SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Colombovac PMV/Pox

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Qualitative composition

Combined Newcastle disease vaccine (inactivated) and pigeon pox vaccine (live), freeze-dried.

Quantitative composition

Colombovac PMV

Active Substances:	Per 0.2 ml dose
Inactivated Newcastle disease virus, strain La Sota:	at least 19.9 AU*

* AU: Antigen Unit

Adjuvants:	Per 0.2 ml dose
Carbomer 934 P	1.0 mg

Excipients:

For a full list of excipients, see section 6.1.

Colombovac Pox

Active Substances:	Per 0.2 ml dose
Live pigeon pox virus strain DD	not less than $10^{3.5}$ $TCID_{50}$
	not more than $10^{4.3}$ $TCID_{50}$

Excipients:

Thimerosal	20 μg
Formaldehyde	not more than 0.05%

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Lyophilisate and solvent for suspension for injection.

4. CLINICAL PARTICULARS

4.1 Target Species

Pigeons from the age of 6 weeks.

4.2 Indications for use specifying the target species

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

4.3 Contraindications

Do not vaccinate unhealthy pigeons.
Do not administer by intramuscular injection.

4.4 Special warnings

None.

4.5 Special precautions for use

(i) Special precautions for use in animals

See section 4.9

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

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.

(ii) Special precautions to be taken by the person administering the veterinary medicinal product to animals

None.

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

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.

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

Vaccination Schedule

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.

Use within 2 hours of reconstitution.

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 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.

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 for 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.

Booster vaccination:

Racing Pigeons

All adult birds 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.

Show Pigeons

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

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

The vaccine induces an active immunity against disease caused by pigeon pox virus and disease caused by paramyxovirus type 1 (PMV-1).

ATCVet code: QI01EH01

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Colombovac PMV

Disodium phosphate dihydrate
Sodium dihydrogen phosphate monohydrate
Thimerosal
Formaldehyde

Colombovac Pox
Disodium phosphate dihydrate
Potassium hydrogen phosphate
Gentamycin

6.2 Incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Colombovac PMV: 18 months
Colombovac Pox: 36 months

Reconstituted vaccine (Colombovac Pox, reconstituted in Colombovac PMV): 2 hours.

Use entire contents when reconstituted.

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

Colombovac PMV
Nature: Glass hydrolytic class I (Ph Eur)
Closure: Bromobutyl rubber stopper with aluminium tear-off cap
Contents: 11 ml (50 doses presentation)

Colombovac Pox
Nature: Glass hydrolytic class I (Ph Eur)
Closure: Bromobutyl rubber stopper with aluminium tear-off cap
Contents: freeze dried pellet

Authorised pack size:
A pack comprising:
One vial containing 50 doses of freeze dried Colombovac Pox vaccine
One vial containing 50 doses of liquid Colombovac PMV vaccine

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

Unused product must be destroyed by incineration.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 42058/4021

9. DATE OF FIRST AUTHORISATION

05 October 1998

10. DATE OF REVISION OF THE TEXT

August 2020

Approved 19 August 2020