PARTICULARS TO APPEAR ON THE OUTER PACKAGE
CARDBOARD BOX OF 1 VIAL CONTAINING 1,000 OR 2,000 DOSES
CARDBOARD BOX OF 10 VIALS CONTAINING 1,000 OR 2,000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac AE lyophilisate for use in drinking water

2. STATEMENT OF ACTIVE SUBSTANCES

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

3. PACKAGE SIZE

1 x 1,000 doses
1 x 2,000 doses
10 x 1,000 doses
10 x 2,000 doses

4. TARGET SPECIES

Chickens.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral administration in drinking water.

7. WITHDRAWAL PERIODS

Withdrawal period: Zero days.

8. EXPIRY DATE

Exp. {mm/yyyy}
Once reconstituted use within 2 hours.

9. SPECIAL STORAGE PRECAUTIONS

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

10. THE WORDS “READ THE PACKAGE LEAFLET BEFORE USE”

Read the package leaflet before use.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

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

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Zoetis UK Limited

14. MARKETING AUTHORISATION NUMBERS

Vm 42058/5134

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS
GLASS VIAL WITH 1,000 OR 2,000 DOSES

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac AE

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

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

1,000 doses
2,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Poulvac AE lyophilisate for use in drinking water for chickens

2. 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.

Tan to brown coloured lyophilisate.

3. Target species

Chickens.

4. Indications for use

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.

5. Contraindications

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

6. Special warnings

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

Laying birds:
Do not use in birds in lay and within 4 weeks before the start 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:
Administration of a 10-fold overdose does not result in any adverse reactions.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. Adverse events

Chickens:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system:
E-mail: adverse.events@vmd.gov.uk
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

8. Dosage for each species, routes and method of administration

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.
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).

9. Advice on correct administration

Use clean vaccination materials.

10. Withdrawal periods

Zero days.

11. Special storage precautions

Keep out of the sight and reach of children.
Store and transport refrigerated (2 °C – 8 °C).
Do not freeze.
Protect from light.
Do not use this veterinary medicinal product after the expiry date which is stated on the label after Exp. The expiry date refers to the last day of that month.
Shelf life after reconstitution according to directions: 2 hours.

12. Special precautions for disposal

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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 42058/5134

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.

15. PID link (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

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

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP
Phone: +44 (0) 345 300 8034

Manufacturer responsible for batch release:
Zoetis Manufacturing & Research Spain S.L.
Carretera De Camprodon S/n
La Vall De Bianya
17813 Girona
Spain

17. Other information

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

POM-VPS Veterinary medicinal product subject to prescription

Gavin Hall
Approved: 21 February 2025