SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB Primer.
Lyophilisate for suspension for spray, eye drop or drinking water administration for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

Active substances:
Live, attenuated avian Infectious Bronchitis Virus, strain H120: $10^{3.0}$ – $10^{5.4}$ EID_{50}

Live, attenuated avian Infectious Bronchitis Virus, strain D274 Clone: $10^{3.0}$ – $10^{5.4}$ EID_{50}

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for spray, eye drop or drinking water administration.

Off-white to cream coloured lyophilisate.
Upon reconstitution, transparent to white opaque suspension (depending on the volume of water used).

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

For active immunisation of chickens against Massachusetts serotype strains and D274 like strains of Avian Infectious Bronchitis virus (IBV).

Onset of immunity: 27 days after vaccination
Duration of immunity: 16 weeks

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals

The vaccine strain may spread to unvaccinated chickens. Safety and reversion to virulence trials have shown that vaccine strain is safe for 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).

4.6 Adverse reactions (frequency and seriousness)

In very rare cases, a slight reaction to vaccination can be observed in the form of transient, mild respiratory symptoms.

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

The safety of the veterinary medicinal product has been demonstrated when administered during lay.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered from day of age onwards by coarse spray and eyedrop before administration of Poulvac IB QX with a 7 to 14 day interval between both administrations. For the associated use, the onset of immunity is 21 days

after the Poulvac IB QX vaccination for the claimed protection against QX-like IBV strain and 27 days after the Poulvac IB Primer vaccination for the claimed protection against Massachusetts and D274-like strains of IBV. An onset of immunity of 21 days after the second vaccination against IBV Variant 2 (IS-1494-like) and 793B serotype strains has also been established for the associated use, with Poulvac IB QX as detailed above, as demonstrated by a reduction of respiratory signs of infectious bronchitis caused by Variant 2 (IS-1494-like) and 793B serotype strains of IBV. The safety parameters are not different from those described for the vaccines administered separately. Safety and efficacy data are available which demonstrate that this vaccine, when administered by the spray route to maternal antibody positive chicks, can be administered on the same day as Poulvac NDW.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the product 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.

4.9 Amounts to be administered and administration route

Vaccination scheme:
Broilers: vaccination from first day of life.
Future layers or breeders: vaccination from first day of life or during the 3rd to 4th week of life for immediate protection of young chickens and priming for subsequent vaccinations with an inactivated vaccine.
Layer or breeders: vaccination from onset of lay.

One dose of vaccine per bird administered by spray administration, eye drop administration or drinking water administration. The amount of water to be used depends on the method of administration:

For spray administration: 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. Recommended volume for one dose is between 0.1 and 0.5 ml.
The spray device used must be set to a droplet size of 0.12 to 0.15 mm in diameter. The distance from the spray head to the bird should be approximately 50 cm.

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: 50 ml per 1000 birds.
One drop (0.05 ml) of the vaccine solution is administered into an eye. In doing so, the head of the animal must be fixed so that the drop does not run down. 1000 doses of the vaccine are dissolved in 50 ml water.

For drinking water administration: Depending on the age of the birds: The amount of water in litres per 1000 chickens should be set according to the age of the chickens in days (up to a maximum of 40 litres).

Water containing a high level of chlorine or metal ions should not be used and conduit pipes, tubing, etc. should be thoroughly clean and free of traces of disinfectants and detergents. It is recommended to add protective proteins in the form of skimmed milk powder (2 g per litre of water) or skimmed milk (1 litre per 50 litres of water) to the water.

The birds should be deprived from water about 2 hours before vaccination. For vaccination, use as many litres of water as the age of the birds in days, per 1000 birds, up to a maximum of 40 litres as indicated above.

Prepare the amount of vaccine to be used within 2 hours. Remove the sealing cap and stopper from the vaccine vial and suspend the vaccine in the corresponding amount of water and mix carefully. Care should be taken to empty the ampoule completely and administer the diluted vaccine immediately.
Make sure that birds do not have access to untreated water until the treated water has been consumed.

One day before and after vaccination no drugs or disinfectants should be applied to the chickens.

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

The vaccine provides active immunisation against avian Infectious Bronchitis Virus (IBV) Massachusetts and D274 like strains.

ATC-vet code: QI01AD07
Pharmacotherapeutic group: Immunologicals for aves, live viral vaccine for domestic fowl, avian 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: 18 months
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

The vaccine is supplied in Type I glass vials complying with Ph. Eur.
The vaccine is supplied in boxes of ten 6 ml volume vials of 1000, 2500 or 5000 doses.
Vials are closed with a butyl rubber stopper and aluminium cap.

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

Zoetis UK Limited

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4103

9. DATE OF FIRST AUTHORISATION

15 April 2005

10. DATE OF REVISION OF THE TEXT

January 2025

Gavin Hall

Approved: 31 January 2025