

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

AviPro IB H120  
Lyophilisate for suspension for chicken

## **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

1 dose contains

### **Active substance:**

Live IB virus, Massachusetts H 120 strain, at least  $10^{3.0}$  EID<sub>50</sub>\* and max.  $10^{4.8}$  EID<sub>50</sub> / dose

Host system: embryonated SPF chickens' eggs

\*EID<sub>50</sub> = 50% embryo infectious dose: the viral titre required to induce infection in 50% of embryos inoculated with the virus

### **Excipients:**

For a full list of excipients, see section 6.1.

## **3. PHARMACEUTICAL FORM**

Lyophilisate for suspension  
Appearance: white-beige

## **4. CLINICAL PARTICULARS**

### **4.1 Target species**

Chicken

### **4.2 Indications for use, specifying the target species**

For active immunisation of healthy susceptible chickens against Infectious Bronchitis (IB).

Start of immunity: within 3 weeks

Duration of immunity: at least 6 weeks

### **4.3 Contraindications**

Do not use in clinically ill or debilitated animals

### **4.4 Special warnings for each target species**

None.

### **4.5 Special precautions for use**

#### Special precautions for use in animals

- It should be ensured that drinking water and drinking vessels contain no detergents and disinfectants.
- Use the entire contents of opened containers in one single session.
- Users should only prepare amounts of vaccine that can be administered within 2 hours.
- An underdosing can result in inadequate development of immunity

#### Special precautions to be taken by the person administering the veterinary medicinal product to animals

This is a live virus vaccine. Any contamination by splashing or spillage must be avoided.

Wash and disinfect hands after use.

Personal protective equipment consisting of goggles and mouth protection or a breathing mask should be worn when handling the veterinary medicinal product

#### **4.6 Adverse reactions (frequency and seriousness)**

**C**hronic **R**espiratory **D**isease (CRD) may be activated in *Mycoplasma*-infected livestock. In this case, appropriate effective antibiotics should be additionally used.

From day 2 after vaccination with AviPro IB H120, mild respiratory sounds and occasional sneezing may occur in individual animals. The clinical symptoms soon resolve, without causing respiratory tract damage or growth suppression. These reactions are very rare.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports)

#### **4.7 Use during pregnancy, lactation or lay**

Following appropriate primary immunisation, there are no safety concerns for use during lay.

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

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product. 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 Amounts to be administered and administration route**

For administration via drinking water and for spraying.

One dose of the vaccine should be administered per animal.

Administration is possible from the first day of life.

Deciding when to vaccinate is dependent on many factors, such as the status of maternal immunity, intended utility, burden of infection, husbandry and management. In general, the following recommendations can be given for vaccination programmes:

*Primary immunisation of breeding and laying animals:*

1. Vaccination: in the 3<sup>rd</sup> week of life
2. Vaccination: in the 10<sup>th</sup> week of life

Depending on the epidemic scenario, further IB vaccinations should be performed at regular, 4 to 12-week intervals during breeding and the laying period. In addition, a booster with an inactivated vaccine can be given prior to the start of lay.

There should be an interval of at least 4 weeks and no more than 8 weeks between the first and second vaccination. Primary immunisation should have finished at least 2 weeks before the start of lay.

In livestock at risk of infection, spray vaccination on the first day of life has proven to be of particular value as an initial vaccination.

#### *Broilers:*

Due to the short lifespan of 35 - 40 days, single vaccination is often sufficient in broilers, with spray vaccination on the first day of life having proven to be of particular value in livestock at risk of infection. This induces immunity which is generally sufficient for the duration of the fattening period.

Route of administration:

##### a) Administration via drinking water

- The required number of vaccine doses and the quantity of water are to be determined (see below).
- Use the entire contents of each vaccine bottle for one coop or drinking system only, as division of the contents may lead to dosing errors.
- All equipment used for vaccination (feeds, tubes, troughs, etc.) should be thoroughly cleaned and free from detergent and disinfectant residues.
- Use only cool, clean and fresh water, preferably free from chlorine and metal ions. Skimmed milk powder (2 – 4 g/litre) or skimmed milk (20 – 40 ml/litre of water) can improve the quality of the drinking water and prolong the activity of the vaccine; however, such additions should be made 10 minutes **prior to** administration of the vaccine.
- Open the vaccine bottle under water and dissolve the contents completely. Ensure complete emptying by rinsing the bottle and rubber stopper with water.
- Water in the troughs must be completely used up prior to vaccination. All feeds should be free from normal water, so that the troughs contain the vaccine solution only. Feeds filled with water must be emptied prior to administering the vaccine solution.

