PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{label }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atrocare 600µg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Atropine Sulphate 600 µg/ml.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

25ml

5. TARGET SPECIES

Horses, dogs and cats

6. INDICATION(S)

Use: As a parasympathalytic and as a partial antidote to organophosphorus poisoning for use in horses, dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See enclosed leaflet

8. WITHDRAWAL PERIOD

9. SPECIAL WARNING(S), IF NECESSARY

See enclosed leaflet.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25^{o}C. Protect from light. Keep vial in outer carton.

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

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

For animal treatment only.

To be supplied only on veterinary prescription.

POM-V

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

Keep out of the reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Animalcare Ltd, York, YO26 6RB

16. MARKETING AUTHORISATION NUMBER(S)

Vm 10347/4016

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE

{Carton }

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Atrocare 600µg/ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Atropine Sulphate 600 µg/ml.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

25ml

5. TARGET SPECIES

Horses, dogs and cats

6. INDICATION(S)

Use: As a parasympathalytic and as a partial antidote to organophosphorus poisoning for use in horses, dogs and cats.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See enclosed leaflet

8. WITHDRAWAL PERIOD

Meat withdrawal:

Not to be used in horses and ponies intended for human consumption. Treated horses may never be slaughtered for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation.

9. SPECIAL WARNING(S), IF NECESSARY

User warnings: Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice immediately and show the doctor the label. Wash hands after use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Do not store above 25ºC. Protect from light.

This product does not contain any antimicrobial preservative.

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

Disposal advice: Dispose of any unused product and empty containers in accordance with guidance form your local waste regulation authority.

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

For animal treatment only.

To be supplied only on veterinary prescription.

POM-V

Keep vial in outer carton.

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

Keep out of the reach 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 10347/4016

ML 123/1

17. MANUFACTURER'S BATCH NUMBER

[Include information under these headings as it appears in the SPC]

PACKAGE LEAFLET FOR:

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

Atrocare 600µg/ml Solution for Injection

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

Presentataion: A sterile, clear solution, with active ingredient:

Altropine Sulphate 600µg/ml

4. INDICATION(S)

Uses: As a parasympatholytic. As a partial antidote to organophosphorous poisoning

5. CONTRAINDICATIONS

Not to be used in horses and ponies intended for human consumption.

Treated horses may never be slaughtered for human consumption.

The horse must have been declared as not intended for human consumption under national horse passport legislation.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Horses, Dogs and Cats

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

Dosage and administration

As a parasympatholytic by subcutaneous injection:

Horses	400kg	20-40 ml	(30-60 µg/kg)
Dogs	10kg	0.5-0.8 ml	(30-50 µg/kg)
Cats	4 kg	0.2-0.3 ml	(30-50 µg/kg)

As a partial antidote to organophosphorous poisoning:

Severe cases:
A partial dose (a quarter) may be given by intramuscular or slow intravenous

injection and the remainder given by subcutaneous injection.
Less severe cases:
The whole dose is given by subcutaneous injection.

All species:

25 to 200 µg/kg body weight repeated until clinical signs of poisoning are relieved. Several sequential injections may be required, depending on the severity of the poisoning. The frequency of the dose administered should be such that the recurrence of moderate or severe signs of poisoning are treated, typically at 3 to 4 hour intervals.
Atropine is only effective several minutes after administration and maximum effect may be delayed to some 5 to 10 minutes after injection.
Atropinisation of the patient should be carefully monitored by clinical observation.
Other antidotes may also be employed.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Pharmaceutical precautions: Do not store above 25^{o}C. Protect from light. This product does not contain any antimicrobial preservative. Any solution remaining in the vial after withdrawal of the required dose should be discarded. For animal treatment only. Keep out of reach of children. Keep vial in outer carton.

12. SPECIAL WARNING(S)

User warnings: Care should be taken to avoid accidental self-injection. If accidental self-injection occurs, seek medical advice immediately and show the doctor the label. Wash hands after use.

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

Disposal: 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

Legal Category: POM-V

To be supplied only on veterinary prescription.

UK Authorised veterinary medical product

Package quantities: 25ml glass vial

Further Information: Nil

Marketing authorisation number: Vm 10347/4016

Manufacturers licence number: 123/1

Approved: 11/08/2017