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Before using veterinary medicinal products, please read the package leaflet provided with the product.

For information regarding each medicinal product, please contact the marketing authorisation holder.

Details of the offer are available from company representatives and at the company's headquarters.

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Alphabetical index of products

1.	Elisol	4	5.	Mycosalmovir®	.10-1
2.	Enflocyna® Sol	5-6	6.	PM-VAC [®]	.12-1
3.	Immunex complex proszek	7	7.	Salmovir [®]	.14-1
4.	Insectin	8-9			

Active ingredients and products list

Ascorbic acid

• Immunex complex – compound preparation, powder

Betaglucan

• Immunex complex – compound preparation, powder

Calcium chloride

• Elisol - compound preparation, oral solution

Enrofloxacin

• Enflocyna Sol – oral solution

• Immunex complex – compound preparation, powder

Magnesium chloride

Elisol – compound preparation, oral solution

1 3 5

Permethrin

Insectin – powder

Sodium chloride

• Elisol - compound preparation, oral solution

Vaccines

- Mycosalmovir injectable emulsion
- PM-VAC injectable emulsion
 Salmovir injectable emulsion

Index of products by therapeutic indication

Antibiotics

Enflocyna® Sol

Calcium and electrolyte products

Elisol

Ectoparasite control products

Insectin®

Immune system stimulating products

Immunex complex powder

Mineral and vitamin products

Immunex complex powder

Vaccines

Mvcosalmovir[®] PM - VAC®

Salmovir®



electrolyte support for victorious flights

for victorious flights

Elisol

Multi-electrolyte solution for pigeons and ornamental bird (chlorides: sodium, calcium, and magnesium)





- strengthens the body
- prevents electrolyte loss and dehydration
- replenishes essential nutrients: potassium, iron, sodium, zinc, manganese, copper, calcium and magnesium

Composition

sodium chloride calcium chloride magnesium chloride

Dietary Additives / Trace Elements (per kg)

3b201 potassium iodide - 46 mg

3b102 iron (III) chloride hexahydrate – 1160 mg

3b602 anhydrous zinc chloride – 177 mg

3b501 manganese chloride tetrahydrate – 144 mg

 $3b403\,copper\,chloride\,dihydrate\,-\,54\,mg$

Technological Additives (per kg)

1aE332 potassium citrate – 18,250 mg

1aE331 sodium citrate – 1,910 mg

Analytical Constituents (per 100 ml)

potassium – 643 mg, sodium – 226 mg, calcium – 13.8 mg, magnesium – 10 mg

crude protein -<5%, crude ash -<2%, crude fat -<1%, crude fiber -<1%, moisture -98%

Properties and indications

Elisol rapidly regulates the water-electrolyte balance, strengthens the body, and prevents electrolyte loss and dehydration. The product is recommended during periods of intense physical exertion, especially in the racing season, during illnesses, particularly those associated with diarrhea, in convalescence, during hot weather and in stressful situations (transport, exhibitions, flock rearrangements). It is also beneficial during the intensive feeding period of young birds.

Directions for use

Elisol should be administered in drinking water at a rate of 10 ml per 1 liter of water (daily dose for 20 pigeons or ornamental birds weighing up to 1 kg):

- Preventively: 2 times per week
- During chick-feeding periods, illness, or hot weather: daily
- During the racing season: administer for 2 days before the flight at 10 ml per 1 liter of water and 15 ml per 1 liter of water on the day of return

Use clean water (preferably boiled) for preparation.

Administer in clean containers.

The solution can also be mixed with food.

Storage conditions

Store at room temperature in the original packaging. Protect from light and moisture.

After opening, seal tightly and use within 4 weeks.

Shelf life: 24 months

Package sizes: 100 ml, 500 ml

Complementary feed mixture for pigeons and ornamental birds.

