Health Corporation USA and its affiliates.

**14. MARKETING AUTHORISATION NUMBERS**

Vm 08327/3004

**15. BATCH NUMBER**

Lot {number}

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

Polyamide - aluminium – PVC / aluminium blister

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

HATCHPAK IB H120 NEO  
HATCHPAK IB H120



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE**

1,000 d.  
2,000 d.

**3. BATCH NUMBER**

Lot {number}

**4. EXPIRY DATE**

Exp. {dd/mm/yyyy}

## **B. PACKAGE LEAFLET**

## PACKAGE LEAFLET:

### 1. Name of the veterinary medicinal product

HATCHPAK IB H120 NEO effervescent tablet for oculonasal suspension for chickens

### 2. Composition

Each dose contains:

**Active substance:**

Live Infectious Bronchitis virus, H120 strain .....3.7 to 4.7 log<sub>10</sub> EID<sub>50</sub> (\*)

(\*) EID<sub>50</sub>: 50 per cent egg infective dose.

Orange mottled, round tablet.

### 3. Target species

One-day-old chickens.

### 4. Indications for use

In one-day-old chickens: active immunisation against Infectious Bronchitis in order to reduce infection with Massachusetts serotype of Infectious Bronchitis virus.

Onset of immunity: 21 days.

Duration of immunity: 6 weeks after a single administration.

### 5. Contraindications

None.

### 6. Special warnings

Vaccinate healthy animals only.

Special precautions safe for use in the target species:

Vaccine viruses can spread to unvaccinated birds. Infection of unvaccinated chickens with the vaccine virus from vaccinated birds does not cause any signs of disease. Reversion to virulence trials carried out in the laboratory have shown that the vaccine viruses do not acquire any pathogenic characteristics after at least 5 passages in chickens.

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

Wear respiratory and eye protection during spraying.

Wash and disinfect hands and equipment after vaccinating.

Laying birds:

The vaccine is only intended for use in newly hatched chicks and is not appropriate after the age of one day. The data available on the properties of the strain are not indicative of a detrimental effect on the reproductive tract.

Interactions with other medicinal products and other forms of interaction:

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with a Boehringer Ingelheim's frozen live vaccine against Newcastle disease containing VG/GA-Avinew strain, and can be administered on the same day but not mixed with a Boehringer Ingelheim's recombinant HVT vaccine expressing the protective antigen of the Infectious Bursal disease virus.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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:

No side effects other than those listed in paragraph "Adverse events" have been observed following the administration of more than 10 times the recommended dose of vaccine.

Major incompatibilities:

The presence of disinfectant and/or antiseptic in water and material used for the preparation of the vaccine solution is not compatible with effective vaccination. Do not mix with any other medicinal product, except live frozen vaccine against Newcastle disease containing VG/GA-Avinew strain.

## **7. Adverse events**

One-day-old chickens:

<b>Very common</b> (> 1 animal / 10 animals treated):
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Bronchial rales*
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\* not associated with respiratory distress or any general sign between 5 and 14 days after vaccination

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.

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

### Route:

Oculonasal route (coarse spray application).

### Reconstitution of the vaccine:

1. Prepare a container filled with the appropriate quantity of clean non-chlorinated drinking water (7 to 30 ml per box of 100 chicks according to the type of sprayer used in the hatchery).
2. Dissolve a number of tablets corresponding to the number of doses to be administered in a container holding the appropriate quantity of clean non-chlorinated water prepared at step 1.
3. Wait until complete dissolution of the tablets before using the vaccine solution. The reconstituted vaccine is a yellow solution, and a foam layer may form over the surface.
4. Where HatchPak Avinew frozen suspension (ampoules carried by a green cane) is to be used concurrently, transfer the content of one ampoule prepared according to the leaflet's instructions into the container, which has previously been used to prepare Hatchpak IB H120 Neo.
5. The reconstituted vaccine prepared according to the instructions is ready for use. It should be used immediately after preparation and therefore the tablets should only be removed from blisters when needed.

### Posology:

One administration to one-day-old chicks.

### Method of administration:

- The vaccine is intended for mass vaccination of chicks in the hatchery, the vaccine solution should be applied as a coarse spray whilst the chicks are in their chick boxes.
- Spray the vaccine solution above the birds using a sprayer that enables production of drops of 100 µm or more and cover the chicks with the vaccine. In this way, the vaccine is administered directly to their eye and additionally the droplets that shine on the down and the box will encourage them to pick them off from each other and from the surface of the box.
- For effective vaccine administration, make sure that the birds are closely confined together during spraying. During and directly after vaccination ventilation should be switched off in order to avoid turbulences.

## **9. Advice on correct administration**

Wait until complete dissolution of the tablets before using the vaccine solution. The presence of disinfectant and/or antiseptic in water and material used for the preparation of the vaccine solution is not compatible with effective vaccination.

## **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 keep unused tablets removed from the blister.

Keep the blisters in the outer carton.

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

Shelf life after opening the immediate packaging: use immediately.

Shelf life after reconstitution according to directions: 2 hours.

## **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. Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

***FOR GB and UK(NI) ONLY: Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirement***

## **13. Classification of veterinary medicinal products**

Veterinary medicinal product subject to prescription.

## **14. Marketing authorisation numbers and pack sizes**

Vm 08327/3004

Cardboard box of 1 blister of 10 tablets of 1,000 or 2,000 doses

Cardboard box of 10 blisters of 10 tablets of 1,000 or 2,000 doses

Not all pack sizes may be marketed.

## **15. Date on which the package leaflet was last revised**

February 2023

Detailed information on this veterinary medicinal product is available in the Union Product Database.

## **16. Contact details**

Marketing authorisation holder:

Boehringer Ingelheim Animal Health UK Ltd  
Ellesfield Avenue  
Bracknell  
Berkshire  
RG12 8YS

Manufacturer responsible for batch release:

Boehringer Ingelheim Animal Health France SCS  
Laboratoire Porte des Alpes  
Rue de l'Aviation  
69800 Saint Priest  
France

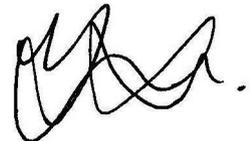
Local representatives and contact details to report suspected adverse reactions:

*To be completed nationally.*

## **17. Other information**

For animal treatment only.

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A handwritten signature in black ink, consisting of several loops and a final flourish.

Approved: 30 March 2023