

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

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

HatchPak IB H120, frozen suspension for ocular use

**2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

**Per one reconstituted dose:**

**Active substances:**

Live infectious bronchitis virus, type Massachusetts, H120 strain ..... 3.7 to 4.7 log<sub>10</sub> EID<sub>50</sub>\*<sup>\*</sup>

\* EID<sub>50</sub>: 50 per cent egg infective doses

**Excipient(s):**

<b>Qualitative composition</b>
<i>Protein hydrolysate</i>
<i>Mannitol</i>
<i>Water for injection</i>

Yellow frozen suspension

**3. CLINICAL INFORMATION**

**3.1 Target species**

Chicken (one day-old chick)

**3.2 Indications for use for each target species**

In chicken (one day-old chick): 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.

**3.3 Contraindications**

None

**3.4 Special warnings**

Vaccinate healthy animals only.

**3.5 Special precautions for use**

Special precautions for safe use in 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:

Care should be taken when handling the vaccine preparation. The cold gas must not be breathed. The manipulation should take place only in well ventilated place to prevent fatal suffocation.

Wear protective gloves and spectacles during the ampoule thawing and opening operations. Skin contact with liquid nitrogen must be prevented as it can cause tissue freezing, resulting in severe burns.

Open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.

Wash and disinfect hands and equipment after vaccinating.

For more information, contact the manufacturer.

Special precautions for the protection of the environment:

Not applicable.

### 3.6 Adverse events

Chicken (one day-old chick)

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

\* not associated with respiratory distress or any general sign, may be observed 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 its local representative or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

### 3.7 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, in particular the strain is compliant to the specifications of the Ph. Eur. with regard to the safety for the reproductive tract.

### 3.8 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 frozen live vaccine against Newcastle disease containing VG/GA-AVINEW strain and with a 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.

### 3.9 Administration route and dosage

Posology:

One administration of the product from day-old, via oculonasal route (spray application).

### 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 that cover the chicks with the vaccine, so the vaccine is administered directly to their eye and the droplets pearls that shine on the down will encourage them to pick them off of each other and from the surface of the box.

For effective vaccine distribution, make sure that birds are closely confined together during spraying. During and after vaccination ventilation should be switched off in order to avoid turbulences.

### 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. Wear protective gloves and spectacles whilst thawing and opening the ampoules. Maximal precautions when handling liquid nitrogen should be taken. Refer to the section 3.5. Special precautions for use.
3. Remove from the liquid nitrogen container only those ampoules carried by a yellow cane which are to be used during the vaccination session.
4. Thaw the contents of the ampoules rapidly by agitation in water at 25-30°C. Proceed immediately to next step.
5. As soon as they are completely thawed, open the ampoules by holding them at arm's length in order to minimise risk of injury should the ampoule break.
6. Once the ampoule is open, draw up the content into a 10-ml sterile syringe.
7. Transfer the suspension into the container containing the appropriate quantity of clean non-chlorinated water prepared at step 1.
8. Draw up 5 ml of the contents of the container into the syringe.
9. Rinse the ampoule with these 5 ml, and then transfer the rinsing liquid into the container.
10. Repeat the rinsing operation once or twice.
11. Where HatchPak Avinew (carried by green cane) is to be used concurrently and presented in a second ampoule, carry out again the steps 3 to 10 (opening the ampoule, drawing up vaccine, rinsing the ampoule) with the second ampoule of vaccine. Then, transfer the contents of this second ampoule into the container which has previously been used for the first vaccine.
12. The reconstituted vaccine prepared as described is ready for use. It should be used immediately after preparation and therefore the vaccine suspension should only be prepared as and when required.
13. Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.

### **3.10 Symptoms of overdose (and where applicable emergency procedures, and antidotes)**

No adverse events other than those listed in section 3.6 have been observed following the administration of more than 10 times the recommended dose of vaccine.

### **3.11 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

### **3.12 Withdrawal periods**

Zero days.

## **4. IMMUNOLOGICAL INFORMATION**

### **4.1 ATCvet code: QI01AD07.**

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

## **5. PHARMACEUTICAL PARTICULARS**

### **5.1 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 veterinary medicinal product, except those mentioned in section 3.8 above.

### **5.2 Shelf life**

Shelf life of the veterinary medicinal product as package for sale: 3 years

Shelf-life after opening the immediate packaging: use immediately

Shelf-life after reconstitution according to directions: 2 hours

### **5.3 Special precautions for storage**

Store and transport the vaccine in liquid nitrogen (-196°C) and regularly check the level of liquid nitrogen.

Store the reconstituted vaccine below 25°C.

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

Type I glass ampoule, 4-ampoule yellow cane.

Ampoule canes are stored in canisters in liquid nitrogen containers.

10 000 doses ampoule

15 000 doses ampoule

Not all pack sizes may be marketed.

