MAKING MG PROTECTION SAFER AND EASIER
1 vaccine up to 3 immunities
IMPACT OF *MYCOPLASMA GALLISEPTICUM* (MG) INFECTION

*Mycoplasma gallisepticum* (MG) is a major respiratory disease to poultry species (chickens and turkeys) worldwide with a huge economic impact. The disease is transmitted both horizontally and vertically and both young and mature birds are susceptible, and once a flock is infected, the flock is infected for life.

Birds infected with MG show airsacculitis, reduced weight gain and feed efficiency. The egg production losses can be severe (up to 16 eggs per hen\(^{(1)}\)) and secondary infections can cause mortality. Flocks infected with MG are more susceptible to other diseases such as IBV, NDV, Infectious Coryza and *Escherichia coli*\(^{(2)}\).

VACCINATION: AN IMPORTANT TOOL TO CONTROL MG

Strict biosecurity with well implemented hygiene procedures are essential to control MG. Furthermore, vaccination has been widely used as a tool to protect against clinical signs and prevent egg production losses. There are commercially available live and killed vaccines. However, there are concerns associated with their safety, efficacy and convenience. Moreover, live vaccines can be adversely affected by antibiotic treatment and there is a risk of spreading to neighboring flocks as well.

VECTORMUNE® FP-MG AND VECTORMUNE® FP-MG + AE

Vectormune® FP-MG and Vectormune® FP-MG + AE were developed by CEVA Santé Animale using the most advanced molecular technology to bring to the poultry industry a novel broad-spectrum vaccine that provides efficacy, safety and convenience in the control of *Mycoplasma gallisepticum*, Fowl Pox and Avian Encephalomyelitis.

Benefits of Vectormune® FP-MG and Vectormune® FP-MG + AE

- **One wing-web injection for protection up to 3 diseases**
  - Reduces the number of vaccinations
  - Less bird handling required
- **Efficacious and safe to use in layers, breeders and turkeys**
  - Safe to use in turkeys
  - No reactions or complications following vaccination
- **No risk of spreading MG to other flocks**
  - The vaccines do not contain live Mycoplasma organism
- **Compatible to use with antibiotic medication programs**
- **No interference with MG serological monitoring**
  - No seroconversion after vaccination
VECTORMUNE® FP-MG AND VECTORMUNE® FP-MG + AE: INNOVATIVE DISEASE CONTROL

Vectormune® FP-MG and Vectormune® FP-MG + AE are genetically engineered live Fowl Pox virus vaccines that allow the Fowl Pox virus to express key protective *Mycoplasma gallisepticum* antigens.

The vaccine combines the safety of the Fowl Pox vaccine with the protection induced by the MG antigens.

This illustration shows the two genes which are removed from the DNA of MG and which are inserted into the DNA of the Fowl Pox virus. These genes express key protective antigens of MG.

*Vectormune® FP-MG and Vectormune® FP-MG + AE*

1 vaccine for protection up to 3 disease

*FP - MG*  
- *Mycoplasma gallisepticum*
- Fowl Pox

*FP - MG + AE*  
- *Mycoplasma gallisepticum*
- Fowl Pox
- Avian Encephalomyelitis
A group of eight-week-old SPF chickens were vaccinated with Vectormune® FP-MG via the wing web route. Two other groups were kept unvaccinated and used as positive or negative controls. At 12 weeks post-vaccination, these chickens were challenged with pathogenic Mycoplasma gallisepticum. The protection was assessed based on clinical signs of MG. (CEVA-Biomune, internal study).

In this comparative trial, two groups of SPF chickens were vaccinated at 8 weeks of age with Vectormune® FP-MG + AE via wing web. A third group of SPF chickens received a live vaccine by eye-drop. Seven to ten days after vaccination, the vaccine “takes” were evaluated. Three weeks post-vaccination, challenge with Mycoplasma gallisepticum was carried out and the protection was assessed based on clinical signs of MG such as: tracheal rales, nasal discharge or coughing in addition to the air sac lesion score (0 – 4). (CEVA-Biomune, internal study).

* Values with different subscripts are statistically significantly different p < 0.05

% protection

<table>
<thead>
<tr>
<th></th>
<th>Vectormune® FP-MG</th>
<th>Vectormune® FP-MG + AE</th>
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</thead>
<tbody>
<tr>
<td>Non-vaccinated</td>
<td>15b</td>
<td>83a</td>
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Air sacs lesion score

<table>
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<tr>
<th></th>
<th>Negative controls</th>
<th>Challenged controls</th>
<th>Commercial live MG vaccine</th>
<th>Vectormune® FP-MG + AE</th>
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<tbody>
<tr>
<td>0a</td>
<td></td>
<td>2.9b</td>
<td>1.9a</td>
<td>1.7a</td>
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</table>

 Vectormune® FP-MG and Vectormune® FP-MG + AE show excellent protection against Mycoplasma gallisepticum
A group of eight-week-old SPF chickens were vaccinated with Vectormune® FP-MG via the wing web route. One group served as a non-vaccinated group. At 12 weeks post-vaccination, both groups were challenged with a virulent Fowl Pox virus. The protection was assessed based on Fowl Pox lesions. (CEVA-Biomune, internal study).

