1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac PMV suspension for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each 0.2 ml dose contains:

Active substance:
Inactivated Newcastle Disease Virus, strain La Sota at least 19.9AU*
* AU: Antigen Unit

Adjuvant:
Carbomer 934 P 1 mg

Excipients:

Qualitative composition of excipients and other constituents	**Quantitative composition if that information is essential for proper administration of the veterinary medicinal product**
Thiomersal	20 µg
Disodium phosphate dihydrate	
Sodium dihydrogen phosphate dihydrate	
Water for injection	

Off-white liquid.

3. CLINICAL INFORMATION

3.1 Target species

Pigeons.

3.2 Indications for use for each target species

For the active immunisation of pigeons to reduce mortality and clinical signs due to paramyxovirus serotype 1 infection.

Onset of immunity: 4 weeks.

Duration of immunity: 1 year.

3.3 Contraindications

Do not vaccinate during the last 2 weeks prior to mating.

3.4 Special warnings

Vaccinate healthy animals only.

3.5 Special precautions for use

Special precautions for safe use in the target species:

Not for intramuscular injection: Intramuscular injection causes severe adverse reactions.
Maternally derived antibody (MDA) can interfere with the development of active immunity. Where it is likely that recent field infection or vaccination of the parent flock has stimulated a high antibody titre and consequently a high level of MDA, the timing of the vaccination programme should be planned accordingly.

In cases of hypersensitivity reactions treat immediately with glucocorticoid intravenously or adrenaline intramuscularly.

The incubation period for pigeon paramyxovirosis may be a few days to several weeks. However, after infection with the wild virus, pigeons may excrete the virus from the eye and in the droppings within 3-4 days. This means that infected birds can be a danger to others some days before their own symptoms appear. Excretion of wild virus from the infected bird continues for up to 6 weeks. This information is important since, in addition to direct bird to bird contact at competitions and shows, the disease can be spread by indirect means such as hands, overalls, caps, boots and contaminated objects such as baskets and trucks.
An owner should forbid visits to the loft by anyone in contact with unvaccinated pigeons and new birds (either purchased or lent for mating) should not be brought in unless vaccinated at least 14 days previously.

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

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or the label to the physician.

Special precautions for the protection of the environment:

Not applicable.

3.6 Adverse events

Pigeons:

Very common (>1 animal / 10 animals treated):	Injection site swelling[1]

[1] Up to 1 cm in diameter, which may last up to 4 weeks or more. They tend to disappear without treatment. In cases of adverse reactions not disappearing spontaneously the veterinary surgeon should be contacted.

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

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

Fertility:
Vaccination is safe in breeding birds provided they are vaccinated before the start of breeding.

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

Subcutaneous use.

Dose: One dose (0.2 ml) per pigeon.

Administration: The vial has to be swirled several times before use.
The vaccine has to be administered by subcutaneous injection dorsally in the neck region (in the direction of the back).

Primary vaccination:

Racing Pigeons

All birds in the loft should be given one vaccination annually not less than 14 days before the beginning of the racing season.
Young birds may be vaccinated with the veterinary medicinal product from 3 weeks of age when a single injection will provide immunity for 1 year.
Following vaccination avoid contact with birds from other lofts for at least 14 days.

Show Pigeons

All birds on the premises should be given one vaccination annually not less than 14 days before the beginning of the show season.
Young birds may be vaccinated with the veterinary medicinal product from 3 weeks of age when a single injection will provide immunity for 1 year. Following vaccination, avoid contact with birds from other sources for at least 14 days.

Booster vaccination:

Racing Pigeons

All adult birds in the loft should be given a single booster vaccination annually. Where the annual booster vaccination may interfere with the training or racing programme, it may be brought forward prior to the commencement of each racing season.

Show Pigeons

All adult birds on the premises should be given a single booster vaccination annually.

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

An overdose may result in an increase of the degree of local 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: QI01EA01

To stimulate active immunity against Paramyxovirus infection serotype 1.

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 first opening the immediate packaging: use immediately.

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

Nature: 20 ml, Type hydrolytic I glass vial (Ph. Eur.)
Closure: Butyl rubber stopper (Ph. Eur.), sealed by 20 mm aluminium “tear-off” cap.

Cardboard box containing: 1 x 50 doses (10 ml) or 1 x 100 doses (20 ml).

Not all pack sizes may be marketed.

5.5 Special precautions for the disposal of unused veterinary medicinal products or waste materials derived from the use of such products

Medicines should not be disposed of via wastewater or household waste.

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 Belgium S.A.

7. MARKETING AUTHORISATION NUMBER(S)

VPA10387/007/001

8. DATE OF FIRST AUTHORISATION

24/11/2014

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

23/07/2025

10. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product not subject to prescription.

Detailed information on this veterinary medicinal product is available in the Union Product Database (*https://medicines.health.europa.eu/veterinary*).