SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac E. coli lyophilisate for suspension for spray vaccination for chickens and turkeys or for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

Active substance:
Live aroA gene deleted *Escherichia coli*, type O78, strain EC34195 5.2×10^6 - 9.1×10^8 CFU*

* Colony forming units when grown on trypticase soy agar plates.

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for spray vaccination or for use in drinking water.

Cream coloured lyophilisate.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens (broilers, future layers/breeders) and turkeys.

4.2 Indications for use, specifying the target species

For active immunisation of broiler chickens, future layer/breeders and turkeys in order to reduce mortality and lesions (pericarditis, perihepatitis, airsacculitis) associated with *Escherichia coli* serotype O78.

Onset of immunity:
Chickens: 2 weeks after vaccination for the reduction of lesions. The onset of immunity has not been established for the mortality claim.
Turkeys: 3 weeks after second vaccination for the reduction of lesions and mortality.

Duration of immunity:
Chickens: 8 weeks for the reduction of lesions and 12 weeks for the reduction of mortality (spray). 12 weeks for the reduction of lesions and mortality (drinking water).
Turkeys: duration of immunity has not been established.

A cross protection study showed reduction of incidence and severity of airsacculitis caused by *E. coli* serotypes O1, O2 and O18 for spray application for chickens. For these serotypes no onset of immunity or duration of immunity was established.

4.3 Contraindications

Do not vaccinate animals undergoing antibacterial or immunosuppressive treatment.

4.4 Special warnings for each target species

Vaccinate healthy animals only.

Do not use antibiotic treatment within 1 week before and after vaccination because antibiotic treatment might impair the efficacy of the vaccine.

No information is available on the influence of high levels of maternally derived antibodies on the efficacy.

4.5 Special precautions for use

Special precautions for use in animals
The vaccine strain can be detected in tissues (liver, heart) until 6 days (chickens) or in tissues (thoracic air sacs) 4 days (turkeys) post vaccination. Vaccinated birds may excrete the vaccine strain by faecal route for up to 5 weeks (chickens) or 7 days (turkeys) post vaccination and the vaccine may remain present in the environment until the end of the finishing or rearing period (chickens) or for 7 days (turkeys).

Therefore, it is recommended to clean and disinfect bird houses where the vaccine was applied after completion of the finishing or rearing period.
The vaccine strain may spread to in-contact birds. The vaccine strain can be identified by its growth properties on biological growth media: it shows normal growth on MacConkey and trypticase soy agar, while no colonies are observed when plated without aromatic amino acids (minimum agar).

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Apply the usual aseptic precautions to all administration procedures.
The use of eye-protection, gloves and a nose-mouth mask by the operator is advised during administration. Immunosuppressed people should not be present during administration of the vaccine. Disinfect hands and equipment after use.
Personnel involved in attending vaccinated animals should follow general hygiene principals and take particular care in handling litter from recently vaccinated animals.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Immunisation has to be considered as one component in a complex control program that addresses all important hygienic and health factors for poultry.

4.6 Adverse reactions (frequency and seriousness)

Chickens (broilers, future layers/breeders) and turkeys:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section 16 of the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

The safety of the veterinary medicinal product has been demonstrated when administered to chickens during lay at one dose by both coarse spray and drinking water administration. However, the efficacy of the veterinary medicinal product has not been demonstrated when administered to chickens during lay. A decision to use this vaccine in chickens during lay should be made on a case by case basis.

The safety of the veterinary medicinal product has not been investigated in turkeys during lay. Do not use in turkeys in lay and within 6 weeks before the start of the laying period.

4.8 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 made on a case by case basis.

4.9 Amount(s) to be administered and administration route

Coarse spray administration for chickens and turkeys or for use in drinking water for chickens.

Vaccination schedule
Chickens: One dose of vaccine from 1 day of age by coarse spray administration or one dose of vaccine from 5 days of age by drinking water administration.
Turkeys: One dose of vaccine from 1 day of age followed by second dose of vaccine 3 weeks later by coarse spray administration.