In a laboratory trial, SPF chickens were vaccinated at 8 weeks of age with Vectormune® FP-MG + AE via wing web. Seven to ten days after vaccination, the vaccine “takes” were evaluated. Three weeks post-vaccination, challenge with Fowl Pox virus and Avian Encephalomyelitis virus were carried out. (CEVA-Biomune, internal study).

**Efficacy of Vectormune® FP-MG against a virulent Fowl Pox Challenge**

<table>
<thead>
<tr>
<th>% protection</th>
<th>Vectoromune® FP-MG</th>
</tr>
</thead>
<tbody>
<tr>
<td>100a</td>
<td></td>
</tr>
<tr>
<td>0b</td>
<td>Non-vaccinated</td>
</tr>
<tr>
<td></td>
<td>Vectoromune® FP-MG</td>
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</tbody>
</table>

**Efficacy of Vectormune® FP-MG + AE against a virulent Fowl Pox Challenge**

<table>
<thead>
<tr>
<th>% protection</th>
<th>Vectoromune® FP-MG + AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>100a</td>
<td></td>
</tr>
<tr>
<td>0b</td>
<td>Challenged controls</td>
</tr>
<tr>
<td></td>
<td>Vectoromune® FP-MG + AE</td>
</tr>
</tbody>
</table>

* Values with different subscripts are statistically significantly different $p < 0.05$

**Avian Encephalomyelitis Protection in Vectormune® FP-MG + AE**

**Efficacy of Vectormune® FP-MG + AE against a Virulent Avian Encephalomyelitis Virus Challenge**

<table>
<thead>
<tr>
<th>% protection</th>
<th>Vectoromune® FP-MG + AE</th>
</tr>
</thead>
<tbody>
<tr>
<td>100a</td>
<td></td>
</tr>
<tr>
<td>0b</td>
<td>Challenged controls</td>
</tr>
<tr>
<td></td>
<td>Vectoromune® FP-MG + AE</td>
</tr>
</tbody>
</table>

* Values with different subscripts are statistically significantly different $p < 0.05$

**Vectormune® FP-MG shows a high level of protection against Fowl Pox Vectormune® FP-MG+AE shows a high level of protection against Fowl Pox and Avian Encephalomyelitis**
**VECTORMUNE® FP-MG AND VECTORMUNE® FP-MG + AE: NO INTERFERENCE WITH MG SEROLOGICAL MONITORING**

MG negative birds were vaccinated by the wing web route with Vectormune® FP-MG at 4 weeks of age. Fowl Pox vaccine “takes” were checked 10 to 14 days post vaccination. Birds were bled at 4 weeks post-vaccination to conduct serological assays for MG. (CEVA-Biomune, internal study).

<table>
<thead>
<tr>
<th>Treatment group</th>
<th>Pox vaccine “takes”</th>
<th>MG SPA¹ No. Positive / Tested</th>
<th>MG HI² No. Positive / Tested</th>
<th>MG ELISA³ No. Positive / Tested</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vectormune® FP-MG</td>
<td>58/60</td>
<td>0/29</td>
<td>0/28</td>
<td>0/28</td>
</tr>
<tr>
<td>Non-vaccinated controls</td>
<td>0/29</td>
<td>0/29</td>
<td>0/28</td>
<td>0/28</td>
</tr>
</tbody>
</table>

1 Serum plate agglutination score from 0 to 4 with positive ≥ 1  
2 Hemagglutination inhibition assay with positive ≥ 40  
3 MG antibody test kit commercially available. Positive S/P value ≥ 0.6

**Vectormune® FP-MG did not induce any serological response in MG SPA, HI and Elisa tests**  
**Vaccination take can be checked by the Pox reactions**

**APPLICATION AND MONITORING OF THE VACCINE TAKE**

Vectormune® FP-MG and Vectormune® FP-MG + AE do not spread from bird to bird. The vaccine should be carefully applied to each bird to reach optimal protection. Apply the vaccine into the wing web with the double pronged applicator. Add the diluent with the vaccine to check site of injection.

Application should be done into the bottom part of the wing in order to avoid the risk of losing vaccine in the feathers present on the upper part of the wing.  
The administration of the vaccine can also be done using a wing web syringe. However, it is important to ensure that the syringe delivers the right dose per bird: 0.01 ml per bird. Particular attention should be paid to ensure that the needles are projected from the syringe only after the syringe body touches the birds’ skin. Otherwise there is a risk that the projected needles will deliver a portion of the vaccine in the feathers of the birds. The syringe must be kept in a vertical position (needles pointing down) to ensure that the correct amount of vaccine is delivered.  
Monitoring of vaccine take should be done between 5 and 8 days post-vaccination at the wing web injection site by evaluation of skin swelling due to fowl pox replication.

