PARTICULARS TO APPEAR ON <THE OUTER PACKAGE> <AND> <THE IMMEDIATE PACKAGE> {NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium calciumedetate 250mg/ml Concentrate for solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sodium calciumedetate Anhydrous 250mg/ml added as Sodium Calciumedetate for dilution.

3. PHARMACEUTICAL FORM

4. PACKAGE SIZE

100ml

5. TARGET SPECIES

Cattle and dogs.

6. INDICATION(S)

Use in the treatment of lead poisoning for cattle and dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dose: Dilute immediately before use with sufficient Sodium Chloride intravenous infusion to give a 50mg/ml solution of Sodium Calciumedetate e.g 1ml of Sodium Calciumedetate injection + 4ml Diluent.

Cattle: 75mg/Kg bodyweight- see package leaflet for withdrawal periods

Dogs: 75mg/kg body weight; total daily dose for dogs not more than 2000mg.

Give by slow intravenous (i.v.) injection. Administer in 4 equally divided doses per day i.e every 6 hours, for 2-5 days. Repeat after two or three days as necessary, if signs of lead poisoning are still present.

8. WITHDRAWAL PERIOD

See package leaflet for withdrawal periods.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindication, warnings etc: See package leaflet for the effects (Kidney nephrosis) of overdosage or too rapid administration. See package leaflet for operator warnings. Further information on dosage, precautions and Disposal advice is included in the package leaflet.

Take adequate precautions to maintain sterility. This product does not contain an anti-microbial preservative. Dilute immediately prior to use. Any unused product should be discarded.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C.

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

Any solution remaining in the vial following withdrawal of the required dose should be discarded.

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

To be supplied only on veterinary prescription.

For animal treatment only.

POM-V

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

Keep all medicines out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Animalcare Ltd, York, YO26 6RB, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10347/4011

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE CARTON

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium calciumedetate 250mg/ml Concentrate for solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Sodium calciumedetate Anhydrous 250mg/ml added as Sodium Calciumedetate for dilution.

3. PHARMACEUTICAL FORM

Concentrate for solution for Injection

PACKAGE SIZE

100ml

5. TARGET SPECIES

Cattle and dogs.

6. INDICATION(S)

Use in the treatment of lead poisoning for cattle and dogs.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Dilute immediately before use with sufficient Sodium Chloride intravenous infusion to give a 50mg/ml solution of Sodium Calciumedetate e.g 1ml of Sodium Calciumedetate injection + 4ml Diluent.

Cattle: 75mg/Kg bodyweight- see package leaflet for withdrawal periods

Dogs: 75mg/kg body weight; total daily dose for dogs not more than 2000mg.

Give by slow intravenous (i.v.) injection. Administer in 4 equally divided doses per dayi.e every 6 hours, for 2-5 days. Repeat after two or three days as necessary, if signs of lead poisoning are still present.

8. WITHDRAWAL PERIOD

Cattle (meat): Cattle should not be slaughtered for human consumption until 3 months have elapsed from the removal of the source of poisoning and the clinical recovery of the animal is achieved.

Cattle (Milk): Milk should be discarded until after milk lead levels on 2 successive days have been determined and have been found to be below 0.02ppm (i.e. below 20µg/l) Bulk milk lead levels may be determined in outbreaks of lead poisoning in herds.

9. SPECIAL WARNING(S), IF NECESSARY

Contraindication, warnings etc: See package leaflet for the effects (Kidney nephrosis) of overdosage or too rapid administration.

Operator warnings:

If accidentally injected to humans, obtain medical help promptly and show the doctor this warning.

Advice to doctor
As excretion is predominantly renal, an adequate urinary flow must be established and maintained. Monitoring of proteinuria and haematuria, and of renal function is advisable. Monitoring of zinc levels may also be required as Sodium Calciumedetate can chelate with several endogenous metals.

Wash hands after use.

Further information on Dosage, Precautions and Disposal advice is included on the package leaflet.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C.

Take adequate precautions to maintain sterility. This product does not contain an anti-microbial preservative. Dilute immediately prior to use. Any unused product should be discarded.

Keep container in outer carton.

