SUMMARY OF PRODUCT CHARACTERISTICS

1. Name

OLVAC A+B+MG

Inactivated vaccine against Newcastle disease (avian pseudopest), Infectious Bronchitis, Egg Drop Syndrome (EDS'76), and Mycoplasma gallisepticum infection.

2. Qualitative and Quantitative Composition

Each 0.5 ml dose contains:

Active ingredients:

- Inactivated Newcastle disease virus: 50 DP50
- Inactivated Infectious Bronchitis virus: 10^7.5 DIE50
- Inactivated Egg Drop Syndrome (EDS) virus: 1000 HAU
- Inactivated Mycoplasma gallisepticum: 3 x 10^10 CFU

Adjuvant:

- Liquid paraffin: 0.3375 ml

Preservative:

- Sodium ethylmercury thiosalicylate: 0.05 mg

3. Pharmaceutical Form

Injectable oil emulsion.

4. Clinical Particulars

4.1 Target Species

Laying hens for table egg production.

4.2 Indications for Use

Active vaccination of laying hens to prevent Egg Drop Syndrome and Mycoplasma gallisepticum infection. Booster vaccination against Newcastle disease and Infectious Bronchitis for birds previously vaccinated with live vaccines. Prevents mortality, clinical signs, and lesions associated with these diseases. Immunity

develops approximately 4 weeks post-vaccination and lasts for the laying cycle.

4.3 Contraindications

None.

4.4 Special Warnings for Each Target Species

Only vaccinate healthy birds.

4.5 Special Precautions for Use

i. In Animals:

Bring vaccine to room temperature before use. Shake well before and during use.

ii. For the Person Administering the Product:

Contains mineral oil. Accidental self-injection may cause severe pain and swelling, especially if injected into joints or fingers. In rare cases, it may result in loss of the affected digit. Seek immediate medical attention even for small amounts. Show the label or package leaflet to the physician. Persistent pain (>12 hours) requires follow-up.

For the doctor:

Accidental injection may cause marked swelling leading to ischemic necrosis and possible digit loss. Immediate and expert surgical evaluation is needed. Early incision and irrigation of the injection site may be necessary.

4.6 Adverse Reactions

None known.

4.7 Use During Laying

Do not use in birds during the laying period.

4.8 Interactions with Other Medicines

No safety or efficacy data available for concurrent use with other vaccines. Do not use other products within 14 days before or after vaccination.

4.9 Dosage and Administration

Administer 0.5 ml subcutaneously in the neck region.

Vaccination Schedule:

Indicated for 16-17 week-old pullets previously vaccinated with live attenuated vaccines against Newcastle disease and Infectious Bronchitis. Additional inactivated MG vaccine may be administered at 6-8 weeks to enhance protection during lay.

4.10 Overdose

Double dosing does not produce specific symptoms.

4.11 Withdrawal Period

Zero days.

5. Immunological Properties

Contains inactivated cultures of Newcastle disease virus, Infectious Bronchitis virus, Egg Drop Syndrome virus (EDS '76), and Mycoplasma gallisepticum. Induces active immunity against these pathogens.

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6. Pharmaceutical Particulars

6.1 List of Excipients

- Sodium ethylmercury thiosalicylate
- Sorbitan monooleate
- Liquid paraffin

6.2 Major Incompatibilities

Do not mix with other medicinal products.

6.3 Shelf Life

24 months unopened if stored correctly. Use immediately after opening.

6.4 Special Storage Precautions

Store refrigerated at +2°C to +8°C. Do not freeze.

6.5 Nature and Composition of Primary Packaging

250 ml dark glass or polypropylene vials with elastomer stoppers and aluminum seals (29 mm diameter).

6.6 Special Precautions for Disposal

Do not discard into the environment. Dispose of unused product or waste in accordance with local regulations.

7. Marketing Authorization Holder

FATRO S.p.A., Via Emilia 285, 40064 OZZANO EMILIA (BO), Italy

8. Marketing Authorization Numbers

- 1 x 250 ml glass vial (500 doses): No. 102300011
- 1 x 250 ml polypropylene vial (500 doses): No. 102300035
- 10 x 250 ml glass vials (5000 doses): No. 102300023
- 10 x 250 ml polypropylene vials (5000 doses): No. 102300047

9. First Authorization Date

October 25, 2001

10. Text Revision Date

November 16, 2006

CONDITIONS OF SALE

Prescription-only. Requires triplicate non-repeatable veterinary prescription.