Ypozane Tablets for dogs

Species: Dogs
Therapeutic indication: **Pharmaceuticals: Hormones and therapeutically related products:** Others
Active ingredient: Osaterone Acetate
Product: YPOZANE 1.875 mg tablets for dogs
YPOZANE 3.75 mg tablets for dogs
YPOZANE 7.5 mg tablets for dogs
YPOZANE 15 mg tablets for dogs
Product index: YPOZANE tablets for dogs

Qualitative and quantitative composition

Each tablet contains 1.875 mg, 3.75 mg, 7.5 mg or 15 mg osaterone acetate

Pharmaceutical form

Round, white, biconvex tablet of 5.5 mm, 7 mm, 9 mm and 12 mm.

Clinical particulars

Target species

Dogs (male)

Indications for use

Treatment of benign prostatic hypertrophy (BPH) in male dogs.

Contra-indications

None

Special warnings for each target species

In dogs with BPH associated with prostatitis, the product can be administered concurrently with antimicrobials

Special precautions for use

Special precautions for use in animals

A transient reduction of plasma cortisol concentration may occur; this may continue for several weeks after administration. Appropriate monitoring should be implemented in dogs under stress (e.g. postoperative) or those with hypoadrenocorticism. The response to an ACTH stimulation test may also be suppressed for several weeks after administration of osaterone.

Use with caution in dogs with a history of liver disease, as safety of use of the product in these dogs has not been thoroughly investigated, and as treatment of some dogs with liver disease has resulted in reversible elevation of ALT and ALP in clinical trials.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Wash hands after administration.

In the case of accidental ingestion by a person, seek medical advice immediately and show the package leaflet or the label to the physician.

A single oral dose of 40 mg osaterone acetate in human males was followed by a sporadic decrease in FSH, LH and testosterone, reversible after 16 days. There was no clinical effect. 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 administering the product.

Adverse reactions

A transient increase in appetite occurs very commonly.

Transient behavioural changes such as increased or decreased activity, or more sociable behaviour, arecommon.

Other adverse reactions, including transient vomiting and/or diarrhoea, polyuria/polydipsia, lethargy or feminisation syndrome including mammary gland hyperplasia occur uncommonly.

A transient reduction in plasma cortisol occurs in most treated animals.

In clinical trials, treatment with the veterinary medicinal product was not discontinued and all dogs recovered without any specific therapy.

Use during pregnancy, lactation orlay

Not applicable

Interactions

None known

Amounts to be administered and administration route

For oral use.

Administer 0.25 – 0.5 mg osaterone acetate per kilogram bodyweight, once a day, for 7 days as follows:

Dog's weight	YPOZANE Tablets to be administered	Number of tablets per day	Treatment duration
3 to 7.5 kg*	1.875 mg tablet	1 Tablet	7 days
7.5 to 15 kg	3.75 mg tablet		
15 to 30 kg	7.5 mg tablet		
30 to 60 kg	15 mg tablet		

*No data are available for dogs less than 3 kg bodyweight.

Tablets can be given either directly into the mouth or with food. The maximum dose should not be exceeded.

The onset of clinical response to treatment is usually seen within 2 weeks. The clinical response persists for at least 5 months after treatment.

Re-evaluation by the veterinarian should take place 5 months after treatment or earlier if clinical signs recur. A decision to retreat at this or at a later time point should be based on veterinary examination taking into account the risk benefit profile of the product. If clinical response to treatment is considerably shorter than expected, a re-evaluation of the diagnosis is necessary.

Overdose

An overdose study (up to 1.25 mg/kg bodyweight for 10 days, repeated one month later) did not show undesirable effects except for a decrease of cortisol plasma concentration.

Withdrawal periods

Not applicable.

Pharmacological particulars

Pharmacodynamic properties

Osaterone is a steroid anti-androgen, which inhibits the effects of an excess production of male hormone (testosterone).

Osaterone acetate is a steroid chemically related to progesterone, and as such it has potent progestagen and potent anti-androgen activity. Also, the major metabolite of osaterone acetate (15β-hydroxylated - osaterone acetate) has anti-androgenic activity. Osaterone acetate inhibits the effects of an excess of male hormone (testosterone) through various mechanisms. It competitively prevents the binding of androgens to their prostatic receptors and blocks the transport of testosterone into the prostate.

No adverse effects on semen quality have been observed.

Pharmacokinetic properties

After oral administration with food in dogs, osaterone acetate is rapidly absorbed (Tmax about 2 hours) and undergoes a first-pass effect mainly in the liver. After a dose of 0.25 mg/kg/day, the mean maximum concentration (Cmax) in plasma is about 60 µg/l.

Osaterone acetate is converted to its main, 15β-hydroxylated metabolite, which is also pharmacologically active. Osaterone acetate and its metabolite are bound to plasma proteins (around 90% and 80% respectively), mainly to albumin. This binding is reversible and not affected by other substances known to specifically bind to albumin.

Osaterone is eliminated within 14 days, mainly in faeces via biliary excretion (60%) and to a lesser extent (25%) in urine. Elimination is slow with a mean half-life (T½) of about 80 hours. After repeated administration of osaterone acetate at 0.25 mg/kg/day for 7 days, the factor of accumulation is about 3- 4 without change in the rates of absorption or elimination. Fifteen days after the last administration, the mean plasma concentration is about 6.5 µg/l.

Pharmaceutical particulars

Excipients

Pregelatinised starch

Carmellose calcium

Maize starch

Talc

Magnesium stearate

Major incompatibilities

Not applicable

Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Special precautions for storage

This veterinary medicinal product does not require any special storage conditions.

Immediate packaging

Carton box containing one aluminium/aluminium blister with 7 tablets.

Disposal

Any unused veterinary medicinal product or waste materials derived from such veterinary

medicinal products should be disposed of in accordance with local requirements.

Marketing Authorisation Number

EU/2/06/068/001-004

Significant changes

Date of the first authorisation or date of renewal

11/01/2007

Date of revision of the text

11/01/2007

Any other information

Nil

Legal category

Legal category:POM-V

GTIN

GTIN description: Ypozane 1.875mg Tablets x 7
GTIN:3597133044386
GTIN description: Ypozane 3.75mg Tablets x 7
GTIN:3597133044379
GTIN description: Ypozane 7.5mg Tablets x 7
GTIN:3597133044362
GTIN description: Ypozane 15mg Tablets x 7
GTIN:3597133044355

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