

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Cardboard box of one or ten glass vials of 1000 or 2500 or 5000 or 10000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB H120

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

2. STATEMENT OF ACTIVE SUBSTANCES

Active substance:

Live, attenuated Infectious Bronchitis Virus, strain H120: $10^{3.0} - 10^{4.9}$ EID₅₀ / ds

3. PHARMACEUTICAL FORM

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

4. PACKAGE SIZE

1 x 1000 doses

10 x 1000 doses

1 x 2500 doses

10 x 2500 doses

1 x 5000 doses

10 x 5000 doses

1 x 10000 doses

10 x 10000 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 {month/year}

Once reconstituted use within 4 hours.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.

Protect from light. Do not freeze.

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

Disposal: read package leaflet.

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

For animal treatment only. 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 42058/4101

17. MANUFACTURER'S BATCH NUMBER
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Lot number

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Glass vial with 1000, 2500, 5000 and 10000 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB H120

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

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Active substance:

Live, attenuated Infectious Bronchitis Virus, strain H120: $10^{3.0} - 10^{4.9}$ EID₅₀ / ds

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

1000 doses

2500 doses

5000 doses

10000 doses

4. ROUTE(S) OF ADMINISTRATION

Oral, eye drop or coarse spray.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Batch Lot number

7. EXPIRY DATE

EXP

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
Poulvac IB H120
Lyophilisate for suspension for spray, eye drop or drinking water
administration for chickens

**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 & Research Spain, S.L.
C/Campródon s/n "La Riba"
17813 Vall de Bianya
Girona
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac IB H120

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

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

Active substance:

Live, attenuated Infectious Bronchitis Virus Strain H120: $10^{3.0} - 10^{4.9}$ EID₅₀ / dose

Off-white to cream coloured lyophilisate.

4. INDICATION(S)

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

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

A mild vaccination reaction can be observed very rarely in the form of transient, slight 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).

If you notice any side effects, even those not already listed in this package leaflet or 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

Vaccination scheme:

For chickens from one day of age.

One dose per chicken to be administered by eye drop, with drinking water or by coarse spray. The quantity of water to be used depends on the method of administration. Never use less than 1 dose per chicken.

For eye drop administration:

Use 30 to 50 ml of deionized water per 1000 doses (birds) depending of 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. 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:

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 1000 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

For spray administration:

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 1000 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.

9. ADVICE ON CORRECT ADMINISTRATION

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

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

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

Protect from light.

Do not freeze.

Shelf-life after reconstitution according to directions: 4 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP.

12. SPECIAL WARNING(S)

Special warnings for each target species

Vaccinate healthy animals only.

Maternally derived antibodies (MDAs) 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.

Special precautions for use in animals

The vaccine strain can spread from vaccinated to non-vaccinated 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).

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 onset of the laying period.

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 decided on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes)

Administration of a 10-fold overdose does not result in symptoms different from those mentioned under section 6.

Incompatibilities

Do not mix with any other veterinary medicinal product.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

October 2018

15. OTHER INFORMATION

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

The vaccine is supplied in quantities of 1000, 2500, 5000 or 10000 doses per vial in boxes of 1 or 10 vials. Not all pack sizes may be marketed.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 14 November 2019

A handwritten signature in black ink, appearing to read 'A. Hunter'.