SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine oculonasal suspension

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance:
One dose (30 µl) contains:
Mycoplasma synoviae strain MS-H live attenuated thermosensitive, at least $10^{5.7}$ CCU*

* colour changing units

Excipients:
For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Eye drops, suspension.
Red orange to straw translucent suspension.

4. CLINICAL PARTICULARS

4.1 Target species

Chickens.

4.2 Indications for use, specifying the target species

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.

4.3 Contraindications

None.

See also section 4.7.

4.4 Special warnings for each target species

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 no antimycoplasma activity, such as penicillin, amoxicillin or neomycin. They should not be given within 2 weeks after vaccination.

Vaccinate healthy animals only.

4.5 Special precautions for use

Special precautions for use in animals
All birds in a flock/common housed group must be vaccinated at the same time.
Only flocks with no antibodies to *M. synoviae* should be vaccinated. Vaccination should be carried out on *M. synoviae* -free birds at least 4 weeks before expected exposure to virulent *M. synoviae*.
Pullets should first be tested for *M. synoviae* 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.
The vaccine strain can be detected in respiratory tract of the chickens until 55 weeks after vaccination.

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.

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.

Special precautions for the protection of the environment
Not applicable.

Other precautions
Not applicable.

4.6 Adverse reactions (frequency and seriousness)

Chickens:
None known.

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See the package leaflet for contact details.

4.7 Use during pregnancy, lactation or lay

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

4.8 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.

4.9 Amount(s) to be administered and administration route

Oculonasal use.

Chickens from 5 weeks of age

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

Thaw the unopened bottle 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 content has been 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.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

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

4.11 Withdrawal period(s)

Zero days.

5. IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Immunologicals for Aves, live bacterial vaccines, mycoplasma.

ATCvet code: QI01AE03

The vaccine induces an active immunity against *Mycoplasma synoviae* in chickens.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

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

6.2 Major incompatibilities

Do not mix with any other veterinary medicinal product.

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 5 years.
Shelf life after thawing and first opening the immediate packaging: 2 hours.

6.4 Special precautions for storage

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.

Protect from direct sunlight.

6.5 Nature and composition of immediate packaging

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

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Pharmsure Veterinary Products Europe Limited
4 Fitzwilliam Terrace
Strand Road
Bray
Wicklow
A98 T6H6
Ireland

8. MARKETING AUTHORISATION NUMBER

Vm 61467/5000

9. DATE OF FIRST AUTHORISATION

14 June 2011

10. DATE OF REVISION OF THE TEXT

December 2025

11. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCT

Veterinary medicinal product subject to prescription.
Find more product information by searching for the 'Product Information Database' or 'PID' on www.gov.uk.

Gavin Hall
Approved: 16 December 2025