

ANNEX I SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Primun Bronchitis H120.

Lyophilisate for suspension for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose of reconstituted vaccine contains:

Active substances:

Live attenuated Avian Infectious Bronchitis Virus (IBV), Massachusetts IBV_H120 strain: 3.0 - 4.0 log₁₀ EID₅₀*

* EID₅₀ = 50% embryo-infective dose.

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension

Appearance: beige coloured freeze-dried pellet.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens

4.2 Indications for use, specifying the target species

For the active immunization of broilers and future layers against avian infectious bronchitis, produced by strains of the Massachusetts serotype.

Onset of immunity: 3 weeks after 1st vaccination.

Duration of immunity in broilers: up to 6 weeks of age (after 2 vaccinations at day 1 and day 21).

Duration of immunity in future layers: up to 10 weeks of age (after 3 vaccinations at days 1, 21 and 49).

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

- Ensure that drinking water and all equipment used for vaccination (tubes, drinkers, etc) are carefully cleaned and do not contain any residues of detergents, disinfectants and metal ions.
- Only prepare the quantity of vaccine that can be administered within 2 hours after reconstitution.
- During its use protect the vaccine suspension from direct sunlight and temperatures above 25°C.
- Use the entire contents of opened containers in one single session.

Special precautions for use in animals

Vaccinated animals may excrete the vaccine strain up to 18 days following vaccination. During this time, the contact of immunosuppressed and unvaccinated birds of all susceptible wild and domestic species with vaccinated chickens should be avoided.

To prevent spread of vaccine virus, vaccinating equipment and chicken houses should be disinfected between flocks.

All chickens on the site should be vaccinated at the same time.

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

Care should be taken when reconstituting and administering the vaccine.

Personal protective equipment consisting of suitable respiratory mask and eye protection should be worn when handling the veterinary medicinal product to avoid direct contact with the aerosolized vaccine.

Personnel performing vaccination should wash and disinfect hands and equipment after use. In case of accidental spillage onto eyes, seek medical advice immediately and show the package leaflet or the label to the physician.

Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots) and take particular care in handling animal waste and bedding materials from recently vaccinated chickens.

4.6 Adverse reactions (frequency and seriousness)

Slight respiratory signs may be noted commonly in vaccinated birds 3 – 10 days after

vaccination. All clinical signs subside within about 5 days.

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

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports)

4.7 Use during pregnancy, lactation or lay

Laying birds

No information is available on the safety of the vaccine during lay.

Do not use in birds in lay and/or within 4 weeks before the start of the laying period.

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

Dosage: 1 dose / chicken

Vaccination scheme:

Broilers: first vaccination on the 1st day of life and revaccination at 3 weeks after first vaccination.

Future layers: first vaccination on the 1st day of life and revaccination at 3 weeks and 7 weeks after first vaccination.

Administration route: oculo-nasal use, nebulisation use or in drinking water use.

Remove the aluminum seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should be removed whilst the vial is immersed in a plastic measuring jug containing the required volume of clean cool water. Half fill the vial with water, replace the stopper and shake to dissolve any remaining vaccine. The vaccine suspension should then be added to the drinking system (oral administration), or filled into the spraying device (coarse spray administration) or into the dropper (oculo-nasal administration).

Oral administration via drinking water:

1. The number of vaccine doses should be dissolved in the amount of drinking water calculated upon previous water consumption of the birds to be immunized.
2. The number of doses should be rounded up for smaller flocks and dissolved accordingly
3. Ensure that drinking water and all equipment used for vaccination (tubes, drinkers, etc.) are carefully cleaned and do not contain any residues of detergents, disinfectants or metal ions.
4. Drinking water should be withdrawn from birds for 2-4 hours prior to vaccination, depending on their age and the temperature of the environment.
5. To preserve virus activity, it is advised to dissolve 2-4 g skimmed milk powder per litre of calculated drinking water or skimmed milk (20 - 40 ml/litre of water), prior to dissolving the vaccine.
6. It is advised to increase the number of drinkers during vaccination. To ensure that all birds have access to the vaccine suspension, it is advised to move birds around the drinkers in the first few minutes of vaccination. The birds can be supplied with fresh drinking water only after the medicated water is consumed entirely.
7. The vaccine should be administered to birds immediately after reconstitution.

