# SUMMARY OF PRODUCT CHARACTERISTICS

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

**HATCHPAK IB H120,** frozen suspension for nebuliser suspension

## 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

**Per one reconstituted dose:**

**Active substances:**
Live Infectious Bronchitis virus, H120 strain..... 3.7 to 4.7 $\log_{10}$ $EID_{50*}$

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

* 50 per cent egg infective doses

## 3. PHARMACEUTICAL FORM

Frozen suspension for nebuliser suspension. Yellow.

## 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 Massuchusetts 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 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.

### 4.5 Special precautions for use

**Special precautions for use in animals**

Vaccinate healthy birds only.

**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.

## 4.6 Adverse reactions (frequency and seriousness)

"Bronchial rales, not associated with respiratory distress or any general sign, may be observed between 5 and 14 days after vaccination in up to 15% of the birds.

## 4.7 Use during pregnancy, lactation or 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, in particular the strain is compliant to the specifications of the Ph. Eur. with regard to the safety for the reproductive tract.

## 4.8 Interaction with other medicinal products and other forms of interaction

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other except with a frozen live vaccine against Newcastle disease containing VG/GA strain and with a recombinant HVT vaccine expressing the protective antigen of the Infectious Bursal disease virus. It is therefore recommended that no other vaccines than these should be administered within 14 days before or after vaccination with the product.

## 4.9 Amounts to be administered and administration route

4.9.1 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 4.5. 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 step1.
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.

4.9.2 Posology

One administration from day-old, via the respiratory route (spray application).

4.9.3 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.

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

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.

### 4.11 Withdrawal period(s)

Zero days.

## 5. IMMUNOLOGICAL PROPERTIES

ATCVet 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

Protein hydrolysate
Mannitol

### 6.2 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 a live frozen vaccine against Newcastle disease containing VG/GA strain.

### 6.3 Shelf life

Shelf life of the medicinal product as package for sale: 3 years
Use immediately after opening the vials and administer within 2 hours after preparation of the vaccine for use.

### 6.4 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 at a temperature lower than 25°C.

### 6.5 Nature and composition of immediate packaging

Type I glass ampoule, 4- yellow ampoules cane.
Ampoule canes are stored in canisters, and within liquid nitrogen containers.

- 10,000 doses ampoule
- 15,000 doses ampoule

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

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant in accordance with national requirements.

## 7. MARKETING AUTHORISATION HOLDER

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

## 8. MARKETING AUTHORISATION NUMBER

Vm 08327/4257

## 9. DATE OF FIRST AUTHORISATION

16 May 2013

## 10. DATE OF REVISION OF THE TEXT

November 2018

## PROHIBITION OF SALE, SUPPLY AND/OR USE

The import, sale, supply and/or use of HatchPak IB H120 is or may be prohibited in certain Member States on the whole or part of their territory pursuant to national animal health policy. Any person intending to import, sell, supply and/or use HatchPak IB H120 must consult the relevant Member State's competent authority on the current vaccination policies prior to the import, sale, supply and/or use of the product.

Approved: 16 November 2018