SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Poulvac SHS Vaccine lyophilisate for suspension for spray, eye drop or nose drop administration for chickens.

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose contains:

Active substance:
Attenuated Avian Pneumovirus, strain clone K $10^{3.2}$ - $10^{4.5}$ *$CCID_{50}$

* CCID50 = Cell Culture Infectious Dose 50%

Excipients:
For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate for suspension for spray, eye drop or nose drop administration

Cream coloured lyophilisate

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

For active immunisation of broiler chickens to reduce clinical signs associated with infection with avian pneumovirus.

Onset of immunity: Immunity to challenge has been demonstrated 4 weeks after vaccination.

4.3 Contraindications

None.

4.4 Special warnings for each target species

Vaccinate healthy animals only

4.5 Special precautions for use

Special precautions for use in animals

In order to prevent risks of dissemination of the vaccine in the site, all the birds at the same site should be correctly vaccinated.

There is a possibility that the virus may be disseminated to other avian species and care should be taken to avoid contact with other birds.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

If the vaccine is administered by spray, personal protective equipment consisting of safety goggles and a dust mask or a helmet with filtered air circulation should be worn.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Do not use in chickens in lay.

4.8 Interaction with other medicinal products and other forms of interaction

Safety and efficacy data are available which demonstrate that this vaccine can be administered on the same day but not mixed with Poulvac NDW (live Newcastle Disease vaccine) and Poulvac IB Primer (live Infectious Bronchitis vaccine) and Mareks vaccines in the Poulvac range at one day of age, with no adverse effects being noted.

No information is available on the safety and efficacy of this vaccine when used with any other veterinary medicinal product except the products mentioned above. 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

One dose per bird from 1 day of age to be administered by spray, eye drop or nose drop.
Only disinfectant-free and/or antiseptic free materials should be used for the preparation of vaccine solution.

Spray

The vaccine should be reconstituted with water of good quality at room temperature, e.g. deionised water or good quality drinking water. Treat water with milk powder if necessary but ensure there are no particles which may block the spray nozzle.

Remove the aluminium seal from the vaccine vial. To dissolve the vaccine pellet, the rubber stopper should be removed whilst the vial is immersed in a clean plastic measuring jug containing 0.2-0.5 litre of water (as noted below for sprayer types). Half fill the vial with water, replace the stopper and shake to dissolve any remaining vaccine. Pour into the jug and stir carefully to ensure even dispersal of the vaccine. The vaccine should then be added to the sprayer.

The quantity of water depends on the method of administration:

Hand spray: 0.2 L/1000 birds
Knapsack spray: 0.5 L/1000 birds, if the birds are housed on the ground.
0.25 L/1000 birds, if the birds are housed in a battery.
Automatic spray equipment: 0.15-0.50 L/1000 birds (hatchery)

If administered by spray, spray equipment, providing a droplet size of 0.12 - 0.15 mm has to be used (hand spray, knapsack spray, automatic spray equipment). The distance from the spraying head to the birds must be approximately 50 cm.

Hold birds in boxes for approximately 30 - 45 minutes. Ensure the temperature of the holding area is 70 - 80 °F and draught free, to avoid chilling.

Spray application is only to be carried out in housings which can be closed properly. Turn off ventilation fans, if any, avoid air movement.

Eye drop/nose drop

30-50 ml/1000 birds, 0.03-0.05 ml/eye or nostril.

Reconstitute vaccine by dissolving in deionised water for eye drop at the rate of 30 ml to 1,000 doses. The deionised water should be at room temperature. Remove the aluminium cap and rubber stopper from the vaccine vial and add deionised water from 30 ml to half fill the vial. Replace the rubber stopper and shake so that all the vaccine material is completely dissolved. Pour the vaccine concentrate into the rest of the 30 ml and mix well.

Administer by dropper at the rate of one drop (0.03 ml) per bird onto one eye. The use of standardised droppers is recommended. Hold the bird so that one eye is pointing upwards and allow one drop of vaccine to fall into the eye. Birds should swallow during vaccination.

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

None.

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against avian pneumovirus.
Pharmacotherapeutic group: immunologicals for aves, domestic fowl, live viral vaccines, avian rhinotracheitis virus

ATCVet Code: QI01AD01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Mannitol
NZ Case Plus
Gelatin
Inositol

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product, except diluents or other component recommended for use with the veterinary medicinal product.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 20 months
Shelf-life after dilution or reconstitution according to directions: 4 hours

6.4 Special precautions for storage

Store and transport refrigerated (2 ° - 8°C). Keep the container in the outer carton.
Protect from light.
Do not freeze.

6.5 Nature and composition of immediate packaging

Vial
Type I glass containing freeze dried pellet of 1,000, 2,000 or 5,000 doses

Closure:
Siliconised Type I rubber secured with an aluminium cap.

Pack sizes:
Cardboard boxes containing 10 vials of 1,000 doses
Cardboard boxes containing 10 vials of 2,000 doses
Cardboard boxes containing 10 vials of 5,000 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

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

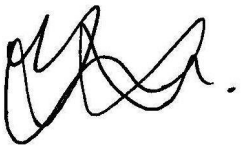
Vm 42058/4112

9. DATE OF FIRST AUTHORISATION

14 January 1998

10. DATE OF REVISION OF THE TEXT

August 2020



Approved: 14 August 2020