Veterinary identification number: α PL0614003p Leaflet preparation date: 2024-11-13



Enflocyna Sol



Oral solution for pigeons, turkeys, chickens, dogs, cattle and pigs (enrofloxacin 50 mg/ml)

Composition

Each ml contains:

Active substance:

Enrofloxacin – 50 mg

Excipient:

Benzyl alcohol (E-1519) – 15.7 mg Clear, slightly yellow solution.

Target species

Cattle, pigs, dogs, hens, turkeys, pigeons.

Indications for use

The veterinary medicinal product is effective for treating general and local diseases caused by microbes susceptible to enrofloxacin, in particular bacterial infections of respiratory and genitourinary systems, as well as bacterial skin infections, wound infections and secondary infections in viral diseases. It has a broad spectrum of action against Gram-positive bacteria (in particular, *Staphylococcus spp.*, *Streptococcus spp.*), Gram-negative bacteria (in particular *E. coli, Salmonella spp.*, *Pasteurella spp.*, *Klebsiella spp.*, *Pseudomonas spp.*) and *Mycoplasma species*.

Efficacy of enrofloxacin has been confirmed in particular in the treatment of the following diseases in the target species:

<u>Cattle (calves):</u> Treatment of respiratory infections caused by *Klebsiella spp., Pasteurella spp., Mycoplasma spp.*, urinary tract infections caused by *Staphylococcus spp., Klebsiella spp., Pseudomonas spp.*, and gastrointestinal infections caused by *E. coli, Salmonella spp.*

<u>Pigs:</u> Treatment of respiratory infections caused by *Klebsiella spp., Pasteurella spp., Mycoplasma spp.*, urinary tract infections caused by *Klebsiella spp., Pseudomonas spp.*, gastrointestinal infections caused by *E. coli, Salmonella spp.*, MMA syndrome caused by *Staphylococcus spp., Streptococcus spp., E. coli, Klebsiella spp.*

<u>Dogs:</u> Treatment of respiratory infections caused by *Staphylococcus spp., Klebsiella spp., Pasteurella spp., Mycoplasma spp.,* urinary tract infections caused by *E. coli, Klebsiella spp., Pseudomonas spp.,* and gastrointestinal infections caused by *E. coli, Salmonella spp.*

<u>Pigeons:</u> Treatment of systemic infections caused by Staphylococcus spp., Escherichia coli, Salmonella spp., Pasteurella spp., Mycoplasma spp., as well as bacterial infections in viral diseases.

<u>Hens, turkeys:</u> Treatment of infections caused by the following bacteria susceptible to enrofloxacin:

- Hens: Mycoplasma gallisepticum, Mycoplasma synoviae, Avibacterium paragallinarum, Pasteurella multocida.
- Turkeys: Mycoplasma gallisepticum, Mycoplasma synoviae, Pasteurella multocida.

Contraindications

Do not use as a preventive measure.

Do not use in case of confirmed cross-resistance to fluoroquinolones in a herd intended to be treated.

Do not use in small breed dogs less than 8 months of age, in large breed dogs less than 12 months of age, whereas in giant breed dogs less than 18 months of age.

Do not use in calves with developed forestomach.

Do not use in case of hypersensitivity to the active substance or to any of the excipients.

Special warnings

Special warnings:

Treatment of infections caused by *Mycoplasma spp.* might not eradicate this bacteria completely.

Special precautions for safe use in the target species:

Principles of prudent use:

If possible, fluoroquinolones should be used based on results of antimicrobial resistance testing.

During product use, comply with the applicable national and local guidelines for using antimicrobial drugs.

Fluoroquinolones should be used in treating only those diseases in which observed response to administration of other classes of antimicrobial drugs is not satisfactory or the response to treatment is expected to be insufficient.

Using the product contrary to provisions of the Summary of Product Characteristics may lead to increased frequency of microbial resistance to fluoroquinolones and decreased efficacy of treatment using other quinolones due to emergence of a potential cross-resistance.

Since the initial approval of enrofloxacin for use in poultry, reduced susceptibility of E. coli to fluoroquinolones and emergence of susceptible microorganisms have been observed to spread. Resistance of *Mycoplasma synoviae* has also been reported in the EU.