Pox syringe for easier wing-web application.
**PROTECTION OF VECTORMUNE® FP-MG AGAINST MG IN TURKEYS**

Efficacy studies were conducted in four week-old, susceptible turkeys vaccinated with Vectormune® FP-MG by wing web application.

Vaccinated and non-vaccinated turkeys were challenged with either the R strain of MG or Fowl Pox virus. Protection was defined by the reduction of airsacculitis [Air sac lesions (0 – 4) caused by MG and lesions associated with Pox virus].

![Graph of Efficacy of Vectormune® FP-MG against a Virulent Mycoplasma gallisepticum Challenge and Fowl Pox Virus Challenge](image)

* Values with different subscripts are statistically significantly different $p<0.05$

**VECTORMUNE® FP-MG: SAFE TO USE IN TURKEYS**

The genes of MG in Vectormune® FP-MG were demonstrated to be stable in vitro and in vivo using molecular biology assays.

Safety of Vectormune® FP-MG was confirmed by demonstration of lack of reversion to virulence after multiple back passages and safety at 10 and 100 times a typical dose.

Studies verified that Vectormune® FP-MG did not shed or spread to co-mingled, non vaccinated contacts, and tissue tropism of Vectormune® FP-MG was not different from that of the FP vaccine.

In addition, Vectormune® FP-MG was demonstrated to be safe in several other animal species and specifically turkeys.

*Vectormune® FP-MG no shedding, no spreading and no reversion to virulence*

References:
1. Mohammed Ho et al.; 1987, Avian Diseases 31 : 477-482
4. Evans, RD & Hafez, YS, 1992, Avian Diseases 36:197-201
**COMPOSITION:** Vectormune® FP-MG and Vectormune® FP-MG+AE are presented in a freeze-dried preparation which contains a live Fowl Pox virus recombinant vaccine indicated for use in chickens and turkey breeders and meat turkeys. The Fowl Pox virus in Vectormune® FP-MG and Vectormune® FP-MG+AE expresses key protective Mycoplasma gallisepticum antigens. Vectormune® FP-MG provides dual protection to Fowl Pox (FP) and Mycoplasma gallisepticum (MG). It also provides protection against Avian Encephalomyelitis when combined with conventional AE virus (Vectormune® FP-MG+AE). **INDICATIONS:** Vectormune® FP-MG and Vectormune® FP-MG+AE are indicated as an aid in the prevention of Fowl Pox and as an aid in the control of Mycoplasma gallisepticum and Avian Encephalomyelitis. Vectormune® FP-MG and Vectormune® FP-MG+AE are administered to chickens of eight weeks of age or older, but at least four weeks prior to the onset of egg production and to turkey breeders and meat turkeys are administered at four weeks of age or older for Vectormune® FP-MG. Vectormune® FP-MG+AE should be applied at 8 weeks or older.

**DOSE AND METHOD OF ADMINISTRATION:** Vectormune® FP-MG and Vectormune® FP-MG+AE are administered via wing web at a dose of 0.01 ml per bird. For vaccination, the pellet should be reconstituted or rehydrated with the appropriate volume of sterile diluent specially formulated for wing web administration (Blue color to facilitate the monitoring and evaluation of the wing web vaccination). Use entire contents within an hour after reconstitution or rehydration of the pellet.

**TARGET SPECIES:** Chickens (breeders and layers) and turkeys (breeders and meat turkeys).

**CONTRAINDICATIONS:** Do not use in sick birds. Chickens and turkeys receiving Vectormune® FP-MG must not have been previously exposed to Fowl Pox virus or vaccines against Fowl Pox due to interference with immunity following vaccination. **SPECIAL PRECAUTIONS FOR USE:** Vaccinate healthy, susceptible birds only. Vectormune® FP-MG and Vectormune® FP-MG+AE must be the first Fowl Pox vaccine administered to the flock. Prior infection of a flock with field Pox virus will interfere with protection of this vaccine. Do not vaccinate within 21 days of slaughter. Do not vaccinate within four weeks of onset of egg production. **INTERACTION WITH OTHER MEDICAMENTS OR MATERNAL IMMUNITY:** The use of antibiotics or anti-mycoplasmic treatments does not interfere with Vectormune® FP-MG and Vectormune® FP-MG+AE because there are no live MG organisms in the vaccine. Maternal immunity to Fowl Pox may play a role in early vaccination. **STORAGE:** Store the vaccine at 2º to 7º C (34º to 45º F).