Administration
Spray application:
Use clean vaccination materials and turn off ventilation until 15 minutes after vaccination.
Remove seal and stopper. Half-fill the vial with chlorine-free water at room temperature. Replace the stopper and shake well until dissolved. Pour the reconstituted vaccine into a clean container and add chlorine-free water to further dilute the vaccine in order to obtain an even distribution when sprayed onto the birds.

No disinfectants or other substances impairing the performance of the live vaccine should be used in the sprayer.
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. The recommended volume for 1 dose is between 0.1 and 0.5 ml. The spraying distance should be between 30 and 80 cm above the animals in order to ensure an even distribution and the recommended droplet size is greater than 100 µm.

In drinking water use:
Make sure that all conduit pipes, tubing, troughs, drinkers etc. are thoroughly clean and free of any trace of disinfectants, detergents, soap, etc. and antibiotics. Contact with disinfectants makes the vaccine ineffective.

Allow water to be consumed so that levels of drinkers are minimal before vaccine is applied. All tubing should be emptied of plain water, so that the drinkers contain only vaccine water.

It may be necessary to withhold water prior to vaccination in order to ensure that all birds drink during the vaccination period.

Open the vaccine vial under water and dissolve thoroughly in a container. Care should be taken to empty the vial and its top completely by rinsing them in water. Do not split large vials to vaccinate more than 1 house or drinking system, as this may lead to mixing errors.

Use cold and fresh non-chlorinated water that is free from metal-ions. Low-fat skimmed milk powder (i.e. < 1% fat) may be added to the water (2–4 grams per litre) or skimmed milk (20–40 ml per litre of water) to improve the water quality and to increase the stability of the bacteria.

Ideally, vaccine should be administered in the volume of water consumed by the birds in up to 3 hours. The aim is to give every bird one dose of vaccine. As a general rule, apply reconstituted vaccine to chlorine-free and fresh water at the rate of 1,000 doses of the vaccine to 1 litre of water per day of age for 1,000 chickens, e.g. 10 litres would be needed for 1,000 10-day old chickens. If in doubt, measure water intake the day before administering vaccine.

Upon reconstitution, transparent to white-yellowish and opaque suspension (depending on the volume of diluent used).

Administer the dissolved vaccine to birds immediately after reconstitution.
Avoid exposure of the vaccine suspension to sunlight.

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

No adverse reactions have been observed after the administration of a 10-fold overdose of the vaccine.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for aves, live bacterial vaccines for domestic fowl.

ATCvet code: QI01AE04

To stimulate active immunity to *Escherichia coli* serotype O78.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Ammonium sulphate
Magnesium sulphate heptahydrate
Potassium phosphate monobasic
Sodium phosphate dibasic heptahydrate

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as package for sale: 30 months.
Shelf life after reconstitution according to directions: 2 hours.

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C). Do not freeze.
Keep the vial in the outer carton in order to protect from light.

6.5 Nature and composition of immediate packaging

Type I borosilicate glass vial of 10 ml for 2,500 and 5,000 dose-presentations and 50 ml for 10,000 and 20,000 dose-presentations with a chlorobutyl rubber stopper sealed with aluminium crimp caps.
Cardboard box of one vial of 2,500, 5,000, 10,000 or 20,000 doses.
Cardboard box of ten vials of 2,500, 5,000, 10,000 or 20,000 doses.

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

Medicines should not be disposed of via wastewater.

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

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/5046

9. DATE OF FIRST AUTHORISATION

15 June 2012

10. DATE OF REVISION OF THE TEXT

June 2024

PROHIBITION OF SALE, SUPPLY AND/OR USE
Not applicable.

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the ‘Product Information Database’ or ‘PID’ on www.gov.uk.

Gavin Hall
Approved: 24 June 2024