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

In case of accidental contact with skin or mucous membranes – immediately flush the affected area with water.

Pregnancy and lactation:

Do not use during pregnancy and the lactation period. Laying birds:

The product can be used in the laying period.

<u>Interaction with other medicinal products and other forms of interaction:</u>

Do not use the product simultaneously with macrolide antibiotics, tetracyclines and theophylline, in pigeons taking coccidiostatics. Magnesium and aluminium compounds may inhibit absorption of enrofloxacin from the gastrointestinal tract

Overdose:

Enrofloxacin displays low toxicity after single-dose administration, and low acute toxicity. LD_{so} is approx. 4000-5000 mg/kg body weight after per os administration in

rats and mice, whereas in rabbits which are more susceptible – 500-800 mg/kg body weight.

After a single-dose

administration of a particularly high amount, toxic effects may be manifested by lethargy, tremor, tonic seizures, ataxia and dyspnoea.





Enflocyna Sol



Oral solution for pigeons, turkeys, chickens, dogs, cattle and pigs (enrofloxacin 50 mg/ml)

Major incompatibilities:

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

Adverse events

Target species: cattle (calves), pigs, dogs, hens, turkeys, pigeons.

Very rare (<1 animal/10 000 animals treated, including isolated reports) Developmental changes in cartilage¹

Gastrointestinal disorders ¹ Nervous system disorders ¹

¹ Long-term use of high therapeutic doses in growing animals Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products

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https://smz.ezdrowie.gov.pl

Dosage for each target species, route(s) and method(s) of administration

Cattle (calves): 0.05-0.10 ml of the product/kg body weight

for 3 to 5 days.

Pigs: 0.05-0.10 ml of the product/kg body weight

for 3 to 5 days.

<u>Dogs:</u> 0.05-0.10 ml of the product/kg body weight

for 3 to 5 days.

<u>Hens and turkeys:</u> 0.2 ml of the product/kg body weight (corr. to 10 mg of enrofloxacin/kg body weight) daily for 3 to 5 consecutive days.

Administer for 3 to 5 consecutive days; in case of mixed infections or chronic progressive infections, for 5 days. If clinical signs do not alleviate within 2 to 3 days, treatment with alternative antimicrobials should be considered based on the results of susceptibility testing.

Pigeons: 0.1 – 0.4 ml of the product/kg body weight.

Administer the product after dilution in water, assuming that the average daily water intake by 20 pigeons is 1 litre. If the water intake is different, this should be taken into account in dosage.

Salmonellosis: 0.4 ml/kg body weight, corr. to 4 ml/1 litre of water daily for 3 days or 2 ml/1litre for 7 to 10 days.

Mycoplasmosis, respiratory infection in pigeons: 0.2 ml/kg body weight corr. to 2 ml/litre of water for 4 to 7 days.

Other bacterial infections: $0.1 \, \text{ml/kg}$ body weight, corr. to ml/litre of water for $3 \, \text{to} \, 4 \, \text{days}$.

Advice on correct administration

Prepared solution of the veterinary medicinal product should be used within 24 hours.

Administer the product after dilution in drinking water, milk or milk replacer. Liquids containing the product should be exchanged every 24 hours.

To ensure a correct dosage, body weight should be determined as accurately as possible.

The intake of the prepared solution depends on the clinical condition of the treated animals.

Concentration of the solution should be properly adjusted, in order to obtain a correct dose of the applied antibiotic in the treated animals

Withdrawal period(s)

Meat and offal:

Calves, pigs: 10 days,

Hens: 7 days,

Turkeys: 13 days,

Dogs – not applicable.

Do not use in pigeons intended for human consumption.

Do not use in laying hens from which eggs are produced for human consumption.

Do not use in young birds reared for laying from which eggs are produced for human consumption within 14 days before the start of the laying period.

