PARTICULARS TO APPEAR ON THE OUTER PACKAGE AND THE IMMEDIATE PACKAGE – Label and base label

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lignol 2.0% w/v solution for injection

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Contains: Active substances: Lignocaine hydrochloride/Lidocaine hydrochloride 2.0% w/v.

Adrenaline acid tartrate/Epineprine acid tartrate 0.00198% w/v

Preservatives: Chlorocresol 0.1% w/v

Sodium metabisulphate 0.1% w/v

3. PHARMACEUTICAL FORM

Solution for injection.

4. PACKAGE SIZE

100 ml

5. TARGET SPECIES

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.

8. WITHDRAWAL PERIOD

Horse meat: Zero days

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for full details.

10. EXPIRY DATE

Once broached, use by:

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.

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

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

Discard unused material.

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

For animal treatment only.

POM-VPS

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

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

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

16. MARKETING AUTHORISATION NUMBER

Vm 10434/4028

17. MANUFACTURER'S BATCH NUMBER

MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET, E.g. Concertina Labels. {NATURE/TYPE}

[The guidance contained below is national specific only and should be used in addition to EU QRD template guidance for both the Package Leaflet AND the Outer/Immediate package, available on the EMA website.]

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

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

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Lignol 2.0% w/v solution for injection

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

Clear, sterile, aqueous solution for injection containing:

Active substances: Lignocaine hydrochloride/Lidocaine hydrochloride 2.0% w/v

Adrenaline acid tartrate/Epineprine tartrate 0.00198% w/v

Chlorocresol 0.1% w/v

Sodium metabisulphite 0.1% w/v

4. PHARMACEUTICAL FORM

5. PACKAGE SIZE

100 ml

6. INDICATION(S)

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

7. CONTRAINDICATIONS

Do not use in cardiac or hepatic insufficiency.

8. ADVERSE REACTIONS

9. TARGET SPECIES

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

For local nerve block by subcutaneous injection:

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

For paravertebral block up to 10 ml each nerve.

11. ADVICE ON CORRECT ADMINISTRATION

12. WITHDRAWAL PERIOD

13. SPECIAL STORAGE PRECAUTIONS

Do not store