

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Colombovac PMV/Pox - Carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac PMV/Pox

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Colombovac PMV/Pox comprises one vial of liquid inactivated, adjuvanted avian paramyxovirus serotype 1 (PMV-1) vaccine containing at least 19.9 AU/0.2 ml dose and one vial of freeze dried pigeon pox (DD strain) vaccine containing $10^{3.5} - 10^{4.3}$ TCID₅₀/dose of attenuated virus.

Contains carbomer 934P (1 mg/dose) as an adjuvant.

Also contains thiomersal (20 µg) and formaldehyde (not more than 0.05%/dose) as excipients.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. PACKAGE SIZE

50 doses

5. TARGET SPECIES

Pigeons

6. INDICATION(S)

The vaccine is indicated for the primary and booster vaccination of healthy, susceptible, immune competent pigeons against infection with PMV-1 and pigeon pox.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Add the contents of the PMV vaccine vial to the pox vaccine vial.
Use the entire contents of the vial once reconstituted.
For use, see leaflet.

0.2 ml of reconstituted vaccine by subcutaneous injection only.

8. WITHDRAWAL PERIOD

Withdrawal period: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

In cases of adverse reaction, consult your veterinary surgeon.
Only healthy birds should be vaccinated.
Aseptic precautions should be observed at all times.

10. EXPIRY DATE

Exp:

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

Dispose of unused vaccine and/or empty vials by incineration.

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

For animal treatment only.

POM-VPS

To be supplied only on veterinary prescription.

14. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER(S)

Vm 42058/4021

17. MANUFACTURER'S BATCH NUMBER

Lot:

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Colombovac PMV/Pox – PMV vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac PMV

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

An inactivated adjuvanted vaccine based on an avian paramyxovirus serotype 1 (PMV-1) strain containing at least 19.9 AU/0.2 ml dose for the primary and booster vaccination of healthy, susceptible, immune competent pigeons against paramyxovirus infections caused by the PMV-1 serotype.

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

50 doses

4. ROUTE(S) OF ADMINISTRATION

Use one vial of Colombovac PMV to reconstitute one vial of Colombovac Pox.
0.2 ml subcutaneous injection only.
Shake the vial before use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Keep out of sight and reach of children.

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

For uses and warnings, see leaflet.
Keep the container in the outer carton.
To be supplied only on veterinary prescription.

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MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Colombovac PMV/Pox – Pox vial label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac Pox

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

A live, freeze dried vaccine based on a pox virus strain DD containing $10^{3.5} - 10^{4.3}$ TCID₅₀/dose of attenuated virus for the primary and booster vaccination of healthy, susceptible, immune competent pigeons against pigeon pox infection.

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

50 doses

4. ROUTE(S) OF ADMINISTRATION

Reconstitute one vial of Colombovac Pox with one vial of Colombovac PMV.
0.2 ml subcutaneous injection only.
Shake the vial before use.

5. WITHDRAWAL PERIOD

Withdrawal period: Zero days.

6. BATCH NUMBER

Lot:

7. EXPIRY DATE

Exp:

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.
Keep out of sight and reach of children.

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

For uses and warnings, see leaflet.
Keep the container in the outer carton.
To be supplied only on veterinary prescription.

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**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:

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

Manufacturer responsible for 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/Pox

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

Lyophilisate and solvent for suspension for injection.

Colombovac PMV/Pox is presented in two vials.

Colombovac PMV/Pox comprises one vial of liquid inactivated, adjuvanted avian paramyxovirus serotype 1 (PMV-1) vaccine containing at least 19.9 AU*/0.2 ml dose and one vial of freeze dried pigeon pox (DD strain) vaccine containing $10^{3.5} - 10^{4.3}$ TCID₅₀/dose of attenuated virus.

Contains carbomer 934P (1 mg/dose) as an adjuvant.

Also contains thiomersal (20 µg) and formaldehyde (not more than 0.05%/dose) as excipients.

Reconstitute one Colombovac Pox vial containing the freeze dried pox vaccine with the contents of one vial of the liquid Colombovac PMV paramyxovirus vaccine immediately before use.

*AU: Antigen Unit.

4. INDICATION(S)

For the primary and booster vaccination of healthy, susceptible, immune competent pigeons against paramyxovirus infection caused by the PMV-1 serotype and as an aid in protection against pigeon pox virus infection.

