

## **PART 1 B**

### **B.1 SUMMARY OF PRODUCT CHARACTERISTICS**

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### 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

DEPARVAX

emulsion for injection for Muscovy ducks and geese

### 2. QUALITATIVE AND QUANTITATIVE COMPOSITION

One dose (0.2ml)\* contains:

Active substances (virus suspensions)

- Inactivated duck parvovirus (strain FM) inducing at least 7.7 log<sub>2</sub> VN titre\*\*
- Inactivated Derzsy's disease virus (strain LB) inducing at least 7.9 log<sub>2</sub> VN titre\*\*

Adjuvant:

- Oil adjuvant (Light liquid paraffin) max. 0.14 ml

Excipients:

- Thiomersal max. 3µg
- PBS ad 0.06 ml

\* Represents the dose for the young birds, the immunising dose for breeder geese is 0.4 ml.

\*\* The geometric mean of the neutralisation titres of ten SPF chickens immunized with one dose of Deparvax.

For full list of excipients: see section 6.1

### 3. PHARMACEUTICAL FORM

Emulsion for injection. Off-white, homogeneous emulsion.

### 4. CLINICAL PARTICULARS

#### 4.1 Target species

Muscovy duck (*Cairina moschata*): at day-old and growing age

Goose (*Anser domesticus*): at day-old and growing age

breeders, 3 weeks before the onset of the laying period.

#### 4.2 Indications for use, specifying the target species

- For active immunisation of Muscovy ducks and geese at day-old and growing age, against duck parvovirus and Derzsy's disease, to reduce mortality and clinical signs (including weight loss) of the disease. The vaccine is suitable for susceptible birds of both species and also for birds possessing maternally derived antibodies.

After the vaccination at day-old age active immunity is developed from the age of 2-3 weeks.

The vaccination of ducklings should be repeated at 14-15 days of age to obtain high level immunity, lasting until 5-9 weeks of age. The booster vaccination of gosling should be provided by vaccinating them between 14-21 days of age.

- For the passive immunisation of goslings against Derzsy's disease to reduce mortality and clinical signs (including weight loss) of the disease, by the immunisation of the parent flock.

To obtain the passive protection of the goslings, breeders previously immunised at day-old or growing age, should be vaccinated twice: 6 and 3 weeks before the onset of lay, before each laying period. The properly immunised breeders supply the progeny with maternally derived antibodies protecting them for at least until the age of 2 weeks throughout the entire laying period.

#### 4.3 Contraindications

Not known.

#### **4.4 Special warnings for each target species**

None

#### **4.5 Special precautions for use**

##### **Special precautions for use in animals:**

- Infection with virulent parvoviruses should be avoided after administering the vaccine to day-old susceptible birds, until the onset of active immunity (14 days).
- Vaccination at day-old age does not provide full protection from the disease in the absence of maternally derived antibodies, if the animals were infected by the germinative route or before the age of 10-14 days.
- For geese the vaccine should be administered by the subcutaneous route only. Do not administer within 3 weeks before the onset of laying period.
- Let warm and keep at room temperature and shake well before use.
- After long storage greyish sediment can be visible which does not influence the vaccines efficacy and disappears after thorough shaking.
- Improper storage or handling of the vaccine may result in loss of efficacy.

##### **Special precautions to be taken by the person administering the medicinal product to animals:**

###### 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 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.

If the vaccine is spilled on the skin or eye rinse immediately thoroughly with water. In case of eye contact seek prompt medical advice and take the package leaflet with you.

###### 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.

#### **4.6 Adverse reactions (frequency and seriousness)**

After the administration of 0.2 ml of the vaccine to day-old or growing Muscovy ducks the injection sites remain free of local adverse reactions. Some pinhead size granules (unabsorbed vaccine residues) may be found at the injection site up to 35 days.

After the administration of 0.2 ml of the vaccine to day-old or growing geese the injection sites remain free of local adverse reactions. Some pinhead size granules (unabsorbed vaccine residues) may be found in 50 % of the birds at the injection site up to 62 days.

After administering 0.4 ml of the vaccine to breeder geese subcutaneously into the lower part of the neck, some pinhead sized granules (unabsorbed vaccine residues) may form at the injection site, in the connective tissue of the skin, which may persist up to 35 days after the vaccination.

#### **4.7 Use during pregnancy, lactation or lay**

Do not use in birds in lay and within 3 weeks before the onset of the laying period.

#### **4.8 Interaction with other medicinal products and other forms of interaction**

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 made on a case by case basis.

#### **4.9 Amounts to be administered and administration route**

Day-old and growing Muscovy ducks (with or without maternally derived antibodies): 0.2 ml of the vaccine should be administered subcutaneously in the neck or intramuscularly into the thigh muscles regardless the age or size of the ducklings. For older ducklings, with well developed breast muscles, the vaccine administration into the breast muscles is also possible.

Day-old and growing geese (with or without maternally derived antibodies): 0.2 ml of the vaccine should be administered subcutaneously in the neck regardless the age or size of the goslings.

Breeder geese: 0.4 ml of the vaccine should be administered subcutaneously in the neck. The vaccine is suitable for the immunization of breeders preimmunised at day-old or growing age with live or inactivated vaccine against Derzsy's disease. Breeders should be vaccinated twice before each laying period. Vaccination of breeders should be completed 3 weeks before the onset of lay.

#### **4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary**

DEPARVAX is safe in the target species when administered in double dose.

#### **4.11 Withdrawal period**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

- To stimulate active immunity in Muscovy ducks and geese against duck parvovirus and Derzsy's disease.
- To stimulate active immunity in goose breeders in order to provide passive immunity to the progeny against Derzsy's disease.

Pharmacotherapeutic group: Inactivated viral vaccines / duck parvovirus + goose parvovirus  
ATC Vet Code: QI01BA01

### **6. PHARMACEUTICAL PARTICULARS**

#### **6.1 List of excipients**

Light liquid paraffin  
Sorbitan oleate  
Polysorbate 80  
Thiomersal  
PBS

#### **6.2 Incompatibilities**

In the absence of compatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

#### **6.3 Shelf life**

Shelf-life of the veterinary medicinal product as packaged for sale: 24 months.  
Shelf-life after first opening the immediate packaging: use immediately.

#### **6.4 Special precaution for storage**

Store and transport in a dry place between +2 and +8 °C. Protect from direct sunlight. Do not freeze.

### **6.5 Nature and contents of immediate packaging**

Type and material of container: low density polyethylene bottle closed with nitril derivated rubber stopper fixed with plastic-aluminium cap.

Package size:	100 ml	500 dose, for day-old or growing birds
		250 dose, for breeder geese
	500 ml	2500 dose for day-old or growing birds
		1250 dose for breeder geese

Not all pack sizes may be marketed.

### **6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products**

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed in accordance with local requirements.

### **7. MARKETING AUTHORISATION HOLDER**

CEVA-PHYLAXIA VETERINARY BIOLOGICALS Co. Ltd.

H-1107 Budapest, Szállás u 5.

Hungary

### **8. MARKETING AUTHORISATION NUMBER**

### **9. DATE OF FIRST AUTHORISATION / RENEWAL OF THE AUTHORISATION**

30/04/2004

### **10. DATE OF REVISION OF THE TEXT**

05/2009