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

Any solution remaining in the vial following withdrawal of the required dose should be discarded.

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

To be supplied only on veterinary prescription.

For animal treatment only.

POM-V

UK authorised veterinary medicinal product.

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

Keep all medicines out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Animalcare Ltd, 10 Great North Way, York, YO26 6RB, UK

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10347/4011

ML 1738/1

17. MANUFACTURER'S BATCH NUMBER

PACKAGE LEAFLET FOR: sodium calciumedetate 250mg/ml Concentrate for Solution for Injection

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

Animalcare Ltd, 10 Great North Way, York, YO26 6RB, UK

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Sodium calciumedetate 250mg/ml Concentrate for Solution for Injection

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

Presentation: A strong sterile solution for injection which must be diluted prior to use. With active ingredient: Sodium Calciumedetate Anhydrous 250mg/ml added as Sodium Calciumedetate.

4. INDICATION(S)

For use in the treatment of lead poisoning, for cattle and dogs.

5. CONTRAINDICATIONS

Contra-indications, Warnings etc: If the product is used in the treatment of any food producing species other than cattle, such animals MUST not enter the food chain. Do not administer more than 2000mg per day to dogs.

6. ADVERSE REACTIONS

General Precautions:

The kidneys of animals with high lead burdens may become overloaded when Sodium Calciumedetate is given, especially if the chelator is administered too rapidly, with resulting adverse reactions or occasional deaths. Overdosage may result in temporary nephrosis. Other antidotes may be employed, and supportive measures may be required. The source of lead causing the poisoning should be identified and removed from the animal’s environment.

7. TARGET SPECIES

Cattle and dogs

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

Dilute immediately before use with sufficient Sodium Chloride Intravenous Infusion BP or Glucose Intravenous Infusion BP to give a 50mg/ml solution of Sodium Calciumedetate, e.g. 1ml Sodium Calciumedetate injection + 4ml diluent.

Cattle: 75mg/kg bodyweight - See Withdrawal Periods.

Dogs: 75mg/kg bodyweight; total daily dose for dogs, not more than 2000mg.

Give by slow intravenous (i.v.) injection. Administer in 4 equally divided doses per day, i.e. every 6 hours, for 2-5 days. Repeat the treatment course after two or three days rest, as necessary, if signs of lead poisoning are still present.

Ensure the animal has unrestricted access to non-contaminated drinking water.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Cattle (meat): Cattle should not be slaughtered for human consumption until 3 months have elapsed from the removal of the source of poisoning and the clinical recovery of the animal is achieved.

Cattle (Milk): Milk should be discarded until after milk lead levels on 2 successive days have been determined and have been found to be below 0.02ppm (i.e. below 20µg/l) Bulk milk lead levels may be determined in outbreaks of lead poisoning in herds.

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25^{o}C. Take adequate precautions to maintain sterility. This product does not contain an antimicrobial preservative. Dilute immediately prior to use. Any unused product should be discarded. Any solution remaining in the vial following withdrawal of the required dose should be discarded. Keep container in outer carton.

12. SPECIAL WARNING(S)

Operator warnings:

If accidentally injected to humans, obtain medical help promptly and show the doctor this warning.

Advice to doctor
As excretion is predominantly renal, an adequate urinary flow must be established and maintained. Monitoring of proteinuria and haematuria, and of renal function is advisable. Monitoring of zinc levels may also be required as Sodium Calciumedetate can chelate with several endogenous metals.

Wash hands after use.

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

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

Date of preparation: July 2008

15. OTHER INFORMATION

Further information: Sodium Calciumedetate acts as a chelating substance enabling lead to be mobilised and excreted, mainly through the kidneys. It may be effective for some other heavy metals such as cadmium, but it is unsuitable for the treatment of arsenic, mercury or thallium poisoning.

Package Quantities: 100ml glass vial

Legal Category: POM-V

To be supplied only on veterinary prescription

UK authorised veterinary medicinal product

Marketing Authorisation Number: 10347/4011

Manufacturers Licence Number: 17381/1

Keep all medicines out of the reach of children.

For animal treatment only.

Approved: 16/08/2017