SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac AE lyophilisate for suspension for use in drinking water

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each dose contains:

Active substance:
Avian encephalomyelitis virus, strain Calnek, sub-strain AE-6710$^{3.1}$ to $10^{5.5}$ EID_{50}.

Excipients

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for use in drinking water.
Brownish powder.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens, from 10 weeks of age.

4.2 Indications for use

For active immunisation of future layers and breeding hens 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.

4.3 Contraindications

Do not vaccinate sick, debilitated or stressed birds.
Do not vaccinate birds of less than 10 weeks of age.

4.4 Special warnings for each target species

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

Special precautions for use in animals
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.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

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

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 made on a case-by-case basis.

4.9 Amounts to be administered and administration route

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.

Vaccination schedule
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. 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).

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

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

4.11 Withdrawal period

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves, live viral vaccines for domestic fowl.
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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sucrose
Sorbitol
Dehydrated non-fat milk
Casein hydrolysate enzymatic (N-Z amine YT)
Potassium glutamate
Potassium dihydrogen phosphate
Dipotassium phosphate

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

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

6.4 Special precautions for storage

Store and transport refrigerated (2 °C – 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.) bromobutyl rubber stoppers sealed with aluminium crimp caps.
Pack sizes: 1 x 1,000 doses and 10 x 1,000 doses.

6.6 Special precautions for the disposal of unused veterinary product or waste materials derived from the use of such products, if appropriate

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 42058/4097

9. DATE OF FIRST AUTHORISATION

26 October 2005

10. DATE OF REVISION OF THE TEXT

14 November 2019

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