1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolethal 200 mg/ml Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:

Active substance:

Pentobarbital Sodium	200	mg

Excipient:

Benzyl Alcohol	0.0104	ml
Cochineal Red A (E124)	0.01	mg

For the full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
A red aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Dogs, cats.

4.2 Indications for use, specifying the target species

Euthanasia of dogs and cats.

4.3 Contraindications

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

4.4 Special warnings for each target species

It may be necessary to increase the dose for older animals weighing more than 10 kg.

4.5 Special precautions for use

Special precautions for use in animals

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

Lethal to humans.
Particular care should be taken to avoid accidental exposure to the product.
To avoid accidental spraying of the product in the face and eyes, care should be taken during the injection to ensure the pressure on the syringe is not too great.
Wear suitable protective gloves and glasses when handling the product. Avoid accidental self-administration and self-injection.

In the case of accidental self-administration (injection, ingestion, skin absorption), seek URGENT medical attention, advising medical services of barbiturate poisoning.
In the case of accidental contact with eyes, irrigate eyes immediately with flowing cold or tepid water.
In the case of contact with skin, wash immediately with water and then thoroughly with soap and water.

4.6 Adverse reactions (frequency and seriousness)

None.

4.7 Use during pregnancy, lactation or lay

Not relevant.

4.8 Interaction with other medicinal products and other forms of interaction

None.

4.9 Amounts to be administered and administration route

For intravenous or intra-cardiac injection at a dosage of 135 mg Pentobarbital sodium/kg bodyweight (0.7 ml Dolethal/kg bodyweight).
Intra-cardiac injection must only be used if the animal is heavily sedated, unconscious, or anaesthetised.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

In case of accidental intoxication, the symptomatic treatment calls for respiratory assistance, forced diuresis and use of bicarbonate solute in order to correct the acidosis induced.

4.11 Withdrawal period(s)

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

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nervous system, products for animal euthanasia, barbiturates; pentobarbital.
ATC vet code: QN51AA01
Euthanasia of dogs and cats.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Benzyl Alcohol
Cochineal Red A (E124)
Isopropyl Alcohol
Propylene Glycol
Water for Injections

6.2 Major incompatibilities

In the absence of incompatibility studies, this veterinary medicinal product must not be mixed with other veterinary medicinal products.

6.3 Shelf life

Shelf-life of the veterinary medicinal product as packaged for sale: 3 years.

Shelf-life after first opening the immediate packaging: 28 days.

6.4. Special precautions for storage

Do not store above 25°C

6.5 Nature and composition of immediate packaging

50 and 100 ml Type II glass vials containing a red aqueous solution closed with a rubber stopper and an aluminium cap. Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal product or waste materials derived from the use of such products

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.

7. MARKETING AUTHORISATION HOLDER

Vetoquinol Ireland Limited
12 Northbrook Road
Ranelagh
Dublin 6
Ireland

8. MARKETING AUTHORISATION NUMBER(S)

VPA10983/015/001

9. DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

1st October 1990

10 DATE OF REVISION OF THE TEXT

15 December 2023