PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthatal 200 mg in 1 ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 200 mg of the active substance, Pentobarbital Sodium, and 0.01 mg of the colourant, Patent Blue (E131).

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

Dogs, Cats and other small animals

6. INDICATION(S)

Solution for euthanasia of dogs, cats and other small animals by i.v. injection.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See accompanying directions.

8. WITHDRAWAL PERIOD

Not for use in animals intended for human or animal consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Not to be used for anaesthesia.

For use in euthanasia only.

The product does not contain a preservative.

This product is not sterile.

Operator Warning:-
Read package leaflet before use.

10. EXPIRY DATE

11. SPECIAL STORAGE CONDITIONS

Protect from light. Do not store above 25°C.

Following withdrawal of the first dose, use the product within 28 days. Not to be diluted with water or any other liquid.

Discard unused material. Avoid the introduction of contamination during use.

Should any apparent growth or discolouration occur, discard the product. Discard if any sediment is observed.

Once broached discard by:

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

Dispose of empty containers and carcasses in accordance with guidance from your local waste regulation authority in the UK.

Dispose of any unused product in accordance with the Misuse of Drugs Regulations 2001 (UK).

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

UK POM-V CD (Sch 3) Prescription Only Medicine – Veterinarian

Vm 28365/4015
To be supplied only on veterinary prescription

Veterinary medicinal product authorised for use in UK and IE.

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 28365/4015

17. MANUFACTURER'S BATCH NUMBER

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (BOTTLE LABEL)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthatal 200 mg in 1 ml Solution for Injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Each ml contains 200 mg of the active substance, Pentobarbital Sodium, and 0.01 mg of the colourant, Patent Blue.

Contains Patent Blue (E131) 0.01mg/ml.

3. PHARMACEUTICAL FORM

Solution for Injection

4. PACKAGE SIZE

100ML

5. TARGET SPECIES

Dogs, cats and other small animals

6. INDICATION(S)

Solution for Euthanasia of dogs, cats and other small animals by i.v injection.

7. METHOD AND ROUTE(S) OF ADMINISTRATION

See accompanying directions.

8. WITHDRAWAL PERIOD

Not for use in animals intended for human or animal consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Operator Warnings: Read package leaflet before use.
Not to be used for anaesthesia.

10. EXPIRY DATE

Expiry:

11. SPECIAL STORAGE CONDITIONS

Keep container in the outer carton.

Protect from light. Do not store above 25°C.

Avoid the introduction of contamination during use.

The product does not contain a preservative.

This product is not sterile. Discard if any sediment is observed. Do not dilute with water or any other fluid.

Following withdrawal of the first dose, use this product within 28 days. Discard unused material.

Once broached discard by:

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

Dispose of empty containers and carcasses in accordance with guidance from your local waste regulation authority in the UK.

Dispose of any unused product in accordance with the Misuse of Drugs Regulations 2001(UK).

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

For animal treatment only.

UK	POM-V	CD	Vm 28365/4015
To be supplied only on veterinary prescription			

Authorised for use in UK and IE

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

Keep out of the reach and sight of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

16. MARKETING AUTHORISATION NUMBER

Vm 28365/4015

17. MANUFACTURER'S BATCH NUMBER

Batch:

18. FURTHER INFORMATION

MNF:

PACKAGE LEAFLET FOR:

Euthatal 200 mg in 1 ml Solution for Injection

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

Marketing Authorisation Holder:
Dopharma Research B.V.
Zalmweg 24
4941 VX Raamsdonksveer
The Netherlands

Manufacturer:
MERIAL S.A.S.
4 Chemin du calquet, 31000 Toulouse, FRANCE
And
Dopharma France
23 Rue Du Prieuré - Saint Herblon
44150 Vair sur Loire
France

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Euthatal 200 mg in 1 ml Solution for Injection

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

Each ml contains 200 mg of the active substance, Pentobarbital Sodium, and 0.01 mg of the colourant, Patent Blue (E131).

4. INDICATION(S)

For the euthanasia of cats and dogs and other small animals.

5. CONTRAINDICATIONS

Do not use for anaesthetic purposes. Not for use in animals intended for human consumption. Carcasses of animals which have been euthanased with the product must not be used for animal consumption. Do not administer by the intramuscular route.

6. ADVERSE REACTIONS

7. TARGET SPECIES

Cats and dogs and other small animals

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

EUTHATAL is primarily intended for, and is most consistently effective when administered by the intravenous route. The solution should be administered at the rate of 1ml per 1.4kg (3lb) bodyweight (approximately 150mg/kg bodyweight) as rapidly as possible.

9. ADVICE ON CORRECT ADMINISTRATION

In some circumstances the intrathoracic or intracardiac routes of administration may be used, but only as a last resort. The choice of these routes should be made in the light of the attendant difficulties, and the unnecessary pain and distress to the animal which could result.

When it is anticipated that euthanasia may be problematic (e.g. aggressive patients), premedication with an appropriate sedative is recommended.

10. WITHDRAWAL PERIOD(S)

11. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C. Protect from light.

Following withdrawal of the first dose, use the product within 28 days.

When the container is broached for the first time, the date on which any product remaining in the container should be calculated. A statement of the in-use shelf-life of the product is given on the package leaflet. This discard date should be written in the space provided on the label.

Do not use after the expiry date stated on the carton and label after "EXP".

Discard unused material.

Should any apparent growth or discolouration occur the product should be discarded.

Discard if any sediment is observed.

12. SPECIAL WARNING(S)

Keep out of the reach and sight of children. For animal treatment only.
For use in euthanasia only.

Avoid the introduction of contamination during use. The product does not contain a preservative. This product is not sterile.

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.

OPERATOR WARNING
Pentobarbital is a potent drug which is toxic to man. Particular care should be taken to avoid accidental ingestion and self-injection. 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

Dispose of empty containers and carcasses in accordance with guidance from your local waste regulation authority in the UK.

Dispose of any unused product in accordance with the Misuse of Drugs Regulations 2001 (UK).

Not to be diluted with water or any other fluid.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

15. OTHER INFORMATION

UK POM-V CD (Sch 3) Prescription Only Medicine – Veterinarian

Vm 28365/4015
To be supplied only on veterinary prescription

Veterinary Medicinal Product authorised for use in UK and IE.

Solution for euthanasia

Approved 19 September 2019