Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Clorketam 100 mg/ml Solution for Injection

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each ml contains:	
Active substance	
Ketamine (as hydrochloride)	100 mg
Excipients	
Chlorobutanol hemihydrate	3 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Solution for injection.
A clear, colourless solution.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats.

4.2 Indications for use, specifying the target species

Restraint - sedation.

GENERAL ANAESTHESIA FOR:

- short minor surgery
- emergency surgery even on pregnant females
- in combination with premedication in obstetrics surgery.

4.3 Contraindications

Do not use in animals with known hypersensitivity to one of the ingredients.
Do not use in animals with cardio-respiratory deficiency.
Do not use in eye surgery due to the oculopalpebral reflex.
Do not use in animals treated with organo-phosphorus agents.
Do not use in animals with hypertension.

4.4 Special warnings for each target species

Difficulty to control haemorrhage may occur due to the increased blood pressure associated with the use of this anaesthetic.
Animals should be allowed to recover in a quiet area.

4.5 Special precautions for use

Special precautions for use in animals

A reduction of temperature may be observed when administering with Halothane.
In cases of pre-existing hepatic or renal deficiencies, the dose should be reduced in accordance with the severity of the pathology.
Eyes of the animal should be protected during anaesthesia.

Special precautions to be taken by the person administering the veterinary medicinal product to animals

Avoid self administration.
In case of accidental self-injection, seek medical advice immediately and show the package leaflet or label to the physician.
Wash off splashes from skin and eyes immediately.

4.6 Adverse reactions (frequency and seriousness)

When ketamine is used alone, slow movements of the head and rigidity or extension of the fore limbs may occur.
Opisthotonous can occur after IV administration.
Convulsive seizure has been reported in cats that receive a clinical dosage of ketamine.
Clorketam is likely to cause respiratory decrease in young following caesarean section.

4.7 Use during pregnancy, lactation or lay

The use is not recommended during lactation since no study has been performed in this condition.

4.8 Interaction with other medicinal products and other forms of interaction

Clorketam could be used in combination with other anaesthetic agents such as barbiturates, thiamylal and volatile anaesthetic agents.

4.9 Amounts to be administered and administration route

	DOSAGE	
ROUTE	**In mg. of Ketamine**	**In ml of Clorketam**
IV	50 to 80 mg/10 kg bw	0.5 ml to 0.8ml/10 kg bw
IM	50 to 200 mg/10 kg bw	0.5 ml to 2ml/10 kg bw

Clorketam is used alone following a premedication such as diazepam, xylazine or medetomidine.
In case of pre-existing hepatic or renal deficiencies, the dose should be reduced in accordance with the severity of the pathology.

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

In case of respiratory depression, adequate pulmonary ventilation with either oxygen or room temperature air is recommended.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Nervous system, anesthetics, general; ketamine.
ATC vet code: QN01AX03

Ketamine is a general anaesthetic widely used in veterinary medicine.

5.1 Pharmacodynamic properties

Ketamine induces anaesthesia and amnesia by functional disruption of the central nervous system through marked CNS stimulation or induction of a cataleptoid state.
Administration of ketamine results in an increase in cardiac output and blood pressure with little change in peripheral resistance.

5.2 Pharmacokinetic properties

Ketamine is absorbed rapidly following parenteral administration. After a single dose of 20mg/kg by IM route, Cmax in cats of 9.33ug/ml is attained after 20 minutes.
Ketamine is distributed very rapidly into the body tissues, primarily adipose tissue, liver, lung and brain. In cats and dogs after an IV injection, the high distribution volume (cats: Vss=4.79 1/kg, dogs: Vss=4.59 1/kg) indicates a strong affinity of ketamine for tissues.
Biotransformation occurs in the liver by N-demethylation and hydroxylation of cyclohexanone ring with formation of water soluble derivatives which are eliminated in urine.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Chlorobutanol hemihydrate
Water for injections

6.2 Incompatibilities

Do not use ketamine and barbiturates in the same syringe.

6.3 Shelf-life

Shelf-life of the veterinary medicinal product as packaged for sale: 2 years.
Shelf-life after first opening the immediate packaging: 3 months.

6.4 Special precautions for storage

Do not store above 25^0C.

6.5 Nature and composition of immediate packaging

10 ml clear, colourless solution packed in amber type II glass vial sealed with chlorobutyl rubber stopper and an aluminium cap.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

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
10 Lad Lane
Lower Baggot Street
Dublin 2
Ireland

8 MARKETING AUTHORISATION NUMBER(S)

VPA 10983/016/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

30th September 2010

10 DATE OF REVISION OF THE TEXT