SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Dolethal 200mg/ml solution for injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

	Per ml
Pentobarbital sodium	200.00 mg

Other constituents include:

Benzyl alcohol	10.40 mg
Ponceau 4R (E124)	0.01 mg

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

A pink liquid solution for injection

4. CLINICAL PARTICULARS

4.1 Target species

Small animals and cattle.

4.2 Indications for use, specifying the target species

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

4.3 Contra-indications

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

4.4 Special warnings for each target species

None

4.5 Special precautions for use

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.

4.6 Adverse reactions (frequency and seriousness)

None

4.7 Use during pregnancy, lactation or lay

Not Applicable

4.8 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).

4.9 Amounts to be administered and administration route

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

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

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.

4.11 Withdrawal period(s)

Not to be used in animals intended for human consumption.

5. 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.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Propylene Glycol Water for
Injections Isopropyl alcohol

6.2 Incompatibilities

None known

6.3 Shelf life

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

6.4 Special precautions for storage

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.

6.5 Nature and composition of immediate packaging

Carton containing colourless multidose glass bottles containing 100 or 250 ml non-sterile aqueous solution. 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 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.

7. MARKETING AUTHORISATION HOLDER

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

8. MARKETING AUTHORISATION NUMBER

Vm 08007/4034

9. DATE OF FIRST AUTHORISATION

02 June 1992

10. DATE OF REVISION OF THE TEXT

November 2022

Approved 18 November 2022