### **5.5 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

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 national collection systems applicable to the veterinary medicinal product concerned.

## **6. NAME OF THE MARKETING AUTHORISATION HOLDER**

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

## **8. DATE OF FIRST AUTHORISATION**

## **9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS**

## **10. CLASSIFICATION OF THE VETERINARY MEDICINAL PRODUCTS**

Veterinary medicinal product subject to prescription.

Detailed information on this veterinary medicinal product is available in the [Union Product Database \(https://medicines.health.europa.eu/veterinary\)](https://medicines.health.europa.eu/veterinary).

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

## **A. LABELLING**

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

**Ampoule/Glass**

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

HatchPak IB H120



**2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)**

10 000 doses

**15 000 doses**

**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, frozen suspension for ocularonasal use

### 2. Composition

Per one reconstituted dose:

#### Active substance:

Live infectious bronchitis virus, type Massachusetts, H120 strain ..... 3.7 to 4.7 log<sub>10</sub> EID<sub>50</sub>\*

\* EID<sub>50</sub>: 50 per cent egg infective doses

Yellow frozen suspension

### 3. Target species

Chicken (one day-old chick)

### 4. Indications for use

In chicken (one day-old chick): 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 for safe use in 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:

Care should be taken when handling the vaccine preparation. The cold gas must not be breathed. The manipulation should take place only in well-ventilated place to prevent fatal suffocation.

Wear protective gloves and spectacles during the ampoule thawing and opening operations. Skin contact with liquid nitrogen must be prevented as it can cause tissue freezing, resulting in severe burns.

Open ampoules holding them at arm's length in order to prevent any risk of injury should an ampoule break.

Wash and disinfect hands and equipment after vaccinating.

For more information, contact the manufacturer.

#### 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, in particular the strain is compliant to the specifications of the Ph. Eur. with regard to the safety for 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 frozen live vaccine against Newcastle disease containing VG/GA-AVINEW strain and with a 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 adverse events other than those listed in section "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 veterinary medicinal product, except those mentioned above.

### **7. Adverse events**

Chicken (one day-old chick)

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

\* not associated with respiratory distress or any general sign, may be observed 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. { national system details }

\*[To be completed nationally according to country's situation]

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

One administration of the product from day-old, via oculonasal route (spray application).

## **9. Advice on correct 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 that cover the chicks with the vaccine, so the vaccine is administered directly to their eye and the droplets pearls that shine on the down will encourage them to pick them off of each other and from the surface of the box.

For effective vaccine distribution, make sure that birds are closely confined together during spraying. During and after vaccination ventilation should be switched off in order to avoid turbulences.

### 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. Wear protective gloves and spectacles whilst thawing and opening the ampoules. Maximal precautions when handling liquid nitrogen should be taken. Refer to the section 6. Special warnings
3. Remove from the liquid nitrogen container only those ampoules carried by a yellow cane which are to be used during the vaccination session.
4. Thaw the contents of the ampoules rapidly by agitation in water at 25-30°C. Proceed immediately to next step.
5. As soon as they are completely thawed, open the ampoules by holding them at arm's length in order to minimise risk of injury should the ampoule break.
6. Once the ampoule is open, draw up the content into a 10-ml sterile syringe.
7. Transfer the suspension into the container containing the appropriate quantity of clean non-chlorinated water prepared at step 1.
8. Draw up 5 ml of the contents of the container into the syringe.
9. Rinse the ampoule with these 5 ml, and then transfer the rinsing liquid into the container.
10. Repeat the rinsing operation once or twice.
11. Where HatchPak Avinew (carried by green cane) is to be used concurrently and presented in a second ampoule, carry out again the steps 3 to 10 (opening the ampoule, drawing up vaccine, rinsing the ampoule) with the second ampoule of vaccine. Then, transfer the contents of this second ampoule into the container which has previously been used for the first vaccine.
12. The reconstituted vaccine prepared as described is ready for use. It should be used immediately after preparation and therefore the vaccine suspension should only be prepared as and when required.
13. Discard any ampoules that have been accidentally thawed. Do not re-freeze under any circumstances.

## **10. Withdrawal periods**

Zero days

## **11. Special storage precautions**

Keep out of the reach and sight of children.

Store and transport the vaccine in liquid nitrogen (-196°C) and regularly check the level of liquid nitrogen.

Store the reconstituted vaccine below 25°C.

Shelf-life after opening the immediate packaging: use immediately.

Shelf-life after reconstitution according to directions: 2 hours.

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

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

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

Veterinary medicinal product subject to prescription.

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

10 000 doses ampoule  
15 000 doses ampoule

Not all pack sizes may be marketed.

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

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

### **16. Contact details**

Marketing authorisation holder:

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:

### **17. Other information**

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

*The information below will be added with a sticker on the leaflet:*

Lot:  
Exp: