PARTICULARS TO APPEAR ON THE OUTER PACKAGE

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinagel-Vet, Gentamicin 0.30% w/w Eye Gel

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Gentamicin 3 mg (as gentamicin sulphate) Benzalkonioum chloride 0.1 mg per g.

3. PHARMACEUTICAL FORM

Eye Gel

4. PACKAGE SIZE

4 g

5. TARGET SPECIES

Dogs and cats

6. INDICATION(S)

Treatment of bacterial eye infections sensitive to gentamicin in dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For external use only

See package leaflet for directions of use.

8. WITHDRAWAL PERIOD

N/A

9. SPECIAL WARNING(S), IF NECESSARY

User warnings – see package leaflet

Care should be taken to avoid contamination of content during use. Replace cap between applications. Do not use in animals hypersensitive to any of the components.

10. EXPIRY DATE

Do not use after the stated expiry date.

Discard product one month after first opening.

11. SPECIAL STORAGE CONDITIONS

Keep tube in the outer carton.

Do not store above 25ºC

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal – see package leaflet

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE *[Distribution category]*

POM-V

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 REACH OF CHILDREN

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Ecuphar n.v/s.a Legeweg 157-I, B-8020 Oostkamp, Belgium.

16. MARKETING AUTHORISATION NUMBER

Vm 32742/4000

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS {tube label}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinagel-Vet, Gentamicin 0.30% w/w Eye Gel

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

Gentamicin 3 mg (as gentamicin sulphate) Benzalkonioum chloride 0.1 mg per g.

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

4g

4. ROUTE(S) OF ADMINISTRATION

5. WITHDRAWAL PERIOD

6. BATCH NUMBER

7. EXPIRY DATE

8. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only. For external use only. Treatment of eye infections

Keep tube in the outer carton. Do not store above 25^{o}C

Keep out of reach of children

For full instructions and warnings: see leaflet

Vm 32742/4000

PACKAGE LEAFLET FOR:

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

Marketing Authorisation Holder:
Ecuphar n.v./s.a.
Legeweg 157 –I
B-8020 Oostkamp
Belgium.

Manufacturer for the Batch release:
BePharBel Manufacturing NV/SA
13 Rue du Luxembourg
6180 Courcelles
Belgium

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Clinagel-Vet, Gentamicin 0.30% w/w Eye Gel

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

Clinagel-Vet contains gentamicin 3 mg (as gentamicin sulphate) per g of gel. It also contains Benzalkonioum chloride 0.1 mg/g as antimicrobial preservative.

4. INDICATION(S)

Clinagel-Vet is indicated for the treatment of infections of the external structures of the eyes and the eyelids caused by bacteria which are sensitive to gentamicin in dogs and cats.

Clinagel-Vet is indicated for the treatment of superficial eye infections caused by bacteria which are sensitive to gentamicin. These infections include:

Bacterial conjunctivitis, Ulcers and abscesses of the cornea, infectious complications caused by corneal or conjunctival foreign bodies, infections associated with physical or chemical trauma.

5. CONTRAINDICATIONS

Hypersensitivity to any components

6. ADVERSE REACTIONS

Local intolerance has not been reported, however benzalkonium chloride can cause allergic reactions. In case of allergic reaction it is recommended to stop the treatment immediately.

7. TARGET SPECIES

Dogs and cats

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

Administer in small amounts (± 1 cm strip) two or three times a day, in the conjunctival sac of the lower eye lid. The duration of the treatment is one to several weeks, depending on the nature and the gravity of the infection. For use under veterinary supervision only. Long-term topical treatment can cause emergence of resistance and re-examination should be performed at intervals. Due to likely variability (time, geographical) in the occurrence of resistance of bacteria for Gentamicin sulphate, bacteriological sampling and susceptibility testing are recommended.

9. ADVICE ON CORRECT ADMINISTRATION

Topical administration in the eye, avoiding contact between the tube and the eye. For external use only.

Pictograms for instructions for use

10. WITHDRAWAL PERIOD(S)

Not applicable

11. SPECIAL STORAGE PRECAUTIONS

Keep tube in outer carton. Do not store above 25 °C. Care should be taken to avoid contamination of content during use. Replace cap between applications. Any contents remaining one month after the date on which the container was first opened should be discarded.

When the container is broached (opened) for the first time, using the in-use shelf-life which is specified on this package leaflet, the date on which any product remaining in the container should be discarded should be determined. This discard date should be written in the space provided.

Keep out of reach of children.

12. SPECIAL WARNING(S)

People with known allergy (hypersensitivity) to aminoglycosides should avoid contact with this product.

Wash hands after use.

For Animal Treatment Only

Do not use concurrently with other antimicrobial ophthalmic products.

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

Dispose of unused packaging in the household refuse. Unused product should be returned to the veterinary surgeon.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

July 2019

15. OTHER INFORMATION

POM – V To be supplied only on veterinary prescription

Vm 32742/4000

Approved: 12 July 2019