Nebulisation use

1. The vaccine should preferably be dissolved in distilled water or alternatively, in clean, cold water preferably non chlorinated and free from metal-ions.
2. The quantity of water needed for spraying depends on various factors such as the animals' age, housing, temperature, stock density and the apparatus used to spray the vaccine. Use only chlorine-free or distilled water.
3. The spraying device should be free from sediments, corrosion and traces of disinfectants (preferably used for vaccination purpose only).
4. The vaccine suspension should be sprayed evenly over the correct number of birds, at a distance of 30-40 cm, preferably when the birds are sitting together in dim light.
5. For 1-day old chicks use 0.25 litre for 1000 birds and for older birds use 0.5 litre for 1000 birds and set the nozzle to produce coarse spray.
For primary vaccination in the field coarse spray (droplet size $\geq 100 \mu\text{m}$) and for revaccinations a droplet size between 50 – 80 μm (fine spray) is recommended.
6. Switch off or reduce the air conditioning if possible when spraying and for approximately 20 - 30 minutes thereafter.

Oculo/ nasal administration.

1. For 1,000 birds, reconstitute the lyophilisate pellet corresponding to 1,000 doses into 3 to 5 ml of physiological saline solution or sterile distilled water and subsequently add physiological saline solution or sterile distilled water to make up to 50 ml.

In case of animals from 1 to 14 days old or smaller breeds, 25 µl-drops should be used. Two drops would be administered for this kind of birds.

The following table provides some advices for oculo-nasal administration:

	Age and type of animal	
	1-14 days old or smaller breeds	> 14 days old
Number of drops	2 drops	1 drop
Size of the drop	25 µl	50 µl
Reconstitution	1 vial in 50 ml of physiological saline solution or sterile distilled water	

2. Use calibrated dropper, so as to distribute 50 or 25 µl-drops. One drop should be applied into one nostril or one eye. In case of dissolution in two drops, instil one drop into one eye and one drop into one of the nostrils.

- Nasal route: Hold the dropper vertically and allow a drop of the solution to fall into one of the bird's nostrils. The beak of the chicken shall be kept closed, covering one nostril, deposit the drop in the other. Do not let go of the chicken until it has inhaled the drop. Avoid covering the nose of the chicken with the dropper tip. Ensure that the nasal drop is inhaled.
- Ocular route: Vaccination by eye drop method is conducted holding the dropper in a vertical position and allowing a full drop of vaccine to fall into the open eye of the bird and holding until the drop of vaccine disappears. Be careful not to harm the cornea with the tip of the dropper.

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

No other clinical signs than those mentioned under 4.6. were observed after administration of ten times the maximum dose via the recommended routes, in this case the signs subside within about 10 days. In addition, complete ciliostasis was detected after the application of an overdose.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Live viral vaccines for domestic fowls. Avian infectious bronchitis (IBV).

ATCvet code: QI01AD07

Live freeze-dried vaccine for active immunization against avian infectious bronchitis virus (IBV).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Disodium phosphate

Potassium dihydrogen phosphate

Lactose monohydrate

Skimmed milk powder

Water for injections

6.2 Major 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: 2 years

Shelf life after reconstitution according to directions: 2 hours

6.4. Special precautions for storage

Store and transport refrigerated (2°C – 8°C).

Protect from light.

Do not freeze.

6.5 Nature and composition of immediate packaging

Lyophilised vaccine:

1000 and 2000 doses in type I glass vials of 10 ml, closed with rubber stopper and sealed with aluminium brown push tear-off caps

Packaging:

Box with 1 vial of 1,000 doses.

Box with 10 vials of 1,000 doses.

Box with 1 vial of 2,000 doses.

Box with 10 vials of 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 requirements.

7. MARKETING AUTHORISATION HOLDER

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8. MARKETING AUTHORISATION NUMBER

9. DATE OF FIRST AUTHORISATION

10. DATE OF REVISION OF THE TEXT

PROHIBITION OF SALE, SUPPLY AND/OR USE

Veterinary medicinal product subject to prescription.

Administer under the direct control or supervision of the veterinarian.