The vaccine should be completely consumed within 2 hours. As there is some variation in the drinking patterns of chickens, it may be necessary to withhold drinking water from the animals prior to vaccination, in order to ensure that all animals will imbibe during the vaccination phase.

The amount of water should be measured in such a way that it will be completely consumed by the animals within 2 hours. The diluted vaccine solution is added to cold, fresh water in such a way as to dissolve roughly 1,000 vaccine doses in one litre of water per day of life for 1,000 chickens, e.g. for 1,000 chickens aged 10 days, 10 litres will be needed.

Under hot climatic conditions and for heavy breeds, this amount may have to be increased up to a maximum of 40 litres per 1,000 animals. In case of doubt, water intake must be calculated on the day prior to vaccination.

Once dissolved, administer the ready-to-use vaccine immediately.

During vaccination via drinking water, the animals must have no access to normal drinking water.

##### b) Administration by spraying

The amount of water required for spraying depends on various factors, such as animal age, husbandry, temperature, stocking density and the device used for spraying the vaccine. It is between 250 and 1000 ml/1000 animals.

As a general rule: The finer the spray mist, i.e. the smaller the droplets, the deeper the penetration of the virus solution into the respiratory tract. This will bring about better immunogenicity but also lower tolerability.

- In general, the initial vaccination is administered as a thick spray (droplet size > 50 µm).
- For booster vaccinations, the vaccine can be administered as a fine spray (droplet size < 50 µm).
- Use distilled water.
- Spray all animals evenly.
- Whilst spraying and for about 20 - 30 minutes thereafter, ventilation should be switched off if possible, or reduced.
- Avoid unsettling the animals, e.g. by dimming light sources.
- Use spray devices for vaccination only and clean only with hot water; never use disinfectants or detergents.

For spray vaccination, only tried and tested devices should be used. The following table shows a few recommendations:

	Vaccination on the first day of life in the transport box	Vaccination with thick mist	Vaccination with fine mist
Mean droplet size	> 50 µm	> 50 µm	< 50 µm
Flow rate/pressure	500 - 600 ml/min at 2-3 bar	500 - 600 ml/min at 2-3 bar	50 ml/min
Vol./1000 animals	250 - 400 ml	500 - 1000 ml	100 - 200 ml
Spraying time for 1000 animals	30 - 40 sec. equivalent to 3 - 4 sec per box of 100 chicks	1 - 2 min	approx. 5 min

In order to reduce the burden of infection prior to onset of immunity, the litter should be removed and the coop cleaned between treatment cycles in the breeding unit. Protect ready-to-use vaccine suspensions from direct sunlight, frost and heat above 25°C.

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

No other signs have been observed as described under 4.6 following administration of a ten-fold dose.

#### **4.11 Withdrawal period(s)**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

Pharmacotherapeutic group: live virus vaccines for poultry, ATCvet code: QI01AD07  
 Massachusetts H 120, the virus strain contained in this vaccine, is apathogenic to chickens and induces an immune response. This immune response can be increased by a second vaccination with a less attenuated form of the Massachusetts vaccine strain.

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Disodium hydrogen phosphate, potassium dihydrogen phosphate, lactose monohydrate, skimmed milk powder

## **6.2 Incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

## **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 18 months

Shelf-life after dilution or reconstitution according to directions: 2 hours

## **6.4. Special precautions for storage**

Store in a refrigerator (2C – 8C).Protect from light and frost.

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

Glass bottle type I (Ph.Eur.) with a crimped and chlorobutyl elastomer closure. The bottles are sealed with aluminium tear-off caps.

The vaccine is available in the following pack sizes:

Pack with 1000 vaccine doses

Pack with 2500 vaccine doses

Pack with 5000 vaccine doses

Pack with 10000 vaccine doses

### **Bundle packs:**

Pack with 10 x 1000 vaccine doses

Pack with 10 x 2500 vaccine doses

Pack with 10 x 5000 vaccine doses

Pack with 10 x 10000 vaccine 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 requirements.

## **7. MARKETING AUTHORISATION HOLDER**

Lohmann Animal Health GmbH, Heinz -Lohmann-Strasse 4, D-27472 Cuxhaven

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

MAA Cyprus: 16022

## **9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION**

Date of first authorization: 02/02/1995

Date of renewal: 01/02/2010

**10 DATE OF REVISION OF THE TEXT**

01/07/2015

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Not applicable.

**GENERAL CLASSIFICATION FOR SUPPLY:**

To be supplied only on veterinary prescription, no repeat prescriptions, available from pharmacies only.