PARTICULARS TO APPEAR ON THE OUTER PACKAGE - CARTON DOLETHAL 200MG/ML SOLUTION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolethal 200mg/ ml SOLUTION FOR INJECTION

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Pentobarbital sodium .....….200.00mg
Benzyl alcohol (preservative) 10.40mg
Ponceau 4R (E124).....0.01mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100ml vial
250ml vial

5. TARGET SPECIES

Small animals and cattle.

6. INDICATION(S)

For euthanasia of small animals (mainly dogs and cats) and cattle.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

0.7ml per kg bodyweight by rapid intravenous injection.
Any volume administered outside the vein will reduce the efficacy of the dose.

8. WITHDRAWAL PERIOD

Not to be used in animals intended for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Not to be used in animals intended for human or animal consumption.
Do not use for anaesthesia.
For further information, see package leaflet.

User information:
In the case of accidental self-administration, by injection, ingestion or skin absorption, seek URGENT medical attention, advising medical service of barbiturate poisoning.
In the event of an accident the following action should be taken:
Skin-Wash immediately with water and then thoroughly with soap and water.
Eyes- Wash immediately with cold water and obtain medical attention.
Ingestion- Obtain medical attention immediately. Wash
out mouth. Keep warm and rest.
Accidental self-injection- Obtain URGENT medical attention, advising medical services of barbiturate poisoning. Do not leave patient unattended.
Advice to Doctor- Maintain airways and give symptomatic and supportive treatment.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

PROTECT FROM LIGHT.

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

Following withdrawal of the first dose use within 3 months.
Destroy any unused product in accordance with the Misuse of Drugs Regulations (2001). Dispose of any part-used and empty containers in accordance with guidance from 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

CD (Sch. 3)

UK AUTHORISED PRODUCT

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4034

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE - LABEL
DOLETHAL 200MG/ML SOLUTION FOR INJECTION

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolethal 200mg/ ml Solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains:
Pentobarbital sodium ..... 200.00 mg
Benzyl alcohol (preservative) .....10.40 mg
Ponceau 4R (E124) 0.01mg

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100ml vial.
250ml vial.

5. TARGET SPECIES

Small animals and cattle.

6. INDICATIONS

For euthanasia of small animals (mainly dogs and cats) and cattle.

7. METHOD AND ROUTE OF ADMINISTRATION

0.7 ml per kg bodyweight by rapid intravenous injection.
Any volume administered outside the vein will reduce the efficacy of the dose.

8. WITHDRAWAL PERIOD

Not to be used in animals intended for human consumption.

9. SPECIAL WARNINGS, IF NECESSARY

Not to be used in animals intended for human or animal consumption. Do not use for anaesthesia.

For further information, see package leaflet.
For full user warnings see package leaflet.

10. EXPIRY DATE

Exp:
Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

PROTECT FROM LIGHT. KEEP CONTAINER IN OUTER CARTON.

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

Following withdrawal of the first dose use within 3 months.
Destroy any unused product in accordance with the Misuse of Drugs Regulations (2001). Dispose of any part-used and empty containers in accordance with guidance from your local waste regulation authority.

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.

POM-V

CD (Sch. 3)

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

Keep out of reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

16. MARKETING AUTHORISATION NUMBER

Vm 08007/4034

17. MANUFACTURER'S BATCH NUMBER

Lot:

PACKAGE LEAFLET FOR:

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

Vetoquinol UK Limited
Steadings Barn
Pury Hill Business Park
Nr. Alderton
Towcester
Northamptonshire
NN12 7LS

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolethal 200mg/ml solution for injection

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

	Per ml
Pentobarbital sodium	200.00 mg
Other constituents include:	
Benzyl alcohol	10.40 mg
Ponceau 4R (E124)	0.01 mg

4. INDICATION(S)

For euthanasia of small animals (mainly dogs and cats) and cattle.

5. CONTRAINDICATIONS

Not to be used in animals intended for human consumption. Do not use for anaesthesia.

Overdose:
In the event of accidental administration to an animal not presented for euthanasia, measures such as artificial respiration, administration of oxygen and the use of analeptics are appropriate.

6. ADVERSE REACTIONS

Interaction with other medicinal products and other forms of interaction

The effects of the product are increased by concomitant administration of sedatives (xylazine or acepromazine).

7. TARGET SPECIES

Small animals and cattle.

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

0.7ml per kg bodyweight by rapid intravenous injection. The product is not intended for dilution with water or any other fluid.

9. ADVICE ON CORRECT ADMINISTRATION

10. WITHDRAWAL PERIOD(S)

Not to be used in animals intended for human consumption.

11. SPECIAL STORAGE PRECAUTIONS

The product solution is not intended for dilution with water or any other fluid. Protect from light.
Following withdrawal of the first dose use within 3 months. Discard any unused materials.

Shelf life of the veterinary medicinal product as packaged for sale: 3 years.
Shelf life after opening the immediate packaging: 3 months.

12. SPECIAL WARNING(S)

Special precautions for use in animals :
Select the needle gauge based on the species and size of animal and check that the syringe and needle are mounted and secured correctly. It is important to ensure that any pressure created during delivery does not lead to the needle disconnecting from the syringe. The amount of the drug to be administered may mean that a smaller gauge needle may not deliver the necessary volume at an appropriate speed. Any volume administered outside the vein will reduce the efficacy of the dose.

Special precautions to be taken by the person administering the veterinary medicinal product to animals :
Care should be taken to ensure the pressure on the syringe is not too great to avoid accidental spraying of the face and eyes (see 'Special precautions for use in animals').
Wear suitable protective gloves and glasses when handling the product. Avoid accidental self- administration and self-injection.

In the case of accidental self-administration, by injection, ingestion or skin absorption, seek URGENT medical attention, advising medical service of barbiturate poisoning.
In the event of an accident the following action should be taken:
Skin-Wash immediately with water and then thoroughly with soap and water. Eyes- Wash immediately with cold water and obtain medical attention.
Ingestion- Obtain medical attention immediately. Wash out mouth. Keep warm and rest.

Accidental self-injection- Obtain URGENT medical attention, advising medical services of barbiturate poisoning. Do not leave patient unattended.
Advice to Doctor- Maintain airways and give symptomatic and supportive treatment.

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

Any unused product must be destroyed in accordance with the Misuse of Drugs Regulations (2001). Any waste materials should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

September 2022

15. OTHER INFORMATION

Vm 08007/4034
Conditions of supply:
To be supplied only on veterinary prescription

POM-V CD (Sch. 3)

Keep out of reach of children
For animal treatment only

Carton containing colourless multidose glass bottles containing 100 or 250 ml non-sterile aqueous solution. Not all pack sizes may be marketed.

PHARMACEUTICAL FORM:

Solution for injection, in the form of a pink liquid

PHARMACOLOGICAL PROPERTIES

The active ingredient in Dolethal is pentobarbital, which is a barbiturate.
Barbiturates act by depressing the central nervous system, inhibiting accumulation of calcium in nervous tissue, which leads to liberation of norepinephrine, acetylcholine, glutamate and gamma-aminobutyric acid. This leads to sedation and coma.
Barbiturates also act on cardiac and respiratory systems bringing on apnoea and cardiac arrest.

Approved 18 November 2022