Special storage precautions

 $Keep\ out\ of\ the\ sight\ and\ reach\ of\ children.$

Store below 25°C. Protect from light. Do not freeze.Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf life after first opening the immediate package: 28 days. Shelf life after dilution in drinking water, milk or milk replacer: 24 hours

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Package size: 100 ml Shelf life: 2 years

For animal use only.
Prescription veterinary medicine.

To be administered under veterinary supervision.

Marketing authorization: 716/99 SPC: 2024-09-26





immune system boost



Immunex complex

Immunity-enhancing powder for pigeons and ornamental birds (yeast rich in beta-1,3/1,6-D-glucan, vitamins A, C, and E, calcium, phosphorus, glucose, extracts of echinacea purpurea and grapes)





- replenishes macro- and microelements
- comprehensive formula including:
 - beta-1,3/1,6-D-Glucan
 - glucose and vitamins C, E, and A
 - brewer's yeast (Saccharomyces cerevisiae)
 - grape seed and echinacea purpurea extract

Composition per 100 g

dried brewer's yeast $\bar{2}5.0$ g, dicalcium phosphate 20.8 g, glucose 19.0 g

Dietary additives / Vitamins per kg

Vitamin C (3a300) – 250,000 mg

Vitamin E (3a700) - 7,710 mg

Vitamin A (3a672a) - 5,074 mg

Sensory additives per kg

echinacea purpurea extract (2b) - 50 g

dried grape extract (2b485) - 170 g

Analytical constituents / Trace elements per 100 g

calcium 5,510 mg, phosphorus 3,600 mg

Analytical Constituents

crude ash 19.2%, moisture content 4.4%, crude protein 4.1%, crude fat 1.1%, crude fiber – 0.4%

Properties

Immunex Complex contains yeast rich in beta-1,3/1,6-D-glucan, which supports immune system function. Vitamins C and E, along with grape extract, serve as powerful antioxidants. Vitamin A plays a crucial role in the visual and reproductive systems. Echinacea purpurea strengthens immune defenses. Calcium and phosphorus contribute to bone health, while glucose provides a primary energy source.

Indications

- during weakened immunity
- as supportive therapy in viral, bacterial, and parasitic diseases
- during recovery from illness
- pre- and post-vaccination support
- during chick rearing
- before flights, exhibitions, and transport

Immunex Complex is especially recommended for young pigeons and racing pigeons during periods requiring peak performance.

Dosage and administration

Administer 2 g (flat teaspoon) per 1 kg of feed, moistened with a small amount of oil or water with honey.

Supportive use:

- during infections daily and for 3 days post-treatment
- before vaccination, flights, exhibitions, and travel for 14 consecutive days
- during chick rearing for 7 days

Preventive use:

- daily for 14 days

Note: If diarrhea has been present in the flock, do not use oil for feed moistening.

A minimum 2-week break is recommended before resuming supplementation.

Storage conditions

Store at room temperature in the original, tightly sealed packaging. Protect from light and moisture.

Package size: 250 g doypack sachet

Shelf life: 2 years

Complementary feed mixture for pigeons and ornamental birds.

 $Veterinary\ identification\ number: \alpha PL0614003p$

Leaflet preparation date: 2024-11-29









Powder for cutaneous use for dogs and pigeons (permethrin – as cis/trans 25:75 – 10 mg/g)

Active substance

Permethrin (as permethrin cis/trans 25:75) 10 mg/g

Therapeutic indications

Insectin is intended for the control of ectoparasite infestations: fleas and ticks in dogs, as well as lice and soft ticks in pigeons.

Contraindications

Do not use in puppies under 12 weeks of age.

Do not use in lactating females.

Do not use in pigeons under 1 month of age.

Do not use in cats. This product may cause severe adverse reactions in cats, including fatal outcomes; therefore, any contact with the product must be avoided. If dogs and cats are kept together, they must be separated for 72 hours following treatment. Ensure that cats do not lick the fur of a treated dog. If this occurs, seek veterinary assistance immediately.

Do not use in cases of hypersensitivity to the active substance or any excipient.

