ANNEX III

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Boxes (1 x 1,000 doses and 10 x 1,000 doses)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

POULVAC AE lyophilisate for suspension for use in drinking water
For chickens

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Avian encephalomyelitis virus vaccine strain Calnek, sub-strain AE-67: $10^{3.1}$ to $10^{5.5}$ EID_{50}/dose.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for use in drinking water.
Brownish powder

4. PACKAGE SIZE

1,000 doses
10 x 1,000 doses

5. TARGET SPECIES

Chickens, from 10 weeks of age.

6. INDICATION(S)

For active immunisation of future layers and breeding chickens in order to provide passive immunity to reduce vertical transmission of avian infectious encephalomyelitis virus.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral administration in drinking water.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

9. SPECIAL WARNING(S), IF NECESSARY

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

10. EXPIRY DATE

EXP:
Use within 2 hours of reconstitution.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated.
Protect from light.
Do not freeze.

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

Disposal: read package leaflet.

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

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

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 42058/4097

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

1,000 doses glass vials

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

POULVAC AE

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Avian encephalomyelitis virus vaccine strain Calnek, sub-strain AE-67: $10^{3.1}$ to $10^{5.5}$ EID_{50}/dose.

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

1,000 doses

4. ROUTE(S) OF ADMINISTRATION

For use in drinking water. Read package leaflet before use.

5. WITHDRAWAL PERIOD

Withdrawal period: zero days.

6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

9. SPECIAL STORAGE CONDITIONS

Store at +2°C to +8°C.

10. NAME OF THE MARKETING AUTHORISATION HOLDER

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

11. MARKETING AUTHORISATION NUMBER

Vm 42058/4097

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
POULVAC AE lyophilisate for suspension for use in drinking water

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 the batch release:
Zoetis Manufacturing & Research Spain, S.L
C/Camprodon s/n “La Riba”
17813 Vall de Bianya
Girona
SPAIN

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac AE lyophilisate for suspension for use in drinking water

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

Avian encephalomyelitis virus vaccine strain Calnek, substrain AE-67: $10^{3.1}$ to $10^{5.5}$ EID_{50}/dose.

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

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

6. ADVERSE REACTIONS

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Chickens, from 10 weeks of age.

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

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 point 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 4 gallons of drinking water.
Never give less than 1 dose of vaccine per bird.
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).

9. ADVICE ON CORRECT ADMINISTRATION

Use clean vaccination materials.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL PRECAUTIONS FOR STORAGE

Store and transport refrigerated (2 °C – 8 °C).
Protect from light.
Do not freeze.
Shelf life after reconstitution according to directions: 2 hours.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

Special warnings for each target species:
In order to prevent spread of vaccine 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:
Vaccinated animals should not be in contact with non-vaccinated animals for 42 days post-vaccination.
The vaccine may induce typical signs of avian encephalomyelitis when administered orally to very young birds (less than 1 week of age).

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

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.

Overdose (symptoms, emergency procedures, antidotes):
Administration of a 10-fold overdose does not result in any adverse reactions.

Incompatibilities:
Do not mix with any other veterinary medicinal product.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2019

15. OTHER INFORMATION

For animal treatment only.

ATCvet code: QI01AD02.
Live viral vaccines for birds.

LEGAL CATEGORY
To be supplied only on veterinary prescription.

Pack sizes:
Boxes with 1 x 1,000 doses or 10 x 1,000 doses.

MARKETING AUTHORISATION NUMBER

Vm 42058/4097

Approved 14 November 2019