# I.B.1. PROPOSAL FOR PACKAGING, LABELLING AND PACKAGE LEAFLET

## LABELLING

**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 for dogs
Cimetidine

### 2. STATEMENT OF ACTIVES AND OTHER SUBSTANCES

Cimetidine 200 mg per tablet.

### 3. PHARMACEUTICAL FORM

Tablet.

### 4. PACKAGE SIZE

30 tablets
100 tablets

### 5. TARGET SPECIES

Dogs.

### 6. INDICATION(S)

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

### 7. METHOD AND ROUTE(S) OF ADMINISTRATION

Oral, 5 mg/kg bodyweight three times daily.
Read package leaflet before use

### 8. WITHDRAWAL PERIOD

Not applicable.

### 9. SPECIAL WARNING(S), IF NECESSARY

Read package leaflet before use

## 10. EXPIRY DATE

Exp. (Month / year)

## 11. SPECIAL STORAGE CONDITIONS

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.

## 12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 13. THE WORDS "FOR ANIMAL TREATMENT ONLY", AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only – to be supplied only on veterinary prescriptions.

## 14. THE WORDS "KEEP OUT OF THE REACH AND SIGHT OF CHILDREN"

Keep out of the reach and sight of children.

## 15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
MK7 7AJ

## 16. MARKETING AUTHORISATION NUMBER(S)

Vm 01708/4639

## 17. MANUFACTURER'S BATCH NUMBER

Batch number.

**MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS**

**Blister Zitac vet 200 mg tablets**

## 1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zitac vet 200 mg tablets for dogs.
Cimetidine.

## 2. NAME OF THE MARKETING AUTHORISATION HOLDER

MSD Animal Health UK Limited
(MSD Animal Health company logo)

## 3. EXPIRY DATE

Exp: (Month / year)

## 4. BATCH NUMBER

Batch number.

## 5. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only

# PACKAGE LEAFLET FOR
# Zitac vet 200mg tablets for dogs

## 1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE , IF DIFFERENT

**Marketing authorisation holder:**
MSD Animal Health UK Limited
Walton Manor
Walton
Milton Keynes
Buckinghamshire
MK7 7AJ

**Manufacturer for the batch release:**
Intervet GesmbH
Siemensstrasse 107
1210 Vienna
Austria

## 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Zitac vet 200 mg tablets for dogs.
Cimetidine

## 3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Cimetidine 200 mg per tablet.

## 4. INDICATION(S)

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

## 5. CONTRAINDICATION(S)

None.

## 6. ADVERSE REACTIONS

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.

## 7. TARGET SPECIES

Dogs.

## 8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

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 | 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.

## 9. ADVICE ON CORRECT ADMINISTRATION

None.

## 10. WITHDRAWAL PERIOD

Not applicable.

## 11. SPECIAL STORAGE PRECAUTIONS

Keep out of the reach and sight 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 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.
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.
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 veterinarian.
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.

## 13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIALS, IF ANY

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

## 14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2020

## 15. OTHER INFORMATION

Presentations:
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

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

Approved 17 July 2020