

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

NOTE: There is no outer carton

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

LDPE BOTTLE 30 ml LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine eye drops suspension

M. synoviae strain MS-H

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

1000 doses

4. ROUTE OF ADMINISTRATION

Ocular use

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

Batch{number}

7. EXPIRY DATE

EXP {month/year}

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

**PACKAGE LEAFLET:
MS-H Vaccine eye drops suspension**

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

Marketing authorisation holder:

Pharmsure International Ltd
Unit 28, Moorlands Trading Estate
Moor Lane
Metheringham
Lincolnshire
LN4 3HX
UK

Manufacturer responsible for batch release:

Laboratoire LCV
Z.I. du Plessis Beuscher
35220 Chateaubourg
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

MS-H Vaccine eye drops suspension

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

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

One dose (30 µl) contains:

Active substance:

Mycoplasma synoviae strain MS-H live attenuated thermosensitive, at least 10^{5.7}
CCU*

*colour changing units

Other ingredients:

Modified Frey's medium containing phenol red and swine serum

4. INDICATION(S)

For vaccination 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.

The animal will be immune for 40 weeks after the vaccination.

The duration of immunity to reduce the number of eggs with abnormal shell formation has not yet been demonstrated.

5. CONTRAINDICATIONS

None.

6. ADVERSE REACTIONS

None.

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

7. TARGET SPECIES

Chickens

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

Ocular 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 30µl should be administered by eye drop.

- 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 PERIOD(S)

Zero days.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.

The MS-H vaccine should always be protected from direct sunlight. Store frozen below -70°C for a maximum of 4 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 after the expiry date which is stated on the label.

12. SPECIAL WARNING(S)

Special precautions for use in animals

Do not use in birds in lay and within 5 weeks before the onset of the laying period. Vaccinate all birds in a flock at the same time.

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.

- 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 the rapid serum agglutination test (RSAT) with blood samples being tested within 24 hours of collection.
- 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.

- 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.
- 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 decided on a case-by-case basis.
- Do not mix with any other veterinary medicinal product.

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

- To avoid skin and eye injuries which may occur by manipulating the frozen bottle, personal protective equipment consisting of gloves and safety glasses should be worn.
- 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.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

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

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

April 2021

15. OTHER INFORMATION

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

MAH Number: Vm 42983/5000

Reviewed: April 2021
AN: 01661/2020

To be supplied only on veterinary prescription.

Approved: 15/04/21

D. Austin