SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

HATCHPAK IB H120 NEO effervescent tablet for oculonasal suspension for chickens

2. QUALITATIVE AND QUANTITATIVE 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

Excipient(s):
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Effervescent tablet for nebuliser suspension.
Orange mottled, round tablet.

4. CLINICAL PARTICULARS

4.1 Target species

One-day-old chickens.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

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

Wear respiratory and eye protection during spraying.
Wash and disinfect hands and equipment after vaccinating.

Special precautions for the protection of the environment:
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

One-day-old chickens:

Very common (> 1 animal / 10 animals treated):	Bronchial rales*

*not associated with respiratory distress or any general sign, are very common between 5 and 14 days after vaccination.Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See also the last section of the package leaflet for respective contact details.

4.7 Use during pregnancy, lactation or lay

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.

4.8 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.

4.9 Amount(s) to be administered and administration route

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 eyes 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.

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

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: immunologicals for Aves, live viral vaccines for domestic fowl, avian infectious bronchitis virus.

ATC Vet Code: QI01AD07.

The vaccine contains live Infectious Bronchitis virus, H120 strain (Massachusetts serotype). The vaccine stimulates active immunity against Infectious Bronchitis.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Citric acid, anhydrous
Sodium hydrogen carbonate
Magnesium stearate
Sunset Yellow FCF (E 110)
Casein hydrolysate
D-Mannitol
Sodium hydroxide
Water for injections

6.2 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 Boehringer Ingelheim's live frozen vaccines against Newcastle disease containing VG/GA-Avinew strain.

6.3 Shelf life

Shelf life of the veterinary medicinal product as package for sale: 2 years.
Shelf life after opening the immediate packaging: use immediately.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Keep the blisters in the outer carton.
Do not keep unused tablets removed from the blister.
Keep the reconstituted vaccine below 25 °C.

6.5 Nature and composition of immediate packaging

Nature of primary packaging:
Polyamide - aluminium – PVC / aluminium blister.

Nature of outer packaging:
Cardboard box.

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.

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 requirement.'

7. MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim Animal Health UK Limited
Ellesfield Avenue
Bracknell
Berkshire
RG12 8YS
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 08327/5005

9. DATE OF FIRST AUTHORISATION

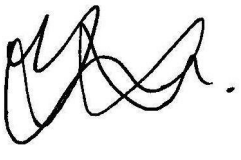
30 January 2017

10. DATE OF REVISION OF THE TEXT

March 2023

11. Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.



Approved: 30 March 2023