Adverse reactions

In dogs, adverse reactions are rare and may include excessive salivation, vomiting, diarrhea, mild muscle tremors, and hyperactivity progressing to depression.

Birds have low sensitivity to permethrin. Adverse reactions affecting the nervous system are exceptionally rare.

If any adverse reactions occur after using this product, or if any unusual symptoms not listed in this leaflet are observed (including reactions in humans due to contact with the product), report them to the appropriate veterinarian, the responsible entity, or the Office for Registration of Medicinal Products, Medical Devices, and Biocidal Products. The reporting form can be downloaded from

https://www.urpl.gov.pl(Veterinary Medicinal Products Division).

Dosage for each species and method of administration

Small dogs: 5–10 g Medium dogs: 10–15 g Large dogs: 15–20 g Pigeons: 1–2 g

Ten applications (shakes of an inverted container) deliver approximately 2.5–3.0 grams of the product onto the skin.

Instructions for proper use

This product is for external use only.

Sprinkle the product over the entire body of the animal, parting the fur or feathers to reach the skin. Avoid dusting around the eyes, ears, nose, and mouth. Leave the product on for several hours, then brush the fur.

]After each treatment, replace the animal's bedding. Repeat the treatment every 2–3 weeks.

Withdrawal period

Dogs - not applicable.

Do not use in pigeons intended for human consumption.

Special precautions for storage

 $Keep\ out\ of\ sight\ and\ reach\ of\ children.$

Store in a dry place at a temperature below 25°C.

Keep away from human food and animal feed.

Do not use this veterinary medicinal product after the expiry date indicated on the label. The expiry date refers to the last day of the specified month.

Special warnings

For each target species:

For external use only.

Do not rub the product into the animal's skin.

To maximize flea eradication, use an appropriate insecticidal treatment in the animal's environment (disinfect bedding, kennels, etc.). It is also recommended to treat all animals kept together.

Precautions for use in animals:

Prevent licking of the product.

Protect the animal's eyes during application.

Precautions for individuals administering the veterinary medicinal product:

The treatment should be carried out outside of living quarters. Avoid excessive dust formation and inhalation of the product. Use general precautions when handling ectoparasiticides, including wearing gloves and protective masks. Avoid contact with eyes. Wash hands after application. If accidental contact occurs with skin or mucous membranes, rinse the affected area immediately with clean water.

Keep children away from treated animals.

Do not allow treated animals to interact with humans, especially children, until the product is removed from their coat

Individuals with known hypersensitivity to permethrin should avoid contact with the product.

Other precautions:

Treated dogs should not be allowed to swim in bodies of water for at least three weeks after application.

Pregnancy and Lactation

 $Do \ not \ use \ during \ pregnancy \ or \ lactation.$

Laying Period

Do not use in laying birds.

Interactions with Other Medicinal Products and Other Forms of Interaction

None known.

Overdose (Symptoms, Emergency Procedures, Antidotes, if necessary)

In case of overdose, intensive symptomatic treatment should be implemented, as there is no specific antidote.

It is recommended to administer sedative, anticonvulsant (diazepam, pentobarbital, propofol), and muscle relaxant medications.

Fluid therapy with crystalloid solutions (physiological saline or multi-electrolyte solutions) is advised.

Affected animals should be bathed in lukewarm water with mild detergents to remove any residual permethrin from the skin.

Pharmaceutical Incompatibilities

As compatibility studies have not been conducted, this veterinary medicinal product must not be mixed with other veterinary medicinal products.







Powder for cutaneous use for dogs and pigeons (permethrin – as cis/trans 25:75 – 10 mg/g)

Special Precautions for Disposal of Unused Veterinary Medicinal Products or Waste Derived from Such Products

This veterinary medicinal product is highly toxic to bees, fish, and crustaceans.

Do not dispose of medicinal products via wastewater or household waste.

Consult a veterinarian for proper disposal methods to help protect the environment.

Additional Information

For further information on this veterinary medicinal product, please contact the responsible entity.

