EMA/25826/2014
EMEA/V/C/002382

EPAR summary for the public

Equisolon

Prednisolone

This document is a summary of the European Public Assessment Report. Its purpose is to explain how the assessment done by the Committee for Medicinal Products for Veterinary Use (CVMP) on the basis of the documentation provided, led to the recommendations on the conditions of use.

This document cannot replace a face-to-face discussion with your veterinarian. If you need more information about your animal's medical condition or treatment, contact your veterinarian. If you want more information on the basis of the CVMP recommendations, read the scientific discussion (also part of the EPAR).

What is Equisolon?

Equisolon is a veterinary medicine that contains the active substance prednisolone. It is available as a powder to be given by mouth.

What is Equisolon used for?

Equisolon is used to treat recurrent airway obstruction (RAO or heaves) in horses in combination with environmental measures. RAO is a chronic (long-term) allergic condition in which horses wheeze, cough and have difficulty in breathing. The environmental measures include keeping horses outside as much as possible or improving the ventilation in the stable, soaking hay or feeding silage (fermented grass) and using bedding with a minimum of dust in the stable. Equisolon should be mixed with a small amount of food and given by mouth at a dose of 1 mg prednisolone per kg bodyweight once a day. The dose may be repeated for ten consecutive days.

How does Equisolon work?

In horses with RAO, the immune system (the body's natural defences) over-reacts to triggering substances (antigens) that are present in dust that the horse breathes in. This results in inflammation and blockage of the airways inside the lungs, leading to difficulty in breathing. The active substance in Equisolon, prednisolone, is a corticosteroid, a medicine that acts to reduce the activity of the immune

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system. This decreases inflammation, thereby helping to keep the airways clear and allowing the horse to breathe more easily.

How has Equisolon been studied?

The use of prednisolone in horses with RAO has been well described in the scientific literature. A field study was conducted in which the same 8 horses with RAO after exposure to hay participated in 4 treatment periods receiving either no treatment or Equisolon at three different doses, each for ten days. In addition to treatment with prednisolone, the exposure to organic dust was reduced by substituting hay with silage and by improving the ventilation in the stable. The main measures of effectiveness were clinical signs of RAO disease as well as the amount of fluid and immune cells in the airways and the air pressure in the lungs.

What benefit has Equisolon shown during the studies?

Treatment with prednisolone at the recommended dose of 1 mg per kg bodyweight over ten days in combination with environmental control resulted in significant improvements in fluid in the airways and clinical signs associated with RAO.

What is the risk associated with Equisolon?

The most common side effects (seen in more than 1 in 10 horses) with Equisolon are suppression of production of cortisol (a natural corticosteroid important in the body's response to stress), and an increase in the level of triglycerides (a type of fat) in the blood. For a full list of all side effects reported with Equisolon, see the package leaflet.

Equisolon must not be used in horses with viral or fungal infections, gastrointestinal or corneal ulcers or in pregnant mares.

What are the precautions for the person who gives the medicine or comes into contact with the animal?

The medicine should not be given to horses by pregnant women as there is a risk of malformation to the unborn baby. The product should not be shaken to prevent dust formation.

What is the withdrawal period?

The withdrawal period is the time allowed after administration of the medicine and before the animal can be slaughtered and the meat used for human consumption. It is also the time allowed after administration of the medicine before milk can be used for human consumption. The withdrawal period for Equisolon for meat is ten days. Equisolon should not be used in mares producing milk for human consumption.

Why has Equisolon been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Equisolon exceed the risks for the approved indication and recommended that Equisolon be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Equisolon:

The European Commission granted a marketing authorisation valid throughout the European Union, for Equisolon on 12/03/2014. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in January 2014.