

## PACKAGE LEAFLET

**ENDOMETROX<sup>®</sup> aerosolum spumescens 45 g**

**Mares**

### **1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURER IF THEY ARE DIFFERENT**

Marketing Authorization Holder and Manufacturer responsible for batch release:

VETPROM AD, Bulgaria,  
2400 Radomir, 26 Otets Paisii Str  
Tel.: 0777/8-24-93, 8-02-68; fax: 0777/8-23-91  
E-mail: [vetprom@abv.bg](mailto:vetprom@abv.bg)

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

ENDOMETROX<sup>®</sup> aerosolum spumescens 45 g

### **3. ACTIVE SUBSTANCE AND EXCIPIENT CONTENT**

Content in 45 g:

**Active substances:**

Tylosin 750 000 IU/ 45g  
Nitroxoline 0,75g/ 45g

**Excipients:**

Dimethyl Sulfoxide  
Polawax A 31  
Cetomacrogol 400  
Ethanol (96 per cent)  
Forane 134 A

### **4. THERAPEUTIC INDICATIONS**

Acute, subacute and chronic catarrhal and purulent-catarrhal endometritis, metritis, parametritis, cervicitis and vaginitis in mares.

### **5. CONTRAINDICATIONS**

Do not use in case of hypersensitivity to the active substance or to some of the excipients.

### **6. ADVERSE REACTIONS**

In very rare cases hypersensitivity (allergic reactions) may occur.

In case of more persistent spraying, restlessness of animals may be observed which manifests with rapid breathing, hitting the floor with a leg, lying down, standing up, turning the head backwards.

The frequency of the adverse reactions is determined by the following classification:

- very common (more than 1 in 10 animals displaying adverse reactions during the course of one treatment)
- common (more than 1 but less than 10 out of 100 animals)
- uncommon (more than 1 but less than 10 out of 1,000 animals)
- rare (more than 1 but less than 10 out of 10,000 animals)
- very rare (less than 1 out of 10,000 animals including isolated reports).

If you notice any serious or other side effect caused by the use of this veterinary medicinal product not listed in this leaflet, please inform immediately your veterinary doctor.

## **7. ANIMAL SPECIES FOR WHICH THIS VETERINARY MEDICINAL PRODUCT IS INTENDED**

Mares.

## **8. DOSAGE FOR EACH ANIMAL SPECIES, METHOD AND ROUTE OF ADMINISTRATION**

Dose:

The contents of one 45 g vial corresponds to one dose. In most cases a single treatment would be sufficient. In case of more severe injuries, treatment can be repeated 2 to 3 times at intervals of 24-48 hours.

Method of administration:

Prior to use, the vial is conditioned to a temperature not higher than 30 °C.

Intrauterine: after preliminary examination and rectal massage of the uterus. Use one hand to fix the cervix, while the other one is on the tip attached to a nozzle. The nozzle is connected to the valve of the vial, and the content is sprayed by using pressure. Product administration continues until the vial content is completely used.

## **9. INSTRUCTIONS FOR PROPER USE**

## **10. WITHDRAWAL PERIOD**

Not for use in horses whose meat is for human consumption.

## **11. SPECIAL REQUIREMENTS FOR STORAGE**

Keep this medicine out of the sight and reach of children.

Store below 25 °C.

Protect from light.

Store in dry places.

Do not use this veterinary medicine after the expiry date which is stated on the label.

Caution! The vial is under pressure. Keep from hitting and heating!

## **12. SPECIAL PRECAUTIONS**

Special warnings for any animal species for which the veterinary medicinal product is intended:

No special warnings.

Special precautions for animals during the use of this product:

Not applicable.

Special precautions for the staff administering the veterinary medicine to the animals:

Not applicable.

Pregnancy:

The safety of this veterinary medicinal product during pregnancy has not been established.

Interactions with other veterinary medicinal products and other forms of interaction:

Not known.

Overdosage (symptoms, emergency measures, antidotes):

None, due to the route of administration.

Incompatibilities:

Not known.

**13. SPECIAL PRECAUTIONS FOR DISPOSAL OF ANY UNUSED PRODUCT OR WASTE MATERIAL**

Do not throw away any veterinary medicines via wastewater or household waste. Ask your veterinary doctor how to throw away veterinary medicines you no longer use. These measures will help protect the environment.

**14. DATE OF LATEST REVISION OF THE PACKAGE LEAFLET**

09/2015.

**15. FURTHER INFORMATION**

For any information in relation to this veterinary medicinal product, please contact the local representative of the marketing authorization holder.

VETPROM AD

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