Package Size: 50 g Shelf Life: 2 years

For animal use only.

Available without a veterinary prescription – OTC.

To be administered by the animal's owner or caregiver.

Marketing authorization number: 742/99 SPC: 2015-02-02













Mycosalmovir



Inactivated vaccine against mycoplasmosis, salmonellosis and paramyxovirus infection in pigeons

Statement of the active substance(s) and other ingredient(s)

Each (0.2 ml) dose of the vaccine contains:

inactivated PMV-1 virus (La Sota strain) not less than 1 ELISA unit.

inactivated cells of *Mycoplasma gallisepticum* not less than 1 FLISA unit

inactivated cells of Salmonella (serotypes: S. typhi, S. paratyphi A, S. paratyphi C, S. typhimuriumvar. Copenhagen, S. anatum, S. senftenberg) not less than 1 ELISA unit per each serotype

1 ELISA unit – amount of antigen enabling sero conversion equal or higher than 1.8 in a vaccinated pigeon

Adjuvant:

Montanide ISA 763 A VG 0.14 ml

Indications for use

Active immunisation of pigeons to reduce mortality and clinical signs of salmonellosis, mycoplasmosis and paramyxovirosis in pigeons.

Onset of immunity: 21 days after revaccination

Duration of immunity: 12 months

Contraindications

Do not use in weak, infested and diseased birds.

Do not use in the moulting period.

Special warnings

<u>Special precautions to be taken by the person administering</u> the veterinary medicinal product to animals:

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.

Laying birds:

Do not use the vaccine during the laying period.

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, therefore a decision to use this vaccine before or after any other veterinary medicinal product needs to be made on a case-by-case basis.

Overdose:

No side effects other than listed in the adverse events section have been observed after administration of a double dose. Major incompatibilities:

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

Adverse events

Target species: pigeon

Rare (1 to 10 animals/10 000 animals treated):

Apathy¹
Loss of appetite²
Reaction at the injection site³

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system:

Office for Registration of Medicinal Products,

Medical Devices and Biocidal Products Al. Jerozolimskie 181C, PL-02-222 Warsaw.

Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605

E-mail: pw@urpl.gov.pl, website: https://smz.ezdrowie.gov.pl

Dosage for each target species, route(s) and method(s) of administration

A dose for one pigeon is 0.2 ml of the oil-based emulsion to be injected subcutaneously in the middle of the neck.

The vaccine should be administered in pigeons 3 to 4 weeks of age. The basic vaccination scheme for young pigeons not immunised against salmonellosis, paramyxovirosis and mycoplasmosis includes two injections at a 4-week interval. The vaccination should be planned so as to administer the second injection not later than within 3 weeks before pigeon races. Adult pigeons immunised with the vaccine many times should be administered a single injection annually, 2 to 3 weeks before pairing or exhibitions.

Advice on correct administration

During vaccination, use sterile needs and syringes.

Once removed from the refrigerator, warm vaccine packages to room temperature and mix thoroughly before commencing the vaccination procedure.

During vaccination, mix package content from time to time. Vaccination should be performed at outdoor temperature not lower than 0°C.

Once opened, do not store and reuse the package.

Withdrawal period(s)

Zero days.

Special precautions for storage

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C). Do not freeze. Protect from light.

Shelf-life after first opening the immediate packaging: 10 hours.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after "Exp". The expiry date refers to the last day of that

month.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product





occurs within a few hours after product administration

² transient event

³ reaction is transient and it takes the form of a small bump





Inactivated vaccine against mycoplasmosis, salmonellosis and paramyxovirus infection in pigeons

or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database

(https://medicines.health.europa.eu/veterinary).

Contact details

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland

Tel./Fax: + 48 (81) 886 33 53, Tel: + 48 (81) 888 91 00 e-mail: sekretariat@biowet.pl Contact details to report suspected adverse events:

Biowet Puławy Sp. z o.o. Henryka Arciucha 2 24-100 Puławy Poland

Tel.: + 48 (81) 888 91 33, Tel: +48 509 750 444

e-mail: biowet@biowet.pl

Package sizes: 50, 100 doses Shelf life: 18 months

For animal use only.

