

## **VETSEAL 2.6G INTRAMAMMARY SUSPENSION**

### **Description and Composition**

VETSEAL 2.6G INTRAMAMMARY SUSPENSION is a white to light brown suspension. Each pre-filled syringe of 4g contains 2.6g Bismuth Subnitrate as its active ingredient.

### **Pharmacodynamics**

Infusion of the product into each udder quarter produces a physical barrier against the penetration of bacteria thereby reducing the incidence of ascending intramammary infections during the dry period.

### **Pharmacokinetics**

Bismuth subnitrate, heavy is not systemically absorbed from the mammary gland, but resides as a seal in the teat until physically removed (Shown in cows with a dry period up to 100 days).

### **Indication**

Prevention of new intramammary infections throughout the dry period.

In cows considered likely to be free of sub-clinical mastitis, the product may be suitable for use on its own in dry cow management for mastitis control.

Selection of cows for treatment with the product should be based on veterinary clinical judgement. Selection criteria may be based on the mastitis and cell count history of individual cows, or recognised tests for the detection of sub-clinical mastitis such as bacteriological sampling.

### **Recommended Dose**

Intramammary use.

Cattle (Dairy cows): Infuse the content of one syringe of the product into each udder quarter immediately after the last milking of the lactation (at drying off). Do not massage the teat or udder after infusion of the product.

Care must be taken not to introduce pathogens into the teat in order to reduce the risk of post-infusion mastitis (aseptic technique).

It is essential that the teat is thoroughly cleaned and disinfected, with surgical spirit or alcohol-impregnated wipes. The teats should be wiped until the wipes are no longer visibly dirty. Teats should be allowed to dry prior to infusion. Infuse aseptically and avoid contamination of the syringe nozzle. Following infusion, it is advisable to use an appropriate teat dip or spray.

Under cold conditions the product may be warmed to room temperature in a warm environment to aid syringeability.

### **Route of Administration**

For intramammary administration.

### **Contraindication**

See section 'Pregnancy and Lactation'. Do not use in lactating cows. Do not use the product alone in cows with sub-clinical mastitis at drying off. Do not use in cows with clinical mastitis at drying off. Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

### **Warning and Precautions**

#### **Special warning for each target species**

None.

### **Special precautions for use**

#### Special precautions for use in animals

It is good practice to observe dry cows regularly for signs of clinical mastitis. If a sealed quarter develops clinical mastitis, the affected quarter should be stripped out manually before appropriate therapy is instituted.

To reduce the risk of contamination, do not immerse the syringe in water.

Use the syringe only once.

Since the product does not have antimicrobial activity, in order to minimise the risk of acute mastitis due to poor infusion technique and lack of hygiene (see section 'Side Effects'), it is crucial to follow the aseptic technique of administration described in section 'Recommended Dose'.

Do not administer any other intramammary product following administration of the product.

In cows that may have sub-clinical mastitis, the product may be used following administration of a suitable dry cow antibiotic treatment to the infected quarter.

#### Special precautions to be taken by the person administering the drug to the animals

Avoid contact with skin or eyes.

Should skin or eye contact occur, wash the affected area thoroughly with water.

If irritation persists, seek medical advice and show the package leaflet or label to the physician.

People with known hypersensitivity to bismuth salts should avoid contact with the product.

Wash hands after use.

#### **Interaction with Other Medicaments**

In clinical trials, the compatibility of the product has only been shown with a cloxacillin-containing dry cow preparation.

#### **Pregnancy and Lactation**

**Pregnancy:** As the product is not systemically absorbed following intramammary infusion, the product can be used in pregnant animals. At calving, the seal may be ingested by the calf. Ingestion of the product by the calf is safe and produces no adverse effects.

**Lactation:** If accidentally used in a lactating cow, a transient rise in somatic cell count (up to 2-fold) may be observed. In such an event, strip out the seal manually, no additional precautions are necessary.

#### **Side Effects**

|                                                                                   |                             |
|-----------------------------------------------------------------------------------|-----------------------------|
| Very rare<br>(<1 animal / 10,000 animals treated,<br>including isolated reports): | Acute mastitis <sup>1</sup> |
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<sup>1</sup>Primarily due to the poor infusion technique and lack of hygiene. See sections 'Warning and Precautions' and 'Recommended Dose' regarding the importance of aseptic technique.

#### **Symptoms and Treatment of Overdose**

Twice the recommended dose has been administered to cows without any clinical adverse effects.

#### **Storage Condition**

Store below 30°C.

#### **Shelf life**

3 years. The syringe must only be used once. Partly used syringes should be discarded.

#### **Withdrawal Period**

Meat & offal: Zero days

Milk: Zero hours

#### **Packing**

4g

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