PARTICULARS TO APPEAR ON THE OUTER PACKAGE

{Carton}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Twinox 400 mg/100 mg tablets for dogs
Amoxicillin + clavulanic acid

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each tablets contains:

Active substances

Amoxicillin (as amoxicillin trihydrate)	400 mg
Clavulanic acid (as potassium clavulanate)	100 mg

Excipient

Erythrosine (E127)	0.5 mg

3. PHARMACEUTICAL FORM

Tablet.

4. PACKAGE SIZE

10 tablets
100 tablets.

5. TARGET SPECIES

Dogs.

6. INDICATIONS

Read the package leaflet before use.

7. METHOD AND ROUTES OF ADMINISTRATION

Oral use. Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Not applicable.

9. SPECIAL WARNINGS, IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP:
Shelf-life of halved tablets: 24 hours

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Divided tablets should be returned to the blister, kept within the outer carton.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS 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 prescription.

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

VIRBAC
1ère avenue – 2065 m – L.I.D.
06516 Carros
FRANCE

16. MARKETING AUTHORISATION NUMBERS

17. MANUFACTURER'S BATCH NUMBER

Lot

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

{Blister}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Twinox 400 mg/100 mg tablets for dogs

Amoxicillin + clavulanic acid

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Virbac

3. EXPIRY DATE

EXP

4. BATCH NUMBER

Lot

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

PACKAGE LEAFLET

Twinox 400 mg/100 mg 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 and manufacturer responsible for batch release:

VIRBAC
1ère avenue- 2065 m-L.I.D.
06516 Carros
FRANCE

Manufacturer responsible for batch release:
VMD n.v./s.a.
Hoge Mauw 900
B-2370 Arendonk
BELGIUM

HAUPT PHARMA LATINA s.R.L.
Borgo San Michele S.S. 156KM 47
04100 Latina
ITALY

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Twinox 400 mg/100 mg tablets for dogs
Amoxicillin + clavulanic acid

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

Each tablet contains:

Active substances

Amoxicillin (as amoxicillin trihydrate)	400 mg
Clavulanic acid (as potassium clavulanate)	100 mg

Excipient

Erythrosine (E127)	0.5 mg

Pale pink, rounded, one side scored, uncoated and divisible tablet

4. INDICATIONS

Treatment of infections caused by micro-organisms sensitive to the combination amoxicillin/clavulanic acid, especially:
- dermatitis (superficial and deep pyoderma) caused by *Staphylococcus (pseud)intermedius*.
- urinary tract infections caused by *E. coli* and *Staphylococcus* spp.
- respiratory tract infections caused by *Streptococcus* spp.
- enteritis caused by *E. coli*

5. CONTRAINDICATIONS

- Do not use in animals with known hypersensitivity to penicillin or other substances of the beta-lactam group or to any of the excipients.
- Do not use in case of serious dysfunction of the kidneys accompanied by anuria and oliguria.
- Do not use in rabbits, guinea pigs, hamsters, chinchillas or gerbils

6. ADVERSE REACTIONS

- Dose independent allergic reactions may occur, such as skin reactions or anaphylaxis. In those cases the treatment must be stopped immediately and a symptomatic treatment should be given.
- Gastro-intestinal disturbances (diarrhoea, vomiting, …) may occur after administration of the product.

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, ROUTES AND METHOD OF ADMINISTRATION

Oral use.

Amounts to be administered:
The recommended dose rate is 10 mg amoxicillin / 2.5 mg clavulanic acid per kg bodyweight (= 12.5 mg of combined active substances) twice a day by the oral route in dogs, i.e. 1 tablet per 40 kg body weight every 12 h.

Body weight (kg)	**Number of tablets (twice daily)**
< 30	Use 40 mg/10 mg tablets or 200 mg/50 mg tablets
(30.1 – 40.0)	1
(40.1 – 60.0)	1 ½
(60.1 – 80.0)	2

In case of complicated infections, especially respiratory infections, a better cure rate is obtained with a double dose, up to 25 mg of the combination of the active substances per kg weight, twice daily.

Treatment duration:
In the majority of cases, a treatment of 5 to 7 days is sufficient.
For chronic and refractory infections, longer courses of antibacterial therapy may be required.
Treatment length should be adapted by the veterinarian, and should be long enough to ensure complete bacteriological cure.

.9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, body weight should be determined as accurately as possible to avoid under-dosing

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children
Do not store above 25°C.
Do not use this veterinary medicinal product after the expiry date which is stated on the blister and the carton.
The expiry date refers to the last day of the month.
Divided tablets should be returned to the blister, kept within the outer carton. Any divided tablet portion remaining after 24 hours should be discarded

12. SPECIAL WARNINGS

Special precautions for use in animals
- Do not use in known cases of resistance to the combination.
- Official, national and regional antimicrobial policies with respect to the use of broad-spectrum antibiotics should be taken into account.
- Do not use in known cases of bacteria sensitive to narrow spectrum penicillins or to amoxicillin as a single substance.
- Due to likely variability (time geographical) in the occurrence of resistance of bacteria for the combination amoxicillin / clavulanic acid, bacteriological sampling and susceptibility testing are recommended
- Use of the product deviating from the instructions given in this leaflet may increase the prevalence of bacteria resistant to the amoxicillin/clavulanate, and may decrease the effectiveness of treatment with β-lactam antibiotics
- In animals with hepatic and renal failure, the dosing regimen should be carefully evaluated.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
Penicillins and cephalosporins may cause hypersensitivity reactions (allergy) following injection, inhalation, ingestion or skin contact. Hypersensitivity to penicillins may lead to cross-reactions to cephalosporins and vice versa.
Allergic reactions to these substances may occasionally be serious.
- Do not handle this product if you know you are sensitised, or if have been advised not to work with such preparations.
- Handle this product with great care to avoid exposure, taking all recommended precautions.
- If you develop symptoms following exposure such as a skin rash, seek medical advice immediately and show the package leaflet or the label to the physician. Swelling of the face, lips or eyes or difficulty with breathing are more serious symptoms and require urgent medical attention.
- Wash hands after use.

Pregnancy or lactation
Laboratory studies in rats and mice have not produced any evidence of teratogenic or foetotoxic effects. No studies have been conducted in pregnant or lactating dogs. Use only according to the benefit/risk assessment by the responsible veterinarian.

Interactions with other medicinal products or other forms of interaction
Chloramphenicol, macrolides, sulfonamides, and tetracyclines may inhibit the antibacterial effects of penicillins.
The potential for allergic cross-reactivity with other penicillins should be considered.
Penicillins may increase the effect of aminoglycosides.

Overdose (symptoms, emergency procedure, antidotes)
Mild gastrointestinal symptoms (diarrhoea, vomiting) may occur more frequently after overdose of the product

Incompatibilities
Not applicable

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

XXXXX

15. OTHER INFORMATION

Delivery: veterinary prescription only.

Pack sizes: 10 or 100 tablets.
Not all pack sizes may be marketed.