SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB H120 lyophilisate for suspension for oculonasal use, ocular use or use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Live attenuated avian infectious bronchitis virus, strain H120: $10^{3.0}$ – $10^{4.9}$ EID_{50}*
*EID_{50} = 50% embryo infective dose.

Excipients:

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for oculonasal use, ocular use or use in drinking water.

Off-white to cream coloured lyophilisate.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

For the active immunisation of chickens (broilers, future layers or breeders) in order to reduce the detrimental effect on the ciliary activity resulting from infection with infectious bronchitis virus (IBV) Massachusetts serotype strains, which is related to the development of respiratory clinical signs.

Onset of immunity: 25 days after vaccination.
Duration of immunity: 16 weeks.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Maternally derived antibodies (MDA) can interfere with the development of active immunity. Where it is likely that recent field infection or vaccination of the parent flock has stimulated a high antibody titre and consequently a high level of MDA, the timing of the vaccination programme should be planned accordingly.

4.5 Special precautions for use

Special precautions for use in animals

The vaccine strain can spread to unvaccinated chickens. Special precautions should be taken to avoid spreading of the vaccine strain to unvaccinated chickens. It is recommended to vaccinate all birds on a site at the same time.

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

Personal protective equipment consisting of goggles and dust masks or a helmet with filtered air circulation should be worn when handling the veterinary medicinal product especially while vaccination according to the spraying method.

Personnel involved in attending vaccinated chickens should follow general hygiene principles (changing clothes, wearing gloves, cleaning and disinfection of boots).

Special precautions for the protection of the environment:

Not applicable.

Other precautions

Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Chickens:

Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Respiratory signs[1]

[1]Generally mild and transient in nature.

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 section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has not been established during lay. Do not use in birds in lay and 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 Amount(s) to be administered and administration route

Vaccination scheme:
For chickens from one day of age.
One dose per chicken to be administered by coarse spray, by eye drop or with drinking water. The quantity of water to be used depends on the method of administration. Never use less than 1 dose per chicken.

For spray administration (oculonasal use):
The product can be used in most types of spray equipment. The equipment should provide coarse spray (droplets between 80 to 160 µm). The distance from the spraying head to the bird must be approximately 50 cm. Dilute and administer the reconstituted vaccine at a rate of one dose of reconstituted vaccine per bird, according to the directions of your specific coarse spray vaccination equipment. It is recommended to use 0.15 to 0.5 litres of water per 1,000 birds depending of the type of spray equipment to be used.

During spraying and for about 20 - 30 minutes thereafter, ventilation should be switched off or reduced. Dimming light sources is recommended to avoid unsettling the animals.

For eye drop administration (ocular use):
Use 30 to 50 ml of deionized water per 1,000 doses (birds) depending on the type of eye-dropper to be used. One drop equal to one dose (0.03 to 0.05 ml depending on the reconstituted volume) of the vaccine solution is administered into one eye per chicken. The deionised water should be at room temperature when used. Hold the chicken so that one eye is pointing upwards and allow one drop of vaccine to fall into the eye. Chickens should swallow during vaccination.

For drinking water administration (use in drinking water):
Discontinue any drinking water medication 24 hours before vaccination. Water containing a high level of free chlorine should not be used. A general indication is that if chlorine can be detected in the water by smell or taste it could deactivate the living virus. If so, half a litre of skimmed milk should be thoroughly mixed into every 20 litres of water or skimmed milk powder added at a rate of two grams per litre of water before adding vaccine.
Only perfectly clean and rust-free utensils and drinkers (preferably plastic) free of any trace of disinfectants, detergents, soap, etc. should be used. Ensure that there is enough drinking trough space to allow all chickens immediate access to the vaccine. No untreated water should be made available until the treated water has been consumed.

Withhold drinking water for 2 hours before vaccination to stimulate thirst. Remove the aluminium seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should then be removed whilst the vial is immersed in a plastic measuring jug containing 1 litre (approximately 1 quart) of clean cool water. Half fill the vial with water, replace the stopper and shake to dissolve any remaining vaccine.
The vaccine concentrate should then be added to and thoroughly mixed with sufficient drinking water to last for approximately 2 hours.

The approximate drinking water requirements for vaccination can be calculated from the age of the chickens. Use as many litres of water as the age of the chickens in days, per 1,000 chickens, up to a maximum of 40 litres per 1,000 chickens.
Distribute the diluted vaccine evenly in the drinkers. Do not expose prepared drinking water vaccine to sunlight.
The vaccine solution is best divided so that the drinkers are charged at least twice with vaccine to ensure a more widespread uptake.
If nipple drinkers are employed, ensure that header tanks are continually refilled with water containing vaccine.
The vaccine may be used in automatic watering equipment. However, the main supply should only be turned on when all the vaccine treated water has been consumed. Return to regular watering only after the vaccine water has been consumed.

Upon reconstitution, transparent to white opaque suspension (depending on the volume of diluent used).

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

Administration of a 10-fold overdose does not result in symptoms different from those mentioned under section 4.6.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, domestic fowl, live viral vaccines, avian infectious bronchitis virus (IBV).

ATCvet code: QI01AD07

This vaccine is intended to stimulate active immunity against Massachusetts strains of infectious bronchitis virus (IBV).

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

D-Mannitol
Gelatin
Myo-Inositol
NZ Case Plus

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf life after reconstitution according to directions: 4 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

Glass vials closed with butyl rubber stopper and sealed with an aluminium crimp cap.

Pack sizes:
Cardboard box of 1 x 1,000 doses
Cardboard box of 1 x 2,500 doses
Cardboard box of 1 x 5,000 doses
Cardboard box of 1 x 10,000 doses
Cardboard box of 10 x 1,000 doses
Cardboard box of 10 x 2,500 doses
Cardboard box of 10 x 5,000 doses
Cardboard box of 10 x 10,000 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

Medicines should not be disposed of via wastewater or household waste.

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

Zoetis UK Limited

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5121

9. DATE OF FIRST AUTHORISATION

17 October 2005

10. DATE OF REVISION OF THE TEXT

December 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE

Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall

Approved: 22 January 2025