SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac AE lyophilisate for use in drinking water for chickens

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:

Avian encephalomyelitis virus, strain Calnek, sub-strain AE-67, live, $10^{3.1}$ - $10^{5.5}$ EID_{50}*
*EID_{50} = 50% embryo infective dose.

Excipients:

Qualitative composition of excipients and other constituents
Sucrose
Sorbitol
Instant non-fat dry milk
N-Z amine YT
L-glutamic acid
Potassium dihydrogen phosphate
Potassium phosphate dibasic trihydrate

Tan to brown coloured lyophilisate.

3. CLINICAL INFORMATION

3.1 Target species

Chickens.

3.2 Indications for use for each target species

For active immunisation of future layers and breeding hens from 10 weeks of age in order to provide passive immunity to reduce vertical transmission of avian infectious encephalomyelitis virus. It has been demonstrated that vaccinated breeding hens are able to confer passive immunity to progeny for up to 12 months post-vaccination i.e. to the end of the laying cycle.

3.3 Contraindications

Do not vaccinate birds of less than 10 weeks of age.

3.4 Special warnings

Vaccinate healthy animals only.

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.

3.5 Special precautions for use

Special precautions for safe use in the target species:
Vaccinated animals should not be in contact with non vaccinated animals for 42 days post-vaccination.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Not applicable.

Special precautions for the protection of the environment:
Not applicable.

Other precautions:
Not applicable.

3.6 Adverse events

Chickens:

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 the national competent authority via the national reporting system. See the package leaflet for respective contact details.

3.7 Use during pregnancy, lactation or lay

Do not use in birds in lay and within 4 weeks before the start of the laying period.

3.8 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.

3.9 Administration routes and dosage

Vaccination schedule:
The vaccine should be administered in the drinking water.
Birds should not be vaccinated before 10 weeks of age or later than 4 weeks before start of lay.
Use clean vaccination materials.
Discontinue use of any medications or sanitising agents being given or used in the water at least 24 hours before administering vaccine and do not resume use for 24 hours following final consumption of the vaccine-containing water.
Water used for administration of the vaccine must be non-chlorinated. Provide enough waterers so that at least two-thirds of the birds may drink at the same time. Scrub waterers with clean non-chlorinated water. Use no disinfectant. Let waterers drain dry.
Turn off automatic waterers. The only available water should be that containing the vaccine given through ordinary waterers. Do not give through medication tanks.
To stimulate thirst, withhold all water from birds for 2 hours before vaccination.
Remove aluminium seal from vial of the vaccine. Remove rubber stopper and half-fill with cool, clean, non-chlorinated water. Replace stopper tightly and shake vial until vaccine is in solution.
Using a clean container, fill it approximately two-thirds full with cool, clean, non-chlorinated water. To this, add dried milk. Use 4 grams of skimmed milk powder if the final volume of water is to be 1 litre. Shake until skimmed milk powder is dissolved. The skimmed milk powder must be added and dissolved first. Then add the rehydrated vaccine at the rate of 1 vial per 1,000 chickens to be vaccinated (if using 1,000 dose presentation) or 1 vial per 2,000 chickens to be vaccinated (if using 2,000 dose presentation). Shake again. Next add the mixture to the final volume of drinking water, at the rate of 1,000 doses of vaccine per 15 litres of drinking water. Never give less than 1 dose of vaccine per bird. Distribute the final volume of vaccine water evenly among the clean waterers. Do not place the waterers in direct sunlight. Resume regular water administration only after all the vaccine water has been consumed (consumption should take 1 hour).

3.10 Symptoms of overdose (and where applicable, emergency procedures and antidotes)

Administration of a 10-fold overdose does not result in any adverse reactions.

3.11 Special restrictions for use and special conditions for use, including restrictions on the use of antimicrobial and antiparasitic veterinary medicinal products in order to limit the risk of development of resistance

Not applicable.

3.12 Withdrawal periods

Zero days.

4. IMMUNOLOGICAL INFORMATION

4.1 ATCvet code: QI01AD02

To stimulate active immunity in hens and to provide passive immunity to progeny in order to reduce vertical transmission of avian encephalomyelitis virus.

5. PHARMACEUTICAL PARTICULARS

5.1 Major incompatibilities

Do not mix with any other veterinary medicinal product.

5.2 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 18 months.
Shelf life after reconstitution according to directions: 2 hours.

5.3 Special precautions for storage

Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.

5.4 Nature and composition of immediate packaging

Type I borosilicate glass vials closed with type I chlorobutyl rubber stoppers sealed with aluminium caps.

Pack Sizes:
1 x 1,000 doses and 10 x 1,000 doses.
1 x 2,000 doses and 10 x 2,000 doses.

Not all pack sizes may be marketed.

5.5 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.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

6. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

7. MARKETING AUTHORISATION NUMBER

Vm 42058/5134

8. DATE OF FIRST AUTHORISATION

26 October 2005

9. DATE OF THE LAST REVISION OF THE SUMMARY OF THE PRODUCT CHARACTERISTICS

November 2024

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

Gavin Hall
Approved: 21 February 2025