EMA/103363/2007
EMEA/V/C/000116

EPAR summary for the public

Slentrol

Dirlotapide

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 Slentrol?

Slentrol contains the active substance dirlotapide which helps to reduce weight in dogs. Slentrol is an oral solution, colourless to pale yellow in colour. It is available in three pack sizes; 20 ml, 50 ml and 150 ml and supplied with appropriate dosing devices.

What is Slentrol used for?

Slentrol is used in adult dogs that are overweight or obese, to help them lose weight. It is to be used as part of an overall weight management programme which also includes appropriate dietary changes and exercise practice.

The medicine is administered to the dog for 2 weeks, and after the first 2 weeks the veterinarian will double the initial dose for a further 2 weeks. Following these initial 4 weeks of therapy, dogs should be weighed monthly during treatment with the product and dose adjustments are made monthly according to the weight loss achieved. The product can be administered with or without food for up to 12 months.

7 Westferry Circus ● Canary Wharf ● London E14 4HB ● United Kingdom
Telephone +44 (0)20 7418 8400 **Facsimile** +44 (0)20 7418 8447
E-mail info@ema.europa.eu **Website** www.ema.europa.eu

An agency of the European Union

How does Slentrol work?

The active substance in Slentrol, dirlotapide, works in the gut by blocking a protein (the microsomal triglyceride transfer protein). This protein is normally involved in the absorption of fats from the diet. By blocking the protein Slentrol decreases the absorption of fats from the gut and this change in fat absorption has an appetite suppressant effect. The majority of the weight loss occurs as a result of appetite suppression.

How has Slentrol been studied?

Slentrol has been studied in a large number of dogs in both laboratory and field trials for up to one year. Two large field trials were conducted, one in Europe and one in the USA, in healthy dogs which had a bodyweight higher than recommended. Some dogs received Slentrol while the remainder received the medicine with the active substance removed (control group). The dogs also received other medicines during the study as required, such as anti-inflammatory drugs (including NSAIDs), antimicrobials, parasiticides, vaccines, dietary supplements, vitamins, hormones and cardiovascular drugs. Specific interactions were not investigated. Certain medications, e.g. drugs that lower serum cholesterol or other serum lipids, or drugs that affect appetite and/or body weight, e.g. long-acting glucorticoids, were not permitted for use during the study.

What benefit has Slentrol shown during the studies?

Slentrol at the recommended dose of 5 mg/ml and using the recommended treatment schedule reduced body weight in obese dogs when compared to the control group. The weight lowering effect was up to 20 % after 6 months of therapy in the initial weight loss phase of treatment. Rebound weight gain was seen after treatment was completed. The treatment is an initial measure in an obesity management programme; it has to be combined with changes in diet, which must be continued after treatment is finished.

What is the risk associated with Slentrol?

Vomiting, sometimes accompanied by signs of lethargy, diarrhoea or softened faeces may occur during treatment. In most cases, these effects are mild and stop without any treatment. Some dogs (less than 10%) experienced repeated vomiting (i.e. more than once every 20 days on average). A reduced appetite may also occur during treatment. This is related to the mode of action of the product.

For a full list of all side-effects reported with Slentrol, see the Package Leaflet.

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

This veterinary medicine has been developed especially for dogs and is not for use in humans. If a person accidentally takes the medicine, seek medical advice immediately and show the package leaflet or the label to a doctor. If accidental skin or eye contact occurs, flush immediately with lots of water.

Why has Slentrol been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Slentrol excede the risks for the management of overweight and obesity in adult dogs and recommended that Slentrol be given a marketing authorisation. The benefit-risk balance may be found in the scientific discussion module of this EPAR.

Other information about Slentrol:

The European Commission granted a marketing authorisation valid throughout the European Union, for Slentrol on 13.04.2007. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in: 04-2013.