

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Poulvac ILT – Outer Label (Lyophilisate)
10x 1000 dose

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac ILT

2. STATEMENT OF ACTIVE SUBSTANCES

Avian laryngotracheitis virus vaccine (live) $10^{2.5}$ to $10^{4.3}$ EID₅₀ / dose

3. PHARMACEUTICAL FORM

Lyophilisate for suspension in the diluent for administration by intraocular route for chickens.

4. PACKAGE SIZE

10 x 1,000 doses

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intraocular route.

8. WITHDRAWAL PERIOD(S)

WITHDRAWAL PERIOD

Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:

Use within two hours after reconstitution.

11. SPECIAL STORAGE CONDITIONS

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

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 reach and sight 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(S)

Vm 42058/4106

17. MANUFACTURER'S BATCH NUMBER

Lot:

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Poulvac ILT – Outer Label (Diluent)
10x 30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac ILT Diluent

2. STATEMENT OF ACTIVE SUBSTANCES

For reconstitution of 1000 doses of vaccine.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

10 x 30 ml

5. TARGET SPECIES

Chickens.

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Intraocular route.

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

For use see leaflet.

10. EXPIRY DATE

EXP:

11. SPECIAL STORAGE CONDITIONS

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

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

For use see leaflet.

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

For animal treatment only.

POM-VPS

14. THE WORDS “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(S)

Vm 42058/4106

17. MANUFACTURER’S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

**Poulvac ILT – Vial Label (Lyophilisate)
1000 doses**

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac ILT

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Avian laryngotracheitis virus vaccine (live) $10^{2.5}$ to $10^{4.3}$ EID₅₀ / dose

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

1,000 doses

4. ROUTE(S) OF ADMINISTRATION

For eye drop administration.

5. WITHDRAWAL PERIOD(S)

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:
Use within two hours after reconstitution.

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

Vm 42058/4106
Zoetis UK Limited, Surrey

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Poulvac ILT – Vial Label (Diluent)
30 ml

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac ILT Diluent

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

For reconstitution of 1000 doses of vaccine.

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

30 ml

4. ROUTE(S) OF ADMINISTRATION

For eye drop administration.

For use see leaflet

5. WITHDRAWAL PERIOD(S)

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

EXP:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

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

Vm 42058/4106
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

POM-VPS

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
Poulvac ILT**

**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.
Ctra. Camprodón s/n "La Riba"
17813 Val de Bianya (Girona)
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac ILT

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

A freeze dried suspension of avian laryngotracheitis virus, Salsbury strain 146, $10^{2.5}$ to $10^{4.3}$ EID₅₀ per dose

4. INDICATION(S)

For the prevention of mortality and clinical signs due to infection with avian infectious laryngotracheitis virus. Onset of immunity is 14 days post vaccination. Duration of immunity has not been assessed, however, experience from field use indicates that once vaccinated birds remain immune to avian infectious laryngotracheitis virus infection during entire laying period.

5. CONTRAINDICATIONS

Do not vaccinate diseased birds (except in case of an emergency vaccination).
Do not use in birds in lay.

6. ADVERSE REACTIONS

About four days after vaccination, redness and some swelling of the conjunctiva, or laboured breathing may be seen. Under good hygienic conditions, this reaction will not last longer than three days.

7. TARGET SPECIES

Chickens.

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

Vaccine is administered to chickens from 4 weeks of age by eye drop.

1000 doses of freeze dried vaccine must be completely dissolved in 30 ml of the sterile diluent provided and a drop of dispenser calibrated to deliver at least three hundredth of a millilitre per drop must be used.

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

Pour the dissolved vaccine into the remaining sterile diluent and shake again until completely mixed. The sterile diluent should be at room temperature when used.

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.

9. ADVICE ON CORRECT ADMINISTRATION

Use clean vaccination materials.

Contact with the disinfectant makes the vaccine ineffective.

Protect the reconstituted vaccine from heat or direct sunlight.

10. WITHDRAWAL PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight of children.

Store and transport at 2°C to 8°C.

Protect from light.

Do not freeze.

12. SPECIAL WARNING(S)

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. Do not mix with any other veterinary medicinal product.

In order to prevent spread of vaccine strain from vaccinated flocks to non-vaccinated flocks, all non-vaccinated birds present on the farm must be vaccinated at the same time.

Special precautions for use in animals

Prevent spread of vaccine virus from vaccinated flocks to non-vaccinated flocks.

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

None

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

For Animal Treatment Only

PACKAGE QUANTITIES

Packs of 10 vials containing 1000 doses

LEGAL CATEGORY

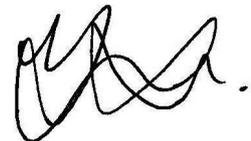
POM-VPS

Prescription Only Medicine – Veterinarian, Pharmacist, SQP

To be supplied only on veterinary prescription.

MARKETING AUTHORISATION NUMBER

Vm 42058/4106



Approved: 14 August 2020