Zitac Vet 100 mg Tablets for Dogs and 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 and Zitac® Vet 200 mg Tablets for Dogs
Product index: Zitac Vet 100 mg and 200 mg Tablets

Presentation

Zitac Vet 100 mg tablets are oblong tablets, scored on both sides, containing cimetidine 100 mg per tablet.

Zitac Vet 200 mg tablets are oblong tablets, scored on both sides, containing cimetidine 200 mg per tablet.

Uses

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

Dosage and administration

Dose and route of administration: 5 mg of cimetidine per kg of bodyweight administered three times daily by the oral route. Tablets may be split to facilitate dosing.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.

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

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 1½

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 recommended. If considered successful, medication should be withdrawn for 2 weeks. If vomiting occurs again, treatment can be re-initiated, without risk for 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.

Contra-indications, warnings, etc

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. If the response to treatment is poor within 15 days, the diagnosis and treatment plan should be re-evaluated. In case of renal dysfunction, adjustment of the dose may be required as the clearance of cimetidine may be decreased. Transient and self-resolving slight swelling of mammary glands may be observed in female dogs (gynaecomastia; anti-androgenic activity). A reduction of prostate weight was also observed in male rats and dogs, with no impact on reproductive performances; this effect was reversible. No other undesirable effects were reported. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon. The use of the 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 veterinary surgeon. 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.

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 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. No signs of overdose are known.

Withdrawal period

Not applicable.

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

Pharmaceutical precautions

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. Do not use after expiry date which is stated on the carton.

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

Legal category

Legal category:POM-V

Packaging quantities

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

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.

Further information

Nil.

Marketing Authorisation Holder (if different from distributor)

Intervet International BV, NL.

Represented by Intervet UK Ltd.

Marketing Authorisation Number

Vm 06376/4056: Zitac Vet 100 mg tablets for dogs

Vm 06376/4057: Zitac Vet 200 mg tablets for dogs

Significant changes

GTIN

GTIN description: Zitac Vet 100mg 3x10tab:
GTIN:08713184062765,
GTIN description: Zitac Vet 200mg 3x10tab:
GTIN:08713184066657

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