SUMMARY OF PRODUCT CHARACTERICTICS

1. NAME OF VETERINARY MEDICINAL PRODUCT

Lignol 2.0 % w/v Solution for Injection

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active ingredients	% w/v
Lidocaine hydrochloride / Lignocaine hydrochloride	2.0
Adrenaline acid tartrate*/ Epinephrine acid tartrate	0.00198

*Including a 10 % manufacturing overage

For a full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Solution for injection.
Sterile, aqueous solution.

4. CLINICAL PARTICULARS

4.1 Target species

Cats, dogs and horses.

4.2 Indications for use, specifying the target species

A local anaesthetic agent for regional nerve block, paravertebral nerve block and infiltration anaesthesia, for use in cats, dogs and horses.

4.3 Contraindications

Do not use in cardiac or hepatic insufficiency.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use

i. Special precautions for use in animals

Do not administer by intravenous injection.

Do not use for more than one induction of anaesthesia in any 24 hours.

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

Following accidental self injection or ingestion seek medical advice taking the vial with you. Following eye contamination or excessive skin contact, irrigate/wash thoroughly with cold running water. Seek medical advice if irritation persists.

iii. Other precautions

None.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

Use with caution in pregnant animals.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

For local nerve block by subcutaneous injection.

Cat infiltration	1 ml
Dog infiltration	1-2 ml
Horse infiltration	50 ml max

For paravertebral block up to 10 ml each nerve.

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

Local anaesthetics may have systemic adverse effects as a result of the raised plasma concentrations which occur when the rate of absorption exceeds the rate of breakdown. Toxicity causes excitation of the central nervous system, which may be followed by systemic depression leading to coma. Convulsions may be controlled with Diazepam.

4.11 Withdrawal periods

Horse meat: zero days.

5. PHARMACOLOGICAL PARTICULARS

Pharmacotherapeutic group: Lidocaine, combinations

ATC Vet Code: QN01BB52

5.1 Pharmacodynamic properties

Lidocaine is a local anaesthetic of the amide type, used both by injection and for local application to mucous membranes.

5.2 Pharmacokinetic properties

Lidocaine has rapid onset of action when injected and spreads rapidly through surrounding tissues. The speed of onset and duration of action of Lidocaine may be increased by the addition of a vasoconstrictor.

Adrenaline is added to local anaesthetics, such as Lidocaine hydrochloride, to slow diffusion and limit absorption as it constricts arterioles and capillaries, so prolonging the duration of the effect and lessening the danger of toxicity.

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Sodium chloride
Sodium metabisulphite
Chlorocresol
Water for injections

6.2 Incompatibilities

None known.

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: 28 days.

6.4 Special precautions for storage

Do not store above 25°C.
Discard unused material.

6.5 Nature and contents of immediate packaging

100 ml neutral amber glass vial fitted with a red rubber plug and an aluminium seal, containing a sterile, aqueous solution.

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

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

7. MARKETING AUTHORISATION HOLDER

Dechra Limited
Snaygill Industrial Estate
Keighley Road
Skipton
North Yorkshire
BD23 2RW
United Kingdom

8. MARKETING AUTHORISATION NUMBER

Vm 10434/4028

9. DATE OF FIRST AUTHORISATION

31 August 1993

10. DATE OF ANY REVISION OF THE TEXT

September 2016

 29 September 2016