

PMV-salmo-vac, emulsion for injection for pigeons

Vaccine against salmonella and paratyphoid

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

Bioveta, a. s., Komenského 212/12, 683 23 Ivanovice na Hané, Czech Republic

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PMV-salmo-vac, emulsion for injection for pigeons

Vaccine against salmonella and paratyphoid

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

One vaccine dose (0.3 ml) contains:

Active substance:
Paratyphoid pseudopestis avium, strain NDV SL-93, inactivated RP $\geq 1^*$
Salmonella typhimurium subsp. *Copenhagen*, strain 1, 4, 12 : i : 1, 2, inactivated RP $\geq 1^*$

*RP = Relative potency (determined by ELISA) compared with the reference serum obtained after vaccination of mice with a vaccine batch that has successfully passed the challenge test on the target species.

Adjuvants:
Montanide ISA 70 VG 0.24 ml

Excipient(s):
Formaldehyde 35 % max. 0.15 mg
Thiomersal 0.026 – 0.035 mg

4. INDICATION

The vaccine is intended for active immunization of pigeons from the third week of age against paratyphoid and salmonellosis caused by *S. typhimurium* var. *Copenhagen*. Immunity starts 4 weeks after vaccination and lasts for one year.

Vaccination reduces the colonization of the strains and their occurrence in faeces: *S. typhimurium* var. *Copenhagen*, *S. enterica* subsp. *Enterica* serovar *typhi*,

S. paratyphi A, *S. hirschfeldii* (*S. paratyphi* C), *S. anatum*, *S. senftenberg*.

5. CONTRAINDICATION

Do not vaccinate sick birds, birds infested with parasites, or birds losing feathers.

6. ADVERSE REACTION

No adverse reactions were observed after vaccination with PMV-Salmo-Vac. Clinical tests performed three weeks after vaccination revealed individual histopathological changes at the injection site, caused by residues of the oil adjuvant. No additional adverse reactions were recorded.

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

7. TARGET SPECIES

Pigeon.

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

Basic vaccination of young pigeons (aged 3 – 4 weeks) which have not been vaccinated against paratyphoid and *Salmonella* yet: 2 doses (by 0.3 ml) at an interval of 4 weeks. The dose is applied intramuscularly into the breast muscle. The second vaccination should be carried out not later than 3 weeks before the flight, exhibition, etc.

Adult pigeons which have been vaccinated with PMV-Salmo-Vac must be revaccinated annually, 2 – 3 weeks before mating.

Method of administration: intramuscular into the breast muscle.

9. ADVICE ON CORRECT ADMINISTRATION

Do not use syringes made of natural rubber or with a rubber plunger. Before use heat the vaccine to room temperature and shake.

It is recommended to vaccinate outside, at temperatures above 0 °C.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTION

Keep out of the sight and reach of children. Store in a refrigerator (2 °C – 8 °C). Protect from frost. Protect from light. Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month. Shelf life after first opening the container: 10 hours.

12. SPECIAL WARNINGS

Special warnings for each target species:

Not applicable.

Special precautions for use in animals:

Not applicable.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

To the user:

This veterinary medicinal product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given. If you are accidentally injected with this veterinary medicinal product, seek prompt medical advice even if only a very small amount is injected and take the package leaflet with you. If pain persists for more than 12 hours after medical examination, seek medical advice again.

To the physician:

This veterinary medicinal product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Use during pregnancy, lactation or lay:

The safety of the veterinary medicinal product was not tested during the egg-laying period.

Interaction with other medicinal products and other forms of interaction:

No information is available on the safety and efficacy of this vaccine immunological veterinary medicinal product when used with any other veterinary medicinal product. A decision to use this vaccine immunological veterinary medicinal product before or after any other veterinary medicinal product therefore needs to be made on a case by case basis.

Overdose (symptoms, emergency procedures, antidotes):

After administration of a double dose of the vaccine, small changes in the muscle tissue may occur at the injection site.

Incompatibilities:

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

In case of accidental self-injection, seek medical advice immediately and show the package leaflet or 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 product should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED
October 2013

15. OTHER INFORMATION

Pack size:
10-ml vial (1 × 25 doses, 10 × 25 doses),
20-ml vial (1 × 60 doses),
50-ml vial (1 × 150 doses)

Not all pack sizes may be marketed.

This veterinary medicinal product is available only on prescription.

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