PARTICULARS TO APPEAR ON THE OUTER PACKAGE/IMMEDIATE PACKAGE

CARTON BOX/LABEL

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equigent 100 mg/ml Solution for Injection for horses
Gentamicin

2. STATEMENT OF ACTIVE SUBSTANCES

Each ml contains 100 mg of Gentamicin (as gentamicin sulfate)

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml
250 ml

5. TARGET SPECIES

Horses (non-food producing horses).

6. INDICATION(S)

Read the package leaflet before use.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Slow intravenous use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Withdrawal period:
Not authorised for use in horses producing meat or milk for human consumption

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Once opened use by:

11. SPECIAL STORAGE CONDITIONS

Keep the vial in the outer carton, in order to protect from light.

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

Read the package leaflet before use

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

Chanelle Pharmaceuticals Manufacturing Ltd.
Dublin Road, Loughrea
Co. Galway
Ireland

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08749/4087

17. MANUFACTURER'S BATCH NUMBER

BN {number}

PACKAGE LEAFLET FOR:
Equigent 100 mg/ml Solution for Injection for horses

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

Marketing authorisation holder :
Chanelle Pharmaceuticals Manufacturing Ltd.,
Dublin Road, Loughrea,
Co. Galway,
Ireland.

Manufacturer responsible for batch release
Chanelle Pharmaceuticals Manufacturing Ltd.,
Dublin Road, Loughrea,
Co. Galway,
Ireland

and

Labiana Life Sciences, S.A.
C/ Venus,
26, Pol. Ind. Can Parellada,
Tarrasa, 08228 Barcelona,
Spain

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Equigent 100 mg/ml Solution for Injection for horses
Gentamicin

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

Each ml contains:

Gentamicin (as gentamicin sulfate)	100 mg
Sodium Metabisulphite	1.0 mg
Sodium Methyl parahydroxybenzoate (E219)	0.9 mg
Sodium Propyl parahydroxybenzoate (E217)	0.1 mg

A clear and colourless to slightly yellow solution, free from particles.

4. INDICATION(S)

For the treatment of infections of the lower respiratory tract in horses caused by aerobic Gram-negative bacteria susceptible to gentamicin.

5. CONTRAINDICATIONS

Do not use in known cases of renal dysfunction.
Do not use in cases of known hypersensitivity to the active substance or to any of the excipients.
Do not exceed the proposed dosing regimen.

6. ADVERSE REACTIONS

A local reaction may occur at the injection site, especially in case of repeated injections in adjacent sites.
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 inform your veterinary surgeon.

7. TARGET SPECIES

Horses (non-food producing horses).

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

Administer by slow intravenous injection. Single dose of 6.6 mg gentamicin/kg body weight (equivalent to 0.066 ml/kg b.w. of the product) given intravenously once daily for 3–5 consecutive days.
The use of gentamicin in foals and neonates is not recommended.

9. ADVICE ON CORRECT ADMINISTRATION

To ensure a correct dosage, bodyweight should be determined as accurately as possible to avoid under- or over-dosing. The dosing regimen must not be exceeded.

10. WITHDRAWAL PERIOD

Not authorised for use in horses producing meat or milk for human consumption

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Keep the vial in the outer carton, in order to protect from light.
Shelf life after first opening the container: 28 days
Do not use after the expiry date (EXP) stated on the carton and vial.

12. SPECIAL WARNING(S)

Special warnings for use in animals
Gentamicin is well known to induce nephrotoxicity even at therapeutic doses in horses. There are also isolated reports of ototoxicity with gentamicin. No margin of safety has been established under the approved dosing regimen. As such, gentamicin has a narrow margin of safety. The product should therefore only be used based on the benefit-risk assessment by the responsible veterinary surgeon for each individual horse, taking into account alternative available treatment.
In order to reduce the nephrotoxic risk, adequate hydration of animals under treatment should be ensured, and fluid therapy should be instituted, if required.
Close monitoring of horses being treated with gentamicin is strongly advised. This monitoring includes assessing relevant kidney parameters in blood (e.g. creatinine and urea) and urinalysis (e.g. gamma glutamyl transferase/creatinine ratio). Therapeutic blood monitoring of gentamicin concentration is also recommended because of known individual animal variations in peak and trough gentamicin plasma concentrations. Where blood monitoring is available, target peak plasma gentamicin concentrations should be approximately 16–20 µg/ml.
Particular caution should be taken when administering gentamicin with other potential nephrotoxic medicinal products (containing e.g. NSAIDs, furosemide, and other aminoglycosides).
Safety of gentamicin has not been established in foals and there is a lack of knowledge of the extra effects of gentamicin on foal kidneys, especially neonates. Current knowledge suggests that foals, especially neonates, are at a higher risk of gentamicin-induced nephrotoxicity compared to adults.
Differences between neonatal foal kidneys and adults include a slower clearance of gentamicin in foals.
As such, no margin of safety has been established in neonatal foals. It is therefore not recommended to use the product in foals.
Whenever possible, use of the product should be based on susceptibility testing of the bacteria isolated from the animal. Gentamicin is a narrow-spectrum Gram-negative bactericidal antimicrobial, without effects on anaerobe bacteria and mycoplasmas. Gentamicin does not penetrate intracellularly, or into abscesses. Gentamicin is de-activated in the presence of inflammatory debris, low oxygen environments and low pH.
The dosing regimen must not be exceeded. Use of the product deviating from the instructions given in the SPC increases the risk of nephrotoxicity, and may increase the prevalence of bacteria resistant to gentamicin.
Extra caution is advised if using gentamicin in old horses, or with fever, endotoxemia, sepsis and dehydration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Gentamicin may cause hypersensitivity (allergic) reactions following exposure. People with known hypersensitivity to gentamicin should avoid contact with the product. Administer the product with caution.
In case of accidental self-injection, seek medical advice immediately and show this package leaflet or the label to the physician.

Pregnancy and lactation:
The safety in pregnant horses is unknown. However, studies in laboratory animals have shown evidence of foetal nephrotoxicity. Use only based on the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction:
This product should not be used in conjunction with other aminoglycoside antibiotics, or with other drugs known to induce either ototoxicity or nephrotoxicity.

Overdose (symptoms, emergency procedures, antidotes):
The product was not specifically tested in overdose studies and therefore, no margin of safety has been determined.

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

Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

To be supplied only on veterinary prescription.
Cardboard box containing one colourless glass injection vial of 100 ml or 250 ml.
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 04 May 2023