PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Colombovac PMV – Carton
50 doses
100 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac PMV

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Inactivated Newcastle Disease Virus, strain La Sota.
One dose contains at least 19.9 AU/0.2 ml dose.
Also contains 1 mg carbomer 934P as adjuvant and 20 micrograms thiomersal as preservative.

3. PHARMACEUTICAL FORM

Suspension for injection for pigeons from the age of 3 weeks.

4. PACKAGE SIZE

50 doses (10 ml)
100 doses (20 ml)

5. TARGET SPECIES

Pigeons

6. INDICATION(S)

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

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Method and route of administration: 0.2 by SC injection only.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.
In cases of hypersensitivity reactions treat immediately with glucocorticoid intravenously or adrenaline intramuscularly.
Avoid accidental self-injection, see package leaflet for details.

10. EXPIRY DATE

Exp:
Use entire contents when first opened.

11. SPECIAL STORAGE CONDITIONS

Store and transport refrigerated (+2°C – +8°C). Do not freeze. Protect from light.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Read the package leaflet before use.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

For animal treatment only.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UK only POM-VPS

Vm 42058/4020

To be supplied only on veterinary prescription.

MARKETING AUTHORISATION HOLDER:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Ireland only: POM(E) VPA 10438/8/1	**MARKETING AUTHORISATION HOLDER:** Zoetis Ireland Limited 25/28 North Wall Quay Dublin 1

16. MARKETING AUTHORISATION NUMBER(S)

UK: Vm 42058/4020
IE: VPA 10438/8/1

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Colombovac PMV - Vial label
50 doses
100 doses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac PMV
Suspension for injection for pigeons

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Inactivated Newcastle Disease Virus, strain La Sota.
One dose contains at least 19.9 AU/0.2 ml dose.
Also contains 1 mg carbomer 934 P as adjuvant and 20 micrograms thiomersal as preservative.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

50 doses (10 ml)
100 doses (20 ml)

4. ROUTE(S) OF ADMINISTRATION

SC injection

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp:
Use entire contents when first opened.

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

UK:
POM-VPS Vm 42058/4020
To be supplied only on veterinary prescription.

Ireland:
POM(E) VPA 10438/8/1

PACKAGE LEAFLET FOR:
Colombovac PMV/Pox

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

MARKETING AUTHORISATION HOLDER:
UK:
Zoetis UK Limited
1st Floor, Birchwood Building
Springfield Drive
Leatherhead
Surrey
KT22 7LP

Ireland:
Zoetis Ireland Limited
25/28 North Wall Quay
Dublin 1

MANUFACTURER RESPONSIBLE FOR THE BATCH RELEASE:
Zoetis Manufacturing & Research Spain, S.L.
Ctra. Camprodon s/n “La Riba”
17813 Vall de Bianya, Girona, Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac PMV

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)

Inactivated Newcastle Disease Virus, strain La Sota.
One dose contains at least 19.9 AU*/0.2 ml dose.
Also contains 1 mg carbomer 934 P as adjuvant and 20 micrograms thiomersal as preservative.
* Antigen Unit

4. INDICATION(S)

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.

5. CONTRAINDICATIONS

Do not use in unhealthy pigeons.
Do not vaccinate during the last 2 weeks prior to mating.
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.
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.
Do not mix with any other veterinary medicinal product.

6. ADVERSE REACTIONS

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 reaction(s) 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).>

An overdose did not result in adverse reactions other than those mentioned above.

If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Pigeons

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Dose: One dose (0.2 ml) per pigeon.
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 bought 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.

9. ADVICE ON CORRECT ADMINISTRATION

The vial has to be swirled several times before use.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Store and transport refrigerated (2°C - 8°C).
Protect from light. Do not freeze.
Use entire contents of vial once opened.
Do not use after the expiry date stated on the label.

12. SPECIAL WARNING(S)

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

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

PACKAGE QUANTITIES

1 x 50 doses (10 ml)
1 x 100 doses (20 ml)
Not all pack sizes may be marketed.

UK:
POM-VPS Prescription Only Medicine – Veterinarian
Vm 42058/4020
To be supplied only on veterinary prescription.

Ireland:
POM(E) Prescription Only Medicine (Exempt)
VPA 10438/8/1

Approved 19 August 2020