PACKAGE LEAFLET

For animal treatment only

MESSIPEN powder for oral solution 10% for Calves, Lambs, Kids, Pigs, Poultry, Dog, Cat

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

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

Powder for oral solution

10%, Ampicilline

for Calves, Lambs, Kids, Pigs, Poultry, Dog, Cat

3. STATEMENT OF THE ACTIVE SUBSTANCE AND OTHER INGREDIENTS

100 g of product contain:

Active substance: Ampicillin as trihydrate 11,5g (equivalent in Ampicillin 10g)

Excipients: Sodium lauryl sulfate, Lactose

4. INDICATIONS

MESSIPEN oral powder 10% is indicated for the treatment of primary and secondary bacterial infections caused by succeptible to $gram^+$ and $gram^-$ ampicillin microorganisms. Specifically, its use is recommended in the following conditions:

Dog-Cat: infections of the respiratory, urogenital and digestive system

Calves-Lambs-Kids: infections of the respiratory and digestive system

Pigs: infections of the respiratory system, colibacillic infections, Metritis-Mastitis-Agalactia syndrome (M.M.A.) and ervsipelas

Poultry: colibacillic infections, pasteurellosis, necrotic enteritis, coryza and secondary infections of Chronic Respiratory Disease (CRD)

5. CONTRAINDICATIONS

Do not administer ampicillin to animals with a known hypersensitivity to penicillin.

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

MESSIPEN® oral powder 10% should not be administered to calves, lambs and kids with a functional rumen.

6. ADVERSE REACTIONS

Following administration of ampicillin, hypersensitivity reactions may be observed and rarely anaphylactic shock. Furthermore, gastrointestinal disturbances may also be observed.

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

Calves, Lambs, Kids, Pigs, Poultry, Dog, Cat

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

MESSIPEN oral powder 10% is administered per os after dissolution via in drinking water or milk in the following dosage rates:

Dog-Cat: 10-20mg ampicillin/ kg of b.w. per 12 hours, that is 0.5-1g MESSIPEN oral powder 10% / 5kg of b.w. per 12 hours. Treatment lasts for 3-5 days.

Calves-Lambs-Kids: 10-20mg ampicillin/ kg of b.w. per 12 hours that is 1-2g MESSIPEN oral powder 10% / 10kg of b.w. per 12 hours. Treatment lasts for 3-5 days.

Pigs: 10-20mg ampicillin/ kg of b.w. per 12 hours that is 1-2g MESSIPEN oral powder 10% / 10 kg of b.w. per 12 hours. Treatment lasts for 3-5 days. In pigs can be administered with drinking water.

Poultry: 3g MESSIPEN® oral powder 10% / 10 L of drinking water for 3-5 days.

In very severe cases 10g MESSIPEN® oral powder 10% / 10 L of drinking water may be administered.

During treatment the medicated water should be the only source of drinking water in birds.

9. ADVICE ON CORRECT ADMINISTRATION

During treatment the drinking water containing MESSIPEN oral powder 10% should be the only source of drinking water for poultry.

People with known hypersensitivity to ampicillin should avoid contact with the veterinary medicinal product.

10. WITHDRAWAL PERIODS

Meat and offals:

Calves-Pigs: 15 days

Lambs-Kids-Poultry: 7 days

Eggs: 7 days

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Shelf life after dilution (in water or milk) according to directions: 1 day

Keep out of the sight and reach of children.

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

12. SPECIAL WARNINGS

Ampicillin exhibit incompatibility with sulphonamides and glucose solutions. Its absorption is reduced in the presence of food.

13.SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, 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 MARCH 2022

15. OTHER INFORMATION

PACKAGES

Foil of 100 g
Tin can of 1 kg
Sack of 5 kg and 25 kg
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