

## **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 nebuliser suspension for chickens

Live Infectious Bronchitis virus, H120 strain

**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. PHARMACEUTICAL FORM**

Effervescent tablet for nebuliser suspension

**4. PACKAGE SIZE**

1 blister of 10 tablets of 1,000 doses (10 x 1,000 doses)

10 blisters of 10 tablets of 1,000 doses (100 x 1,000 doses)

1 blister of 10 tablets of 2,000 doses (10 x 2,000 doses)

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

**5. TARGET SPECIES**

One-day-old chickens.

**6. INDICATION(S)**

Read the package leaflet before use.

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

Read the package leaflet before use.

**8. WITHDRAWAL PERIOD(S)**

Withdrawal period(s): Zero days.

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

Read the package leaflet before use.

**10. EXPIRY DATE**

EXP {month/year}

Once reconstituted use within 2 hours.

**11. SPECIAL STORAGE CONDITIONS**

Store and transport refrigerated.

Do not keep unused tablets removed from the blister.

Keep the blisters in the outer carton.

**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. To be supplied only on veterinary prescription.

**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**

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

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

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

**16. MARKETING AUTHORISATION NUMBER**

Vm 08327/4280

VPA10454/061/001

**17. MANUFACTURER'S BATCH NUMBER**

Lot {number}

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS**

Polyamide - aluminium – PVC / aluminium blister

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

HATCHPAK IB H120 NEO

Effervescent tablet for nebuliser suspension for chickens

1,000 d.

2,000 d.



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

BOEHRINGER

**3. EXPIRY DATE**

EXP {month/year}

**4. BATCH NUMBER**

Lot {number}

**5. THE WORDS “FOR ANIMAL TREATMENT ONLY”**

For animal treatment only.

**B. PACKAGE LEAFLET**

**PACKAGE LEAFLET:**  
**HATCHPAK IB H120 NEO effervescent tablet for nebuliser suspension 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:

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

Boehringer Ingelheim Vetmedica GmbH, 55216 Ingelheim/Rhein, Germany

Manufacturer responsible for 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**

HATCHPAK IB H120 NEO

Effervescent tablet for nebuliser suspension for chickens

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

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.

**4. INDICATION(S)**

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. ADVERSE REACTIONS**

Bronchial rales, not associated with respiratory distress or any general sign, are very common between 5 and 14 days after vaccination.

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**

One-day-old chickens.

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

### Route:

Respiratory route (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 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).  
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 blister: use immediately.  
Shelf life after reconstitution according to directions: 2 hours.

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

Special warnings for each target species:

Vaccinate healthy birds only.

Special precautions for use in animals:

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:

Wash and disinfect hands and equipment after vaccinating.  
For more information, contact the manufacturer.

Lay:

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.

Interaction 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 (symptoms, emergency procedures, antidotes):

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

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.

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

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

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

February 2021

**15. OTHER INFORMATION**

For animal treatment only. To be supplied only on veterinary prescription. The vaccine contains live Infectious Bronchitis virus, H120 strain (Massachusetts serotype). The vaccine stimulates active immunity against Infectious Bronchitis.

Pack sizes:

Box of 1 blister of 10 tablets of 1,000 or 2,000 doses  
Box of 10 blisters of 10 tablets of 1,000 or 2,000 doses.

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

Approved: 11/06/21

A handwritten signature in black ink, appearing to read "D. Austin", with a horizontal line extending from the end of the signature.