European Medicines Agency
Veterinary Medicines

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EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

YARVITAN

EPAR summary for the public

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 Yarvitan?

Yarvitan contains the active substance mitratapide which helps to reduce weight in dogs. Yarvitan is an oral solution, colourless to slightly yellow in colour. It is available in three pack sizes; 55 ml or 120 ml bottles for dogs weighing up to 36 kg and a 210 ml bottle for dogs weighing up to 48 kg.

What is Yarvitan used for?

Yarvitan is used in adult dogs that are overweight or obese, to help them lose weight. It is used as part of a programme that also includes controlling the dog's intake of food. The medicine is administered to the dog for 3 weeks, followed by a 2-week medicine-free interval, when the veterinarian will adjust the dog's feeding according to its energy requirements. The dog then receives the medicine for a further 3 weeks, at the same time as the adjusted diet. The dose to use is calculated according to the weight of the dog and the Yarvitan solution is given with the animal's food.

How does Yarvitan work?

The active substance in Yarvitan, mitratapide, 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 Yarvitan decreases the absorption of fats from the gut. Yarvitan also has a slight appetite decreasing effect due to its mode of action.

How has Yarvitan been studied?

Yarvitan has been studied in dogs in both laboratory and field trials. Two large field trials were conducted, one in Europe and one in the USA, in healthy dogs which had a bodyweight 20% higher than recommended. About three-quarters received Yarvitan 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 vaccines, worming tablets, anti-flea or anti-tick treatments, antibiotics and anti-inflammatory medicines.

7 Westferry Circus, Canary Wharf, London E14 4HB, UK
Tel. (44-20) 74 18 84 00 Fax (44-20) 74 18 84 47
E-mail: mail@emea.europa.eu http://www.emea.europa.eu

What benefit has Yarvitan shown during the studies?

Yarvitan at the recommended dose and using the 3-2-3 week treatment schedule reduced body weight in obese dogs when compared to the control group. The weight lowering effect was relatively moderate (in the range of 6-7 % of the weight before treatment). 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 Yarvitan?

Vomiting, diarrhoea or softened faeces may occur during treatment. In most cases, these effects are mild and stop without any treatment. 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 Yarvitan, 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 eye contact occurs, flush immediately with lots of water.

Why has Yarvitan been approved?

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Yarvitan exceed its risks for the management of overweight and obesity in dogs and recommended that Yarvitan be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

Other information about Yarvitan:

The European Commission granted a marketing authorisation valid throughout the European Union, for Yarvitan to Janssen Animal Health B.V.B.A. Belgium on 14/11/2006. Information on the prescription status of this product may be found on the label/outer package.

This summary was last updated in September 2006.