SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac® PMV

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Per 0.2 ml dose
Active Substance:
Inactivated Newcastle Disease Virus, strain La Sota at least 19.9 AU*
* AU: Antigen Unit

Adjuvants:

Carbomer 934 P	1 mg

Excipients:

Thiomersal	20 µg

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Suspension for injection

4. CLINICAL PARTICULARS

4.1 Target Species

Pigeons

4.2 Indications for use, specifying the target species

For the active immunisation of pigeons to prevent mortality and clinical signs due to infection with paramyxovirus serotype 1 infection.
Onset of immunity: one month after inoculation
Duration of immunity: 12 months.

4.3 Contraindications

Do not use in unhealthy pigeons
Do not vaccinate during the last 2 weeks prior to mating

4.4 Special warnings for each 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.

4.5 Special precautions for use, including special precautions to be taken by the person administering the veterinary medicinal product to animals

(i). Special precautions for use in animals

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 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 competition 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.

(ii). 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.

4.6 Adverse reactions (frequency and seriousness)

A transient swelling at the injection site of up to approximately 1 cm in diameter may occur very commonly, which may last up to 4 weeks or more. Swellings normally tend to disappear without treatment. In cases of adverse reactions not disappearing spontaneously the veterinary surgeon should be contacted.
The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 animals in 100 animals)
- uncommon (more than 1 but less than 10 animals in 1,000 animals)
- rare (more than 1 but less than 10 animals in 10,000 animals)
- very rare (less than 1 animal in 10,000 animals, including isolated reports).

4.7 Use during pregnancy, lactation or lay

Do not use in birds in lay or within 4 weeks before the onset of the laying period. Vaccination is safe in breeding birds provided they are vaccinated before the start of breeding.

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

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 Colombovac PMV 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 Colombovac PMV 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.

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

An overdose did not result in adverse reactions other than those mentioned in section 4.6 Adverse reactions.

4.11 Withdrawal period

Zero days

5. IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Paramyxovirus infection type 1.

ATCVet Code: QI01EA01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Thiomersal
Carbomer 943 P
Disodium phosphate.dihydrate
Sodium dihydrogen phosphate dihydrate
Water for injection

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf-life as packaged for sale: 18 months
Shelf-life after first opening the immediate packaging: Use immediately

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

Nature:	20ml, Type hydrolytic I glass vial (Ph. Eur.)
Closure:	Bromobutyl rubber stopper (Ph. Eur.), sealed by 20 mm aluminium “tear-off” cap
Contents:	Either 1 x 50 doses (10 ml) or 1 x 100 doses (20 ml) Colombovac PMV.

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 products should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4020

9. DATE OF FIRST AUTHORISATION

28 February 2005

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 19 August 2020