PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Poulvac Hitchner B1 – Outer Label
10x 1000 dose
10x 2500 dose
10x 5000 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Hitchner B1

2. STATEMENT OF ACTIVE SUBSTANCES

Newcastle Disease virus strain B1 $10^{5.5}$ – $10^{7.2}$ EID_{50} / dose

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

10 x 1,000 doses
10 x 2,500 doses
10 x 5,000 doses

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Reconstituted vaccine should be used immediately.

11. SPECIAL STORAGE CONDITIONS

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

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

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

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.
POM-VPS
To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 42058/4100

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Poulvac Hitchner B1 – Vial Label
1000 dose
2500 dose
5000 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Hitchner B1

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Newcastle Disease virus strain B1 $10^{5.5}$ – $10^{7.2}$ EID_{50} / dose.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1,000 doses
2,500 doses
5,000 doses

4. ROUTE(S) OF ADMINISTRATION

For drinking water, spray, intranasal or eye drop administration after reconstitution with diluent.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Reconstituted vaccine should be used immediately.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.
POM-VPS

Vm 42058/4100

PACKAGE LEAFLET:
Poulvac Hitchner B1

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

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

Manufacturer responsible for batch release:
Zoetis Manufacturing and Research Spain, S.L.
Ctra. Camprodón s/n "la Riba"
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac Hitchner B1

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

A freeze-dried pellet containing Newcastle Disease virus strain B1, $10^{5.5}$ – $10^{7.2}$ EID^{50} per dose.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not vaccinate unhealthy birds.

6. ADVERSE REACTIONS

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.
If you notice any side effects, even those not already listed in this package leaflet or if you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens.

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

For drinking water, spray, intranasal or eye drops 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.

1. 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.
2. 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.
3. The vaccine concentrate should then be added to and thoroughly mixed with sufficient drinking water to last for approximately 2 hours.
4 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

5. Distribute the diluted vaccine evenly in the drinkers.
6. Do not expose prepared drinking water vaccine to sunlight.
7. Return to regular watering only after the vaccine water has been consumed.
8. The vaccine solution is best divided so that the drinkers are charged at least twice with the vaccine to ensure a more widespread uptake.
9. If nipple drinkers are employed, ensure that header tanks are continually refilled with water containing vaccine.
10. 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.

NB: Check that all 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 fi ne (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 the 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 upward and allow one drop of vaccine to fall into the eye.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Not applicable.

10. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport at +2°C to +8°C. Protect from light. Do not freeze.
Do not use this veterinary medicinal product after the expiry date which is stated on the label.
Shelf-life after reconstitution according to directions: use immediately.

12. SPECIAL WARNING(S)

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.

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.

Lay:
Do not use in birds in lay

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 MD Vac 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.

Overdose (symptoms, emergency procedures, antidotes):
No adverse reactions exceeding those reported in section 6 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 %.

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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

LEGAL CATEGORY

POM-VPS

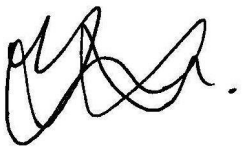
To be supplied only on veterinary prescription.
For animal treatment only.

PACKAGE QUANTITIES

1,000 dose, 2,500 dose and 5,000 dose vials.
Not all pack sizes may be marketed.

MARKETING AUTHORISATION NUMBER

Vm 42058/4100



Approved: 14 August 2020