



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/299803/2011
EMA/V/C/000161

EPAR summary for the public

MS-H Vaccine

Mycoplasma synoviae strain MS-H vaccine (live attenuated)

This is a summary of the European public assessment report (EPAR) for MS-H Vaccine. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use MS-H Vaccine.

For practical information about using MS-H Vaccine, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is MS-H Vaccine and what is it used for?

MS-H Vaccine is a vaccine used in chickens from five weeks of age to protect them against *Mycoplasma synoviae*. This bacterium causes infections in birds, generally in the lungs and the 'air sacs', the specialised bags within the bird's body where air is stored during breathing. Infection with *Mycoplasma synoviae* may result in difficulty breathing and is also associated with poor quality of the eggshell. MS-H Vaccine is used in young chickens intended to produce eggs for broilers (for meat) and layers (for egg production) to reduce the damage to air sacs and reduce the number of eggs with abnormal shells.

For further information, see the package leaflet.

How is MS-H Vaccine used?

MS-H Vaccine is available as eye drops and can only be obtained with a prescription. MS-H Vaccine is given as one eye drop into one eye. The whole flock should be vaccinated at the same time. Protection starts four weeks after vaccination. Protection against damage to air sacs lasts for 40 weeks, but the duration of protection against abnormal shells forming is not known.

For further information, see the package leaflet.



How does MS-H Vaccine work?

MS-H Vaccine contains a live, attenuated strain of *Mycoplasma synoviae*. 'Attenuated' means that the strain has first been weakened so that it does not cause disease.

MS-H Vaccine, like all vaccines, works by 'teaching' the immune system (the body's natural defences) how to defend itself against a disease. When MS-H Vaccine is given to chickens the immune system recognises the weakened strain as 'foreign' and makes defences against it. In the future, if the animals are exposed to *Mycoplasma synoviae*, the immune system will be able to respond more quickly. This will help to protect against the disease.

What benefits of MS-H Vaccine have been shown in studies?

The company presented data from laboratory studies and from one field trial. The laboratory studies included a challenge model of *Mycoplasma synoviae* infection as well as a study looking at the effect of vaccination on eggshell abnormalities. The field study looked at how vaccinated chickens fared when moved to flocks with a history of *Mycoplasma synoviae* infection.

The laboratory studies showed that MS-H Vaccine reduces damage to the air sacs and reduces the number of eggs with shell abnormalities. The field study did not bring additional information.

What are the risks associated with MS-H Vaccine?

The vaccine has no known side effects.

It should not be used in birds in lay or within five weeks of the start of the laying period.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

The person administering the vaccine should wear protective equipment, consisting of gloves and safety glasses to avoid skin and eye injuries which may occur by manipulating the vaccine bottle which is frozen. Any accidental splashing to the face and eyes should be thoroughly washed with water.

What is the withdrawal period in food-producing animals?

The withdrawal period is the time required after administration of a medicine before an animal can be slaughtered and the meat used for human consumption. It is also the time required after administration of a medicine before eggs may be used for human consumption.

The withdrawal period for MS-H vaccine for meat and eggs is zero days.

Why is MS-H Vaccine approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that MS-H Vaccine's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about MS-H Vaccine:

The European Commission granted a marketing authorisation valid throughout the European Union, for MS-H vaccine on 14 June 2011. The full EPAR for MS-H Vaccine can be found on the Agency's website: [ema.europa.eu/Find medicine/Veterinary medicines/European public assessment reports](http://ema.europa.eu/Find%20medicine/Veterinary%20medicines/European%20public%20assessment%20reports). For more

information about treatment with MS-H Vaccine, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in March 2016