

## **SUMMARY OF PRODUCT CHARACTERISTICS**

### **1. NAME OF THE VETERINARY MEDICINAL PRODUCT**

Bovalto Pastobov

### **2. QUALITATIVE AND QUANTITATIVE COMPOSITION**

#### **Active substance:**

*Mannheimia haemolytica*\* type A1 antigen: leucotoxin minimum of 68 ELISA.U\*\*

\* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica*

\*\* 1 ELISA.U: q.s. to obtain a *Mannheimia haemolytica* antibody titre of 1 ELISA unit in mice after two administrations of vaccine

#### **Adjuvant(s):**

Aluminium (as hydroxide) .....4.2 mg

#### **Excipient(s):**

Thiomersal .....0.2 mg

Excipient ..... q.s.p. 1 dose of 2 ml

For a full list of excipients, see section 6.1.

### **3. PHARMACEUTICAL FORM**

Suspension for injection – Milky beige

### **4. CLINICAL PARTICULARS**

#### **4.1 Target species**

Cattle.

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

Active immunisation of cattle to reduce clinical signs and lesions of *Mannheimia haemolytica*\* A1 induced respiratory disease.

#### **4.3 Contraindications**

None

#### **4.4 Special warnings**

None

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

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

Shake well before use.

Apply usual aseptic procedures

Vaccinate only healthy animals

Apply usual procedures for the handling of the animals.

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

In the case of accidental self-injection, seek medical advice immediately and show the package insert or the label to the physician.

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

Vaccination by the subcutaneous route is followed by a limited 2-5 cm local reaction (oedema developing as a nodule) that regresses within 3 weeks. Vaccination by the intramuscular route can cause a transient, diffuse oedema and slight local reaction up to 5 cm diameter that regresses within 1-2 weeks. After subcutaneous and intramuscular injection granulomas up to 5 cm diameter may occur. Vaccination (by the subcutaneous or intramuscular route) may sometimes induce slight (1°C) transient (24-72 hours) hyperthermia and also hypersensitivity reactions.

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

Pregnancy: Can be used during pregnancy.

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

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.

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

Intramuscular or subcutaneous route.

Inject one 2-ml dose according to the following schedule:

- Primary vaccination preferably before the risk period  
First injection: at the minimum age of 4 weeks.  
Second injection: 21-28 days later.

- Booster vaccination injection preferably before each risk period:  
one injection no later than one year after the previous vaccination.

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

Vaccination with a double dose by the subcutaneous route is followed by a limited 2-5 cm local reaction (oedema developing as a nodule) that regresses within 3 weeks. Vaccination with a double dose by the intramuscular route can cause a transient, diffuse oedema and slight local reaction up to 5 cm diameter that regresses within 1-2 weeks. After subcutaneous and intramuscular injection granulomas up to 5 cm diameter may occur. For both subcutaneous or intramuscular route, slight (1°C) transient (24-72 hours) hyperthermia could be observed.

#### **4.11 Withdrawal period(s)**

Zero days.

### **5. IMMUNOLOGICAL PROPERTIES**

Adjuvanted, inactivated vaccine against *Mannheimia haemolytica*\* A1 respiratory infections of cattle. The vaccine induces an immune response against *Mannheimia haemolytica*\* A1 demonstrated by challenge and by the presence of antibodies against the *Mannheimia haemolytica*\* capsular and leucotoxin antigens. Booster vaccination results in an anamnestic response in the antibodies against *Mannheimia haemolytica*\* capsular and leucotoxin antigens.

\* *Mannheimia haemolytica* was formerly called *Pasteurella haemolytica*

**ATCvet code:** QI02AB04

### **6. PHARMACEUTICAL PARTICULARS**

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

Aluminium hydroxide  
Thiomersal  
Salts  
Water for injection

#### **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: 18 months  
Any open bottle should be used within one working day.

#### **6.4 Special precautions for storage**

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

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

Type I glass bottle  
Butyl elastomer closure.  
Aluminium cap

Box of 1 dose-glass bottle.  
Box of 5 dose-glass bottle.  
Box of 10 dose-glass bottle.  
Box of 10 glass bottles of 1 dose.  
Box of 50 glass bottles of 1 dose.  
Box of 100 glass bottles of 1 dose.  
Box of 10 glass bottles of 5 doses.  
Box of 10 glass bottles of 10 doses.

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 product or waste materials should be disposed of in accordance with national requirements.

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

Boehringer Ingelheim Animal Health UK Limited  
Ellesfield Avenue  
Bracknell  
Berkshire  
RG12 8YS  
United Kingdom

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

Vm 08327/4173

### **9. DATE OF FIRST AUTHORISATION**

27 August 1997

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

November 2018

**PROHIBITION OF SALE, SUPPLY AND/OR USE**

Condition of supply: subject to medical prescription

Approved: 13 November 2018

A handwritten signature in black ink, appearing to read "D. Austin", with a horizontal line extending to the right.