



## EUROPEAN PUBLIC ASSESSMENT REPORT (EPAR)

### YPOZANE

#### 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 Ypozane?

Ypozane are round, white tablets that contain osaterone acetate as the active substance. The medicine is available as 1.875 mg, 3.75 mg, 7.5 mg or 15 mg tablets, which can be used for dogs of different weights (small, medium sized, large or very large dogs).

#### What is Ypozane used for?

Ypozane is used in male dogs for the treatment of "benign prostatic hypertrophy", which means an increase of the size of the prostate gland that is not related to cancer (benign). The prostate is a gland that produces a fluid that is part of the semen. When it is enlarged, it can lead to abdominal pain, constipation and difficulties in urinating in the dogs affected.

Ypozane is given daily for 7 days. Its effect can be seen within about 2 weeks, and lasts for 5 months.

#### How does Ypozane work?

Osaterone acetate is a hormone that is chemically related to progesterone, and as such it has anti-androgen and progestagen activity. In male dogs, it blocks the transport of the male hormone testosterone into the prostate. By inhibiting testosterone, Ypozane helps the prostate to shrink back to its normal size.

#### How has Ypozane been studied?

Data were provided on the pharmaceutical quality of the product, the tolerance of Ypozane in dogs and the safety of the tablets when handled by humans.

The effectiveness of osaterone acetate was investigated in a large study undertaken in a number of veterinary practices across Europe. Dogs with enlarged prostates from various breeds, age groups and weights, were either treated with Ypozane or with another product, which is already authorised in the EU for this indication. The dogs received once a day for 7 days, one Ypozane tablet appropriate for their size to correspond to a daily dose of 0.25 – 0.5 mg osaterone acetate per kilogram bodyweight.

### **What benefit has Ypozane shown during the studies?**

Treatment with Ypozane was effective in the treatment of benign prostatic hypertrophy. A clinical response to treatment (reduction of prostate volume) was seen within 14 days, which lasted for at least 5 months. After this time, the dog should be re-examined by a veterinarian and treatment might be repeated. Ypozane has no adverse effects on semen quality.

### **What is the risk associated with Ypozane?**

Ypozane should be used with caution in dogs which have had liver problems.

The most common side effects are a transient increase in appetite, and changes in the behaviour of the dog (changes in activity levels, more sociable behaviour). Some dogs might also show vomiting, diarrhoea or increased thirst, or might develop a “feminisation syndrome”. This is when male dogs suddenly become attractive to other male dogs or the size of their mammary glands increases. All these effects disappear after a while without specific treatment.

### **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. Wash hands after administration.

In female laboratory animals, osaterone acetate caused serious adverse effects on reproductive functions. Therefore, women of child-bearing age should avoid contact with, or wear disposable gloves, when handling the tablets.

### **Why has Ypozane been approved?**

The Committee for Medicinal Products for Veterinary Use (CVMP) concluded that the benefits of Ypozane exceed its risks for the treatment of benign prostatic hypertrophy (BPH) in male dogs and recommended that Ypozane be given a marketing authorisation. The benefit-risk balance may be found in module 6 of this EPAR.

### **Other information about Ypozane:**

The European Commission granted a marketing authorisation valid throughout the European Union, for Ypozane to Virbac S.A. on 11.01.2007. Information on the prescription status of this product may be found on the label/outer package.

**This summary was last updated on 11.01.2007.**