

## PACKAGE LEAFLET

*For animal treatment only*

### **MESSIPEN injectable suspension** of ampicillin for sheep, goats

#### **1.NAME AND ADDRESS OF THE MARKETING AUTHORIZATION HOLDER AND OF THE MANUFACTURING AUTHORIZATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT**

Marketing Authorisation Holder:

**PROVET S.A.**

120, Eleftherias Avenue, Eleousa, Zitsa, 45500 Ioannina, Greece

Tel.: +30 2105508500, +30 2105575770-3

E-mail: [vet@provet.gr](mailto:vet@provet.gr)

Manufacturer responsible for batch release:

**PROVET S.A. (FACTORY)**

Nikiforou Foka & Ag.Anargyron, Thesi Vrago,

193 00 Aspropyrgos, Attiki, Greece

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

**MESSIPEN**

injectable suspension

Ampicillin 150 mg/ml

for sheep, goats

#### **3.STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENT(S)**

1 ml of suspension contains:

**Active substance:** Ampicillin (as trihydrate) 150 mg

**Excipients:** Phenol crystals, Polysorbate 80, Ethyl oleate

#### **4. INDICATIONS**

MESSIPEN injectable suspension is recommended for the treatment of bacterial infections caused by Gram positive and negative microorganisms. Specifically, it is recommended in the following cases:

**Infections of the digestive system:** MESSIPEN injectable suspension is very effective against infections of the gastrointestinal system caused by Gram negative microorganisms, such as *Escherichia coli* and *Salmonella* spp. The product is excreted in high concentrations via the bile, it is thus effective against diarrhea of lambs and kids.

**Infections of the respiratory system:** MESSIPEN injectable suspension is recommended for the control of various infections of the respiratory system, such as pneumonia, bronchitis, as well as other secondary bacterial infections, that accompany viral respiratory infections.

**Infections of the urinary & genital system:** MESSIPEN injectable suspension is excreted in high concentrations unchanged, via the urine, hence it is highly recommended for the treatment of nephritis and cystitis.

MESSIPEN injectable suspension is used for the systemic treatment of infections caused by Gram negative bacteria, primarily located in the breast such as *Escherichia coli*. It is also effective against secondary bacterial complications, localized infections, trauma, abscesses, post-surgery infections as well as arthritis.

#### **5. CONTRAINDICATIONS**

Do not administer to animals with known hypersensitivity to penicillin.

Do not administer to rabbits and rodents, such as guinea pigs, hamsters and gerbils.

#### **6. ADVERSE REACTIONS**

Not mentioned.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

## **7. TARGET SPECIES**

Sheep, Goats

## **8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION**

Administered intramuscularly.

**Sheep-Goats:** 5-10 mg/kg of body weight every 12 hours for 3-5 days.

## **9. ADVICE ON CORRECT ADMINISTRATION**

Because ampicillin is in an oily carrier, always use dry syringes.

People with known hypersensitivity to penicillin should not come in contact with the product.

## **10. WITHDRAWAL PERIOD(S)**

Sheep: Meat: 4 days

Milk: 4.5 days (108 hours)

Goats: Meat: 6 days

Milk: 4.5 days (108 hours)

## **11. SPECIAL STORAGE PRECAUTIONS**

Keep out of the sight and reach of children.

Store at temperatures below 25°C.

Store in a dry place. Protect from light.

Shelf-life after first opening of the container according to instructions: 14 days

Do not use this veterinary medicinal product after the expiry date which is stated on the label. The expiry date refers to the last day of that month.

## **12. SPECIAL WARNINGS**

Intravenous administration is not recommended.

Ampicillin presents incompatibility with glucose solutions and sulfonamides.

## **13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTEMATERIALS, IF ANY**

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

## **14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED**

JANUARY 2011

## **15. OTHER INFORMATION**

### **PACKAGES**

Vials of 15 ml, 40 ml and 100 ml

Not all pack sizes may be marketed.

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

**\*under veterinary medical prescription\***

**KEEP OUT OF THE SIGHT AND REACH OF CHILDREN**