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MSD Animal Health UK Limited

Telephone:01908 685685 (Customer Support Centre)

Website:www.msd-animal-health.co.uk

Email:vet-support.uk@msd.com

Zitac® vet 100 mg tablets for dogs
Zitac® vet 200 mg tablets for dogs

Species: Dogs

Therapeutic indication:Pharmaceuticals: Enteric preparations

Active ingredient: Cimetidine

Product: Zitac® vet 100 mg tablets for dogs
Zitac® vet 200 mg tablets for dogs

Product index: Zitac® vet 100 mg and 200 mg tablets

Incorporating:

Qualitative and quantitative composition

Active substance:

Zitac vet 100 mg: cimetidine 100 mg per tablet.

Zitac vet 200 mg: cimetidine 200 mg per tablet.

For the full list of excipients, see section “Pharmaceutical particulars”.

Pharmaceutical form

Tablet, scored on both sides.

Clinical particulars

Target Species

Dogs.

Indications for use

Symptomatic treatment for the reduction of vomiting associated with chronic gastritis in dogs.

Contraindications

None.

Special warnings for each target species

Treatment with cimetidine is symptomatic only and does not result in resolution of histopathological changes associated with gastritis. It is recommended that dogs showing persistent vomiting should undergo appropriate investigations to diagnose the underlying cause before starting treatment. This is especially important in older animals. The reduction of gastric acidity caused by cimetidine may contribute to bacterial overgrowth and antigenic stimulation.

Special precautions for use

In case of renal dysfunction, adjustment of the dose may be required as the clearance of cimetidine may be decreased. If the response to treatment is poor within 15 days, the diagnosis and treatment plan should be reevaluated.

Operator warnings

None.

Adverse Reactions

Dogs:

Very common (>1 animal / 10 animals treated):

Very rare (<1 animal / 10,000 animals treated, including isolated reports):

1 Transient and self-resolving, slight swelling (gynaecomastia); anti-androgenic activity.

2 reversible, with no impact on reproductive performances

Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or the national competent authority via the national reporting system. See the package leaflet for respective contact details.

Use during pregnancy or lactation

The use of the veterinary medicinal product during pregnancy and lactation in the target species has not been investigated. Therefore, use of the veterinary medicinal product during pregnancy and lactation should be based on a risk benefit-assessment by the responsible veterinarian.

Interactions

Due to inhibition of cytochrome P-450 activity by cimetidine, the metabolism and elimination of some drugs can be reduced. Clinically relevant interactions may occur with compounds having a narrow therapeutic index, e.g. beta-blockers, calcium channel blockers, benzodiazepines,

barbiturates, phenytoin, theophylline, aminophylline, warfarin and lidocaine. Doses of such drugs may need to be reduced when administered concomitantly with cimetidine.

The increased gastric pH resulting from cimetidine administration may lead to reduced absorption of drugs requiring an acid medium for absorption. It is recommended that at least 2 hours should elapse between administration of cimetidine and aluminium or magnesium hydroxide, metoclopramide, digoxin or ketoconazole when possible.

Amounts to be administered and administration route

For oral use

Dose and route of administration: 5 mg of cimetidine per kg of bodyweight administered three times daily by the oral route (see respective indicative table below). The concomitant use of appropriate dietary measures is strongly recommended. In clinical trials the efficacy of cimetidine has only been studied concomitantly with a hypoallergenic diet.

Table: Number of Zitac vet 100 mg tablets to be administered three times daily according to body weight.

Weight (kg)	**Number of Zitac vet 100 mg tablets**
6 to 10	½
11 to 20	1

Table: Number of Zitac vet 200 mg tablets to be administered three times daily according to body weight.

Weight (kg)	**Number of Zitac vet 200 mg tablets**
11 to 20	½
21 to 40	1
41 to 60	1 ½

Recommended treatment scheme: reduction of vomiting is achieved in about 2 weeks. Animals should however be treated for at least 2 weeks after the remission of clinical signs, so a minimum treatment duration of 28 days is usually necessary and therefore recommended. If considered successful, medication should be withdrawn for 2 weeks. If vomiting occurs again, treatment can be re-initiated without risk of intolerance.

Depending on the response, treatment can be adapted to the individual animal until the response is considered to be adequate and continued. Dietary measures should always be maintained.

Overdose

Acute exposure to cimetidine yielded LD50 values above 2600 mg/kg, i.e. over 170 times the recommended daily dosage in dogs. A target animal safety study in dogs demonstrated that the

veterinary medicinal product administered orally at 75 mg cimetidine/kg/day (five times the recommended daily dose) for a period of 91 days was well tolerated by dogs.

Withdrawal periods

Not applicable.

Pharmacological particulars

ATCvet Code: QA02BA01

Pharmacodynamic properties

Cimetidine is an antagonist of the histamine H2-receptors present in the gastric parietal cells. Stimulation of H2-receptors by histamine activates gastric acid secretion. Cimetidine, via its antagonistic properties toward histamine H2-receptors, strongly reduces gastric acid secretion. This may result in the diminution of gastric irritation and subsequent vomiting during chronic gastritis. No accompanying improvement in the inflammatory status of the gastric mucosa was observed in dogs.

Pharmacokinetic particulars

After oral administration of the veterinary medicinal product at a dose rate of 5 mg/kg body weight to fasted dogs, maximal plasma levels of approximately 2 µg/ml are reached after 1.5 hours post-administration. Bioavailability is about 95%. The extent of absorption of cimetidine in dogs is delayed and reduced by approximately 40 % in the presence of food (Cmax fasted 2.94 mcg/ml, Cmax fed 1.12 mcg/ml, AUC0-∞ fasted 8.23 mcg.h/ml and AUC0-∞ fed 5.43 mcg.h/ml). However, this does not affect the efficacy of treatment.

The plasma half-life of cimetidine is approximately 2 hours at a dosage of 5 mg/kg. Cimetidine is rapidly and almost completely excreted into the urine. No drug accumulation occurs after repeated oral treatment at 5 mg/kg three times daily over 30 consecutive days.

Pharmaceutical particulars

Excipients

Lactose monohydrate

Microcrystalline cellulose

Maize starch pregelatinised

Sodium starch glycolate type A

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

Store the blisters in the original package to protect from light. Remaining tablet halves should be stored in the original blister pocket in order to protect from light.

Immediate packaging

The tablets are packed in push-through blisters (white opaque PVC/Aluminium foil) in an outer printed carton box.

Authorised pack sizes:

Carton box containing 30 tablets (3 blister with 10 tablets per blister)

Carton box containing 100 tablets (10 blister with 10 tablets per blister)

Not all pack sizes may be marketed.

Disposal

Medicines should not be disposed of via wastewater.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any national collection systems applicable to the veterinary medicinal product concerned.

Marketing Authorisation Holder (if different from distributor)

Intervet International B.V. represented by MSD Animal Health UK Limited.

Marketing Authorisation Number

UK(GB): Vm 06376/5044-5

UK(NI): Vm 06376/3046-7

Significant changes

Date of the first authorisation or date of renewal

22 February 2007

Date of revision of the text

April 2025.

Any other information

For animal treatment only. Keep out of the sight and reach of children.

Legal category

Legal category:POM-V

NOAH Compendium

GTIN

GTIN description: Zitac Vet 100mg 3x10tab:

GTIN:08713184062765

GTIN description: Zitac Vet 200mg 3x10tab:

GTIN:08713184066657