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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

Incorporating:

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

Transient modifications of appetite can be observed, either increased (very common) or decreased (very rare).

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

Other adverse reactions, including transient vomiting and/or diarrhoea, polyuria/polydipsia or lethargy occur uncommonly. Mammary gland hyperplasia occurs uncommonly and can be associated with lactation in very rare cases.

Transient side-effects of changes in the hair coat such as hair loss or hair modification have been seen very rarely following administration of Ypozane.

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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))

- common (more than 1 but less than 10 animals in 100 animals treated)

- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)

- rare (more than 1 but less than 10 animals in 10,000 animals treated)

- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

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
3 to 7.5 kg*	1.875 mg tablet	1 Tablet
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

PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: drugs used in benign prostatic hypertrophy.

ATC vet code: QG04C X

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

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

Lactose monohydrate

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

1.875mg tablets

Vm 05653/5023

3.75mg tablets

Vm 05653/5025

7.5mg tablets

Vm 05653/5026

15mg tablets

Vm 05653/5024

Significant changes

Date of the first authorisation or date of renewal

Date of first authorisation: 11/01/2007

Date of latest renewal: 19/12/2011

Date of revision of the text

31/08/2021

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