

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE IMMUNOLOGICAL VETERINARY MEDICINAL PRODUCT

Poulvac ILT

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition

Avian Infectious Laryngotracheitis virus vaccine (live), freeze dried for veterinary use.

Quantitative composition

<u>Active substances:</u>	<u>Per dose</u>
1. Freeze dried fraction	
Avian Infectious Laryngotracheitis virus, Salsbury strain 146:	$\geq 10^{2.5}$ EID ₅₀
Excipients	
Stabilising medium	QS 1 dose
For a full list of excipients, see section 6.1	
2. Liquid Diluent	
Buffer solution	QS 1 dose

3. PHARMACEUTICAL FORM

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

4. CLINICAL PARTICULARS

4.1 Target Species

Chickens

4.2 Indications for use, specifying the target species

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.

4.3 Contra-Indications

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

4.4 Special Warnings

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.

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

Use clean vaccination materials.

Protect the vaccine from exposure to heat and/or direct sunlight.

Avoid contact with disinfectants as this makes the vaccine ineffective.

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

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

None

4.6 Adverse reactions (frequency and seriousness)

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.

4.7 Use during pregnancy, lactation or lay

Do not use in laying chickens.

4.8 Interactions 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.

4.9 Amounts to be administered and administration route

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.

Contact with the disinfectant makes the vaccine ineffective.

Protect the reconstituted vaccine from heat or direct sunlight.

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

Administration of an overdose does not result in significantly worse adverse reactions to those seen after administration of a single dose.

4.11 Withdrawal period

Zero Days

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against avian laryngotracheitis virus.

ATC Vet code: QI01AD08

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose

Monobasic sodium phosphate

Dibasic potassium phosphate

Bovine serum albumin

Phosphate Buffer saline

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf-life

Vaccine

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.

Liquid diluent

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.

Shelf-life after dilution or reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

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

6.5 Nature and composition of immediate packaging

Vial: Type I (Ph. Eur.) Borosilicate glass bottles. 6 ml capacity
Closure: Type I (Ph. Eur.) chlorobutyl rubber stoppers sealed with aluminium caps.
Pack Sizes: Pack of 10 vials containing 1000 doses.

Diluent:

Vial: (Ph. Eur.) LDPE Plastic bottles
Closure: Type I (Ph. Eur.) chlorobutyl rubber stoppers sealed with aluminium caps.
Pack Size: Diluent is supplied in 30 ml LDPE plastic bottles.

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 42058/4106

9. DATE OF FIRST AUTHORISATION

26 October 2005

10. DATE OF REVISION OF THE TEXT

December 2022

Revised: December 2022
AN: 00897/2022

Approved 22 December 2022

A handwritten signature in black ink, appearing to read "J. Hunter.", is positioned below the approval date. The signature is stylized, with a large, looped initial "J" followed by the name "Hunter." in a cursive script.