# 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