Gallimune 302 ND+IB+EDS

Introduction

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Presentation

Inactivated vaccine in an oily adjuvant against Newcastle Disease, Infectious Bronchitis and Egg Drop Syndrome (EDS76). The vaccine stimulates active immunity of breeder and layer pullets against Egg Drop Syndrome (EDS76) (without priming), Newcastle Disease and Infectious Bronchitis, subsequent to priming with live vaccines against these diseases.

Uses

Booster immunization of breeder and layer pullets after vaccination with live vaccines against:

- Newcastle Disease virus in order to reduce egg drop linked to Newcastle Disease infection,
- Infectious Bronchitis virus in order to reduce egg drop linked to Infectious Bronchitis infection caused by the Mass41 strain,

Active immunization of breeder and layer pullets in order to reduce egg drop linked to infection with Egg Drop Syndrome virus (EDS76) without priming.

Newcastle Disease, Infectious Bronchitis and Egg Drop Syndrome components:

- Onset of immunity: 4 weeks after vaccination,
- Duration of immunity: one laying period.

Dosage and administration

Administer one dose (0.3 ml) by intramuscular route from the age of 18 weeks and at least 4 weeks after the priming with live vaccines against Newcastle Disease (strain Hitchner B1 or VG/GA) and Infectious Bronchitis (strain Mass H120).

Shake well before use.

Apply usual aseptic procedures.

Do not use syringes with natural rubber or butyl elastomer pistons.

Equipment including needles and syringes must be sterile before use.

Contra-indications, warnings, etc

Keep out of the reach and sight of children.

For animal treatment only.

No information is available on the safety and efficacy from the concurrent use of this vaccine with any other. It is therefore recommended that no other vaccines should be administered within 14 days before or after vaccination with the product.

Only healthy animals should be vaccinated.

Apply the usual aseptic procedures when vaccinating.

Not recommended to be used within 2 weeks before the onset of lay and during the laying period.

No palpable reactions were observed following the injection of one dose of vaccine.

In clinical studies, lesions linked to the oily adjuvant were observed histologically three weeks after injection in 87% of cases, e.g. small quantities of oily residues and occasional aseptic micro-abscesses.

Transitory apathy and slight oedema at injection site may occur after administration of a double dose of vaccine.

USER SAFETY

To the user

This product contains mineral oil. Accidental injection/self-injection may result in severe pain and swelling, particularly if injected into a joint or finger, and in rare cases could result in the loss of the affected finger if prompt medical attention is not given.

If you are accidentally injected with this product, seek prompt medical advice even if only a very small amount is

injected and take the package leaflet with you.

If pain persists for more than 12 hours after medical examination, seek medical advice again.

Hands should be washed after vaccinating.

To the physician

This product contains mineral oil. Even if small amounts have been injected, accidental injection with this product can cause intense swelling, which may, for example, result in ischaemic necrosis and even the loss of a digit. Expert, PROMPT, surgical attention is required and may necessitate early incision and irrigation of the injected area, especially where there is involvement of finger pulp or tendon.

Withdrawal periods

Zero days.

Pharmaceutical precautions

Store and transport between +2°C and +8°C, protected from light. Do not freeze.

Use immediately after opening.

Do not mix with any other vaccine/immunological product.

Any unused product or waste material should be disposed of in accordance with national requirements.

Legal category

POM-V

Packaging Quantities

Polypropylene bottles containing 1000 doses.

Further information

None.

Marketing authorisation number

Vm 08327/4215.