

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 19.9AU*

* AU: Antigen Unit

Adjuvant(s):

Carbomer 934 P1 mg

Excipient(s):

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 active immunisation of pigeons to reduce mortality and clinical signs due to paramyxovirus type 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

Special precautions for use in animals

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

The incubation period for pigeon paramyxovirus 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 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.

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 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.

4.9 Amounts to be administered and administration route

Dose: One dose (0.2ml) 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 may result in an increase of the degree of local reactions.

4.11 Withdrawal period(s)

Zero days.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

To stimulate active immunity against Paramyxovirus infection type 1.

ATC Vet 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: Butyl rubber stopper (Ph.Eur.), sealed by 20mm aluminium "tear-off" cap

Contents: Either 1 x 50 doses (10ml) or 1 x 100 doses (20ml) 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 Belgium S.A.
2nd Floor, Building 10
Cherrywood Business Park, Loughlinstown
Co Dublin
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA10387/007/001

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 16th December 2002

Date of last renewal: 15th December 2007

10 DATE OF REVISION OF THE TEXT

October 2017