Prescription-only – Rp.

To be administered under veterinary supervision.

Marketing authorization: 986/00 SPC: 2025-05-16









Inactivated vaccine against pigeon paramyxovirus infection, injectable emulsion

Composition

Each (0.2 ml) dose of the vaccine contains:

Active substance:

Inactivated PMV-1 (La Sota strain) – not less than 1 ELISA unit 1 ELISA unit – amount of antigen enabling seroconversion equal or higher than 1.8 in a vaccinated pigeon

Adjuvant:

Liquid paraffin - 109 mg

White emulsion.

Target species

Pigeons

Indications for use

The vaccine is intended for use in active immunisation of pigeons, to reduce mortality, clinical signs and paramyxovirus-induced lesions.

Onset of immunity: 3 weeks after vaccination.

Duration of immunity: 1 year.

Contraindications

Do not vaccinate pigeons in the moulting period or infested birds

Do not use in pigeons treated with immunosuppressants.

Special warnings

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 veterinary medicinal 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.

Laying birds:

Do not use the vaccine during the laying period.

Interaction with other medicinal products and other forms of interaction:

None found. It is recommended not to administer other vaccines within 7 days before and after administration of the product.

Overdose:

No side effects other than listed in the adverse events section have been observed after administration of a double dose.

Major incompatibilities:

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

Adverse events

Target species: pigeons

Rare	Apathy ¹
(1 to 10 animals/10 000	Loss of appetite ²
animals treated):	Reaction at the injection site ³
Frequency unknown, cannot be determined based on available data:	Hypersensitivity reaction (anaphylaxis) ⁴

occurs within a few hours after product administration

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl.

Dosage for each target species, route(s) and method(s) of administration

Subcutaneous administration.

1 dose is 0.2 ml of the oil-based emulsion.

The vaccine should be used in young pigeons less than 3 weeks of age, but not later than within 2 weeks before pigeon races or exhibitions.

Adult pigeons should be immunised every 12 months.

The best vaccination time is 2-3 weeks before pigeon pairing. Dose per one pigeon regardless of age is 0.2 ml of the emulsion, to be injected subcutaneously in the middle of the back part of the neck.

Advice on correct administration

Before the vaccination procedure, warm the vial with the vaccine to ambient temperature and mix thoroughly.

Vaccination should be planned so as to use the entire package contents during one day.

Vaccination should be performed at outdoor temperature not lower than $0^{\circ}C$.

Birds should be revaccinated every vear

Withdrawal period(s)

Zero days.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator ($2^{\circ}C - 8^{\circ}C$). Do not freeze. Protect from light.

Do not use this veterinary medicinal





² transient event

³ emerges as a bump spontaneously subsiding after a few days

⁴ if the event occurs, administer adrenalin and anti-histamine drugs immediately





Inactivated vaccine against pigeon paramyxovirus infection, injectable emulsion

product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Use the contents of the immediate package within 10 hours.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

Detailed information on this veterinary medicinal product is available in the Union Product Database (https://medicines.health.europa.eu/veterinary).

Contact details

e-mail: sekretariat@biowet.pl

Marketing authorisation holder and manufacturer responsible for batch release:
Biowet Puławy Sp. z o.o.
Henryka Arciucha 2
24-100 Puławy
Poland
Tel./Fax: + 48 (81) 886 33 53, Tel.: + 48 (81) 888 91 00

Contact details to report suspected adverse events: Biowet Puławy Sp. z o.o.

Henryka Arciucha 2 24-100 Puławy

Poland

Tel: + 48 (81) 888 91 33, + 48 509 750 444

e-mail: biowet@biowet.pl

Package size: 20 ml bottle containing 100 doses of vaccine

Shelf life: 18 months

For animal use only.

Prescription veterinary medicine.

To be administered under veterinary supervision.

