PARTICULARS TO APPEAR ON THE OUTER PACKAGE {Cardboard Boxes}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HATCHPAK IB H120 NEO
Effervescent tablet for oculonasal suspension

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each dose contains:
Live Infectious Bronchitis virus, H120 strain 3.7 to 4.7 $\log_{10}$ EID_{50}

3. 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)

4. TARGET SPECIES

One-day-old chickens.

5. ROUTES OF ADMINISTRATION

Oculonasal route (coarse spray application)

6. WITHDRAWAL PERIODS

Withdrawal period(s): Zero days.

7. EXPIRY DATE

EXP {month/year}

Once reconstituted use within 2 hours.

8. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated.
Do not keep unused tablets removed from the blister.
Keep the blisters in the outer carton.

9. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use

10. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

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

Keep out of the sight and reach of children

12. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

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

13. MARKETING AUTHORISATION NUMBER

Vm 08327/5005

14. BATCH NUMBER

Lot {number}

15. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: Read package leaflet

16. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

POM-V

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS Polyamide - aluminium – PVC / aluminium blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HATCHPAK IB H120 NEO

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

1,000 d.

2,000 d.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {month/year}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

BOEHRINGER

PARTICULARS TO APPEAR ON THE 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 $\log_{10}$ EID_{50} (*)

(*) EID_{50}: 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 WARNING(S)

Special warnings for each target species:
Vaccinate healthy animals 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.
Wear respiratory and eye protection during spraying.
For Animal Treatment Only

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 events" 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.

7. ADVERSE EVENTS

One-day-old chickens:

Very common (> 1 animal / 10 animals treated):
Bronchial rales, 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, or via your national reporting system.

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

Route:
Oculonasan route (course 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 ºC – 8 ºC).
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

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

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

UK
Vm 08327/5005

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.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST REVISED

February 2023

16. CONTACT DETAILS

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

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

17. OTHER INFORMATION

For animal treatment only.
Manufactured using technology under license from Phibro Animal Health Corporation USA and its affiliates

<Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.>

MINIMUM PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGING WHERE THERE IS NO PACKAGE LEAFLET, I.e. Combined label and package leaflet {NATURE/TYPE}

[This template should only be used when all printed information is directly visible on the immediate container and cannot be used if a fold-out or concertina format is proposed.]

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

2. COMPOSITION

3. PACKAGE SIZE

4. TARGET SPECIES

5. INDICATIONS FOR USE

6. CONTRAINDICATIONS

7. SPECIAL WARNINGS

8. ADVERSE REACTIONS

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

10. ADVICE ON CORRECT ADMINISTRATION

11. WITHDRAWAL PERIOD

12. SPECIAL STORAGE PRECAUTIONS

13. SPECIAL PRECAUTIONS FOR DISPOSAL

14. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

15. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

16. DATE ON WHICH THE LABEL WAS LAST REVISED

17. CONTACT DETAILS

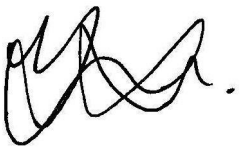
18. OTHER INFORMATION

19. THE WORDS "FOR ANIMAL TREATMENT ONLY"

20. EXPIRY DATE

21. BATCH NUMBER

22. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"



Approved: 30 March 2023