

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton Box Zitac vet 200 mg tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zitac vet 200 mg tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Cimetidine 200 mg per tablet.

3. PACKAGE SIZE

30 tablets
100 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use, 5 mg/kg bodyweight three times daily.

7. WITHDRAWAL PERIODS

Withdrawal period:
Not applicable.

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE 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.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use.

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Intervet International B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 06376/5045

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister Zitac vet 200 mg tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zitac vet 200 mg tablets.

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Cimetidine 200 mg per tablet.

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Zitac vet 200 mg tablets for dogs.

2. Composition

Active substance:

Cimetidine 200 mg per tablet

White, oblong tablets, scored on both sides.

3. Target species

Dogs.

4. Indications for use

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

5. Contraindications

None.

6. Special warnings

Special warnings:

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 safe use in the target species:

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 re-evaluated.

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

None.

Pregnancy and 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.

Interaction with other medicinal products and other forms of interaction:

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:

No signs of overdose are known.

7. Adverse events

Dogs:

Very common (>1 animal / 10 animals treated):	Mammary gland swelling ¹
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Prostate weight reduction ²

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 product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system at:

Website: <https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine>

e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

For oral use.

Dose and route of administration: 5 mg of cimetidine per kg of bodyweight

administered three times daily by the oral route. 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 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 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.

9. Advice on correct administration

None.

10. Withdrawal periods

Not applicable

11. Special storage precautions

Keep out of the sight and reach of children.

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.

12. Special precautions for 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 applicable national collection systems. These measures should help to protect the environment.

Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing Authorisation Numbers and pack sizes

Vm 06376/5045

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.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and contact details to report suspected adverse reactions:

Intervet International B.V.
Wim de Körverstraat 35
5831 AN Boxtmeer
Netherlands

Manufacturers responsible for batch release:

Intervet GesmbH
Siemensstrasse 107
1210 Vienna
Austria

Contact details to report suspected adverse reactions.

Tel.: +44 (0)1908 685685

17. Other information

POM-V

Gavin Hall
Approved: 22 April 2025