There is no outer package

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {LDPE BOTTLE 30 ml LABEL}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

1,000 doses

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

EXP {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine oculonasal suspension

2. COMPOSITION

One dose (30 µl) contains:

Active substance:
Mycoplasma synoviae strain MS-H live attenuated thermosensitive, at least $10^{5.7}$ CCU*
*colour changing units.

Excipients:
Modified Frey's medium containing phenol red and swine serum.

Red orange to straw translucent suspension.

3. TARGET SPECIES

Chickens.

4. INDICATIONS FOR USE

For active immunisation of future broiler breeder chickens, future layer breeder chickens and future layer chickens from 5 weeks of age to reduce air sac lesions and reduce the number of eggs with abnormal shell formation caused by *Mycoplasma synoviae*.

Onset of immunity: 4 weeks after vaccination.
Duration of immunity to reduce air sac lesions: 40 weeks post vaccination.
Duration of immunity to reduce the number of eggs with abnormal shell formation: has not been established.

5. CONTRAINDICATIONS

None.

6. SPECIAL WARNINGS

Do not use antibiotics with anti-mycoplasma activity 2 weeks before or 4 weeks after vaccination. Such antibiotics include e.g., tetracycline, tiamulin, tylosin, quinolones, lincospectin, gentamicin or macrolide antibiotics.

Where antibiotics must be used, preference should be given to agents with non-mycoplasma activity, such as penicillin, amoxycillin or neomycin. They should not be given within 2 weeks after vaccination.

Special precautions for safe use in the target species

- All birds in a flock/common housed group must be vaccinated at the same time.
- Only flocks with no antibodies to MS (*M. synoviae*) should be vaccinated. Vaccination should be carried out on MS-free birds at least 4 weeks before expected exposure to virulent MS.
- Pullets should first be tested for MS infection. Testing for the presence of *M. synoviae* in the flock is normally by way of an indirect diagnostic assay (e.g. the rapid serum agglutination test (RSAT) or ELISA) with blood samples being tested within 24 hours of collection. Testing by a direct diagnostic assay (e.g. PCR) for the presence of *M. synoviae* is preferable due to the time required for seroconversion after infection.
- The vaccine strain can spread from vaccinated to unvaccinated birds, including wild species. This may occur during the whole life of the vaccinated bird. Special precautions should be taken to avoid spreading of the vaccine strain to other bird species, and it is essential that all birds in the flock/common housed group are vaccinated.
- Distinguishing between field strains and the vaccine strain of *M. synoviae* can be performed by Hammond classification or High-Resolution Melt (HRM) testing by a laboratory.
- Infection with *M. synoviae* induces a transient positive antibody response to *Mycoplasma gallisepticum*. Although no data are available on the matter, it is likely that vaccination with this product will also induce a positive antibody response to *Mycoplasma gallisepticum* and may therefore interfere with the serological monitoring of *Mycoplasma gallisepticum*. If necessary, further differentiation of the 2 *Mycoplasma* species can be done by using PCR in a laboratory. Samples that can be used for PCR include swabs taken from pathological sites such as trachea, palatine cleft, air sacs or joints.
- The vaccine strain can be detected in respiratory tract of the chickens until 55 weeks after vaccination.

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

- Personal protective equipment consisting of gloves and safety glasses should be worn when handling the veterinary medicinal product.

- If vaccine is accidentally splashed into the operator's eyes, the eyes and face should be thoroughly washed with water to avoid any potential reaction to culture medium constituents.

Laying birds:
Do not use in birds in lay and within 5 weeks before the start of 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. 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.

Overdose:
No adverse reactions have been noted following an 8-fold overdose.

Major incompatibilities:
Do not mix with any other veterinary medicinal product.

7. ADVERSE EVENTS

Chickens:

None known.

Reporting adverse events is important. It allows continuous safety monitoring of a 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 authorisation holder the contact details at the end of this leaflet, or via your national reporting system: Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine

E-mail: adverse.events@vmd.gov.uk

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

Oculonasal use.

Chickens should be vaccinated once by applying one eye drop (30 µl) from 5 weeks of age and at least 5 weeks before the onset of the laying period.

9. ADVICE ON CORRECT ADMINISTRATION

Chickens from 5 weeks of age

One dose of 30 μl should be administered by the oculonasal route.

- Thaw unopened bottles rapidly between 33-35 °C for a time period of 10 minutes in a thermostatic water bath. Do not thaw at higher temperatures or for longer time periods. Use at room temperature (22-27 °C) within 2 hours
    - after thawing. Mix the contents of the bottle by gentle agitation during thawing. Invert the bottle repeatedly following thawing to ensure the contents have resuspended.
    - Remove the aluminium seal and rubber stopper before using a plastic dropper tip or other administration device. Use calibrated dropper or device, so as to distribute 30 µl drop of vaccine. Avoid introduction of contamination.
    - Hold the bird with its head tilted to one side. Invert the dropper bottle or prepare the device allowing a single drop to form at the tip and fall freely into the open eye, gently flooding it. The drop (before release) and tip should NOT touch the eye surface.

Allow the bird to blink before releasing it.

10. WITHDRAWAL PERIODS

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

Protect from direct sunlight.
Store frozen below -70 °C for a maximum of 5 years.
After removal from the deep freeze, further short term storage is allowed at or below -18 °C for no more than 4 weeks. Vaccine should not be stored back in -70 °C after storage at or below -18 °C.

Once thawed, use within 2 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.

12. SPECIAL PRECAUTIONS FOR DISPOSAL

Medicines should not be disposed of via wastewater.

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

Veterinary medicinal product subject to prescription.

14. MARKETING AUTHORISATION NUMBERS AND PACK SIZES

Vm 61467/5000

Plastic LDPE bottle of 30 ml (1,000 doses) with butyl rubber stopper and sealed with an aluminium cap.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. CONTACT DETAILS

Marketing authorisation holder:
Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road
Bray
Wicklow
A98 T6H6
Ireland

Contact details to report suspected adverse reactions:
Pharmsure International Ltd
Unit 28, Moorlands Trading Estate
Moor Lane
Metheringham
Lincolnshire
LN4 3HX
UK
Email Address: orders@pharmsure.co.uk
Telephone: +44 (0)1526 321681

Manufacturer responsible for batch release:
Laboratoire LCV
Z.I. du Plessis Beuscher
35220 Chateaubourg
France

17. OTHER INFORMATION

POM-V 'Veterinary medicinal product subject to prescription'
For animal treatment only.

Gavin Hall
Approved: 16 December 2025