



EUROPEAN MEDICINES AGENCY
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EPAR summary for the public

Zycortal

Desoxycortone pivalate

This is a summary of the European public assessment report (EPAR) for Zycortal. It explains how the Agency assessed this veterinary medicine to recommend its authorisation in the European Union (EU) and its conditions of use. It is not intended to provide practical advice on how to use Zycortal.

For practical information about using Zycortal, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

What is Zycortal and what is it used for?

Zycortal is a veterinary medicine used to treat dogs with Addison's disease. Addison's disease is a condition, known as hypoadrenocorticism, where the adrenal glands (located above the kidneys) do not produce enough of two steroid hormones, called cortisol and aldosterone. The lack of aldosterone can cause fluid loss, dehydration and weight loss. Zycortal is used long-term to replace the missing aldosterone. A corticosteroid medicine is likely to be needed, in addition, to replace the cortisol. Zycortal contains the active substance desoxycortone pivalate.

How is Zycortal used?

Zycortal is available as a prolonged-release suspension for injection. Prolonged-release means that the active substance is released slowly over a few weeks after being injected. Zycortal is given as an injection under the skin at an initial dose of 2.2 mg/kg. Around 25 days after the first injection the dog's response is evaluated before a second injection is given. The dose to be given and the interval between treatments depend on the dog's response as well as the blood levels of certain electrolytes (sodium and potassium). When satisfactory results are obtained then the treatment should continue to be given long-term using the same dose and interval between treatments.

Zycortal can only be obtained with a prescription. For further information, see the package leaflet.



How does Zycortal work?

Desoxycortone pivalate is a synthetically produced steroid hormone very similar to the natural hormone aldosterone. It works in the same way as aldosterone to retain sufficient water in the body (by retaining sodium and eliminating potassium). Dogs with Addison's disease have insufficient levels of aldosterone in their blood and Zycortal is used to replace the missing hormone.

What benefits of Zycortal have been shown in studies?

The effectiveness of Zycortal was investigated in a field study involving 152 dogs with Addison's disease. Zycortal was given by injection under the skin to 113 dogs and 39 dogs were given a similar medicine, which also contains desoxycortone pivalate, for injection into the muscle. All dogs also received corticosteroids given by mouth. In this study, Zycortal was shown to be at least as effective as the other similar medicine. 90 days after start of treatment, 84% (92 out of 109) of Zycortal-treated dogs had improved clinical signs and normal sodium and potassium blood levels.

What are the risks associated with Zycortal?

The most common side effects with Zycortal (which may affect more than 1 in 10 dogs) are polydipsia (increase in water intake) and polyuria (increase in urine production).

For the full list of all side effects reported with Zycortal, see the package leaflet.

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

Safety information has been included in the summary of product characteristics and the package leaflet for Zycortal, including the appropriate precautions to be followed by healthcare professionals and animal owners or keepers.

In case of skin or eye contact the affected area should be rinsed immediately with water. If irritation occurs, seek medical advice immediately and show the package leaflet or the label to the doctor.

In case of accidental self-injection, medical advice should be sought immediately and the package leaflet or label shown to the doctor. This medicine may cause pain and swelling at the injection site if accidentally self-administered.

Zycortal may cause adverse effects on male reproductive organs and as a result can affect fertility.

Pregnant and breast-feeding women should avoid giving this medicine because it can affect the normal development of unborn and newborn children.

Why is Zycortal approved?

The Agency's Committee for Medicinal Products for Veterinary Use (CVMP) concluded that Zycortal's benefits are greater than its risks and recommended that it be approved for use in the EU.

Other information about Zycortal

The European Commission granted a marketing authorisation valid throughout the EU for Zycortal on 06/11/2015.

The full EPAR for Zycortal can be found on the Agency's website: [ema.europa.eu/Find/medicine/Veterinary medicines/European public assessment reports](http://ema.europa.eu/Find/medicine/Veterinary%20medicines/European%20public%20assessment%20reports). For more information about treatment with Zycortal, animal owners or keepers should read the package leaflet or contact their veterinarian or pharmacist.

This summary was last updated in September 2015.