Marketing authorization number: 743/99

SPC: 2025-01-17









Inactivated vaccine against salmonellosis and paramyxovirus infection in pigeons

Composition

Each (0.2 ml) dose of the vaccine contains:

Active substances:

inactivated PMV-1 virus (*La Sota* strain) not less than 1 ELISA unit.

inactivated cells of *Salmonella* (serotypes: *S. typhi, S. paratyphi A, S. paratyphi C, S. typhimuriumvar. Copenhagen, S. anatum, S. senftenberg*) not less than 1 ELISA unit for each serotype.

1 ELISA unit – amount of antigen enabling seroconversion equal or higher than 1.8 in a vaccinated pigeon

Adjuvant:

Montanide ISA 763 A VG 0.14 ml White emulsion.

Target species

Pigeons

Indications for use

Active immunisation of pigeons to reduce mortality and clinical signs of salmonellosis and pigeon paramyxovirus.

Onset of immunity: approx. 21 days after revaccination.

Duration of immunity: approx. 12 months.

Contraindications

Do not use in weak, infested and diseased birds.

Do not use in the moulting period.

Special warnings

Special warnings:

Vaccinate healthy animals only.

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 veterinary medicinal 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.

Laying birds:

Do not use the vaccine during the laying period.

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, therefore it is not recommended to administer other vaccines within 14 days before and after vaccination using this product.

Overdose:

No side effects other than listed in the adverse events section have been observed after administration of a double dose. Major incompatibilities:

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

Adverse events

Target species: pigeons

Rare (1 to 10 animals/10 000 animals treated):

Apathy¹
Loss of appetite²
Reaction at the injection site³

occurs within a few hours after product administration

³ reaction is transient and it takes the form of a small bump

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorization holder using the contact details found at the end of this leaflet, or via your national reporting system: Department for Documentation Assessment and Pharmacovigilance of Veterinary Medicinal Products, Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, Al. Jerozolimskie 181C, PL-02-222 Warsaw, Tel.: +48 22 49-21-687, Fax: +48 22 49-21-605,

https://smz.ezdrowie.gov.pl.

Dosage for each target species, route(s) and method(s) of administration

Subcutaneous injection.

Dose for one pigeon is 0.2 ml of the oil-based emulsion to be injected subcutaneously in the middle of the neck.

The basic vaccination scheme for young pigeons unvaccinated against salmonellosis and PMV includes two injections at a 4-week interval. The first injection should be administered in pigeons 3 to 4 weeks of age, whereas the second not later than within 3 weeks before pigeon races.

Adult pigeons revaccinated many times with Salmovir should be administered a single injection annually, 2 to 3 weeks before pairing or exhibitions.

Advice on correct administration

Use sterile needs and syringes.

Once removed from the refrigerator, warm vaccine packages in ambient temperature and mix thoroughly before commencing the procedure.

During vaccination, mix pac-

kage content from time

to time.

Vaccination should be performed at outdoor temperature not lower than 0°C.

Once opened, do not store and reuse the package.





² transient event





Inactivated vaccine against salmonellosis and paramyxovirus infection in pigeons

Withdrawal period(s)

Zero davs.

Special storage precautions

Keep out of the sight and reach of children.

Store in a refrigerator (2°C – 8°C). Do not freeze. Protect from light.

Do not use this veterinary medicinal product after the expiry date which is stated on the label after EXP. The expiry date refers to the last day of that month.

Shelf-life after first opening the immediate packaging: use immediately.

Special precautions for disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon how to dispose of medicines no longer required.

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Poland

Tel: +48 (81) 888 91 33, +48 509 750 444

e-mail: biowet@biowet.pl

Shelf life: 18 months

Shelf life after first opening of the immediate packaging:

use immediately

Package sizes: 20 doses, 50 doses, 100 doses

For animal use only.

Prescription veterinary medicine.

To be administered under veterinary supervision.

Marketing authorization number: 202/95 SPC 2025-01-17







Biowet Puławy Sp. z o.o.
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