SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Hitchner B1

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active Substance:	Per dose
Newcastle Disease virus strain B1	$10^{5.5}$ - $10^{7.2}$ EID_{50}

Excipient(s):

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for oral solution, nebulisation solution, nasal drops solution or eye drops solution.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

For the active immunisation of chickens to reduce clinical signs due to infection with Newcastle disease virus. The onset of immunity is from three weeks after vaccination. Immunity has been shown to last for at least 6 weeks.

4.3 Contraindications

Do not vaccinate unhealthy birds.

4.4 Special warnings

None.

4.5 Special precautions for use, including special precautions to be taken by the person administering the medicinal product to animals

i Special precautions for use in animals

It is accepted that spray administration offers benefits over water administration in terms of ease of application and percentage of birds

vaccinated. Nevertheless, greater secondary problems can result under certain management conditions. Spray vaccination should not be used if inter-current infection is suspected.

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

Live Newcastle disease virus may cause conjunctivitis in man. When administering vaccine by the spray method operators must protect eyes and nose by wearing standard goggles and mask or a full face mask that comply with BS EN 166:2002 and BS EN 149:2001.

4.6 Adverse reactions (frequency and seriousness)

Reactions to vaccination occur seldom after intranasal, intraocular or drinking water administration. Mild respiratory distress is observed in up to 4% of birds vaccinated by the spray route. These symptoms typically appear within 4 to 9 days of the administration of the vaccine and may last several days.

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine, when administered by eye drop at one day of age, can be administered on the same day as Poulvac IBMM and Poulvac MDVac (frozen wet) administered by eye drop and by injection, respectively, and that Poulvac Bursine 2 may be administered by eye drop within 7 days.

Safety and efficacy data are available which demonstrate that this vaccine, when administered by eye drop at 4 weeks of age, can be administered on the same day as Poulvac ILT, Poulvac AE and Poulvac Bursine 2 by eye drop.

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

For drinking water, spray, intranasal or eye drop administration.

Drinking Water:

For birds 2 weeks of age or older. Never use less than one dose per bird. 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 by taste it could deactivate the living virus. If so 1 pint (500 ml) of skimmed milk should be thoroughly mixed into every 5 gallons (20 litres) of water before adding the vaccine. Only perfectly clean and rust free utensils and drinkers (preferably plastic) should be used and disinfectants and detergents must not be used for cleaning. Ensure that there is enough drinking trough space to allow all birds immediate access to the vaccine. No untreated water should be available until the treated water has been consumed. Withhold the water 1-2 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 one 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 are:-

Age of Birds	Quantity per 1,000 birds	
	Litres	Gallons
First week	2-4	½-1
Weeks 2-4	8-10	2-2½
Weeks 5-7	12-16	3-4
8 weeks and over	18-20	4½-5

- Distribute the diluted vaccine evenly in the drinkers.
- Do not expose prepared drinking water vaccine to sunlight.
- Return to regular watering only after the vaccine water has been consumed.
- The vaccine solution is best divided so that the drinkers are charged at least twice with the 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.

N.B. Check that the birds are never left without water after vaccine treatment.

Spray:

For birds 4 weeks of age or older

Hitchner B1 vaccine, has been successfully used in most types of spray equipment, the droplet sizes varying from coarse (Knapsack) to very fine (aerosol).

The vaccine should be dissolved as described under drinking water administration. The vaccine concentrate should then be added to the water in the sprayer tank and thoroughly mixed.

Intranasal:

For use in birds from one day of age. Reconstitute the vaccine as directed below. Fit the drop dispenser on the bottle. Place finger over one nostril of the bird, allow one drop of the vaccine to fall into the other nostril. Vaccination is completed when the vaccine is inhaled into nasal cavity. Do not release the bird until this occurs.

Eye drop:

For use in birds from one day of age. Reconstitute the vaccine as directed below. Fit the drop dispenser on the bottle. Hold the bird so that one eye is pointed upwards and allow one drop of vaccine to fall into the eye.

Reconstitution for intranasal and eye drop routes:

Remove the aluminium foil and rubber stopper from the vaccine vial and add sterile diluent to half fill the vial. Replace the rubber stopper and shake so that all the vaccine material is completely dissolved.

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

No adverse reactions exceeding those reported in section were recorded following administration of a tenfold overdose by the oral, intranasal or eye drop routes. The administration of a tenfold overdose by the spray route results in an increased incidence of respiratory distress and may result in mortality rates of up to 8 %.

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Stimulates active immunity against Newcastle disease.

ATCVet Code: QI01AD06

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Pharmatone
Bacto-peptone
Sucrose
NZ Amine type YT
Glutamine Acid sodium salt

6.2 Incompatibilities

Safety and efficacy data are available which demonstrate that this vaccine can be mixed and administered with Poulvac IBMM, Poulvac ILT, Poulvac AE and Poulvac Bursine 2 when administering by eye drop. Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 30 months.
Shelf-life after reconstitution according to directions: use immediately.

6.4 Special precautions for storage

Store and transport at 2-8°C.
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

The lyophilised vaccine is bottled in Type 1 Borosilicate Glass bottles with aluminium seals and rubber stoppers.
Fill volume for the 1,000, 2,500 or 5,000 dose presentation is 3.4 to 3.7 ml.

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, if appropriate

Dispose of waste material by boiling, incineration or immersion in an appropriate disinfectant approved for use by the competent authorities.

7. MARKETING AUTHORISATION HOLDER

Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

8. MARKETING AUTHORISATION NUMBER

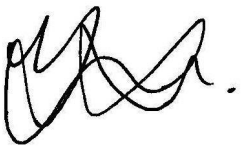
Vm 42058/4100

9. DATE OF FIRST AUTHORISATION

26 October 2005

10. DATE OF REVISION OF THE TEXT

August 2020



Approved: 14 August 2020