5. CONTRAINDICATIONS

Only healthy birds should be vaccinated.
Administer the vaccine only by the subcutaneous route,

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 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).

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

Administer 0.2ml of reconstituted vaccine by subcutaneous injection. Administer into the neck in the direction of the back.

Reconstitution

Shake the liquid Colombovac PMV vial before withdrawing all of the contents. Inject all of this liquid vaccine into one vial containing the freeze dried pellet of Colombovac Pox vaccine. Shake again before use.

Dosage regimen

1. **Racing pigeons:** All birds in the loft should be given a vaccination annually from the early new year not less than 21 days before the beginning of the racing season.

Birds may be vaccinated with Colombovac PMV/Pox from 6 weeks of age when a single injection will provide immunity for one year for paramyxovirus and throughout the greatest season for risk for pox, the spring and summer months

when vaccinated in the first quarter of the year. Following vaccination, avoid contact with birds from other lofts for at least 21 days to allow immunity to develop.

All late-hatched young pigeons should be given one vaccination from 6 weeks of age and not mixed with birds from other lofts for at least 21 days.

All adult birds on the in the loft should be given a single booster vaccination annually from the early New Year. 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.

- 2. Show pigeons:** All birds on the premises should be given one vaccination annually not less than 21 days before the beginning of the show season.

Birds may be vaccinated with Colombovac PMV/Pox from 6 weeks of age when a single injection will provide immunity for one year for paramyxovirus and throughout the greatest season for risk for pox, the spring and summer months when vaccinated in the first quarter of the year. Following vaccination, avoid contact with birds from other lofts for at least 21 days to allow immunity to develop.

All adult birds on the premises should be given a single booster vaccination annually in the early new year.

9. ADVICE ON CORRECT ADMINISTRATION

Aseptic precautions should be observed at all times.

10. WITHDRAWAL PERIOD

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Store and transport refrigerated (2°C – 8°C).

Do not freeze.

Protect from light. Keep out of sight and reach of children.

Use the entire contents of both vials when first opened.

Use within 2 hours of reconstitution.

Do not use after the stated expiration date.

12. SPECIAL WARNING(S)

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.

As vaccination can be disruptive during the breeding season, it is advised that birds are not vaccinated from pairing up until production of the first egg.

In cases of anaphylactoid reaction, treat immediately with glucocorticoid intravenously or adrenaline intramuscularly.

In any animal population there will be a small number of individuals which fails to respond fully to vaccination. Successful vaccination depends upon correct storage and administration of vaccine and the animal's ability to respond. Immune competence can be influenced by genetic factors, intercurrent infection, age, nutritional status, concurrent drug therapy, stress, etc.

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. The advice or your veterinary surgeon may be sought in such cases.

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

Dispose of unused containers by incineration.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2020

15. OTHER INFORMATION

A pack comprising:

One vial containing 50 doses of freeze dried Colombovac Pox vaccine.

One vial containing 50 doses of liquid Colombovac PMV vaccine.

FURTHER INFORMATION

An owner should prohibit visit to the loft by anyone in contact with unvaccinated pigeons and new birds (either purchased or lent for mating) should not be bought-in unless vaccinated at least 21 days previously.

Pigeon Paramyxovirus

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 systems appear. Excretion of wild virus from the infected bird continues for up to 6 weeks.

In addition to direct bird to bird contact at competitions and shows, the disease can spread by indirect means such as hands, overalls, cap, boots and contaminated objects such as baskets and trucks.

Pigeon Pox

The incubation period of Pigeon Pox is usually 5 to 15 days and the disease may manifest as crusty skin lesions around the eye, beak and on the feather follicles, or mucosal, diphtheroid lesions of the larynx or gullet. Virus may be excreted in saliva,

nasal and eye secretions but rarely in the droppings, and is also present in crusty scab material from any skin lesions. Virus can be spread directly from bird to bird, or via feeding or drinking utensils or by other direct means. A pigeon from an infected loft can carry the pox virus and may infect other birds without itself showing signs of disease.

MARKETING AUTHORISATION NUMBER

Vm 42058/4021

Approved 19 August 2020

A handwritten signature in black ink, consisting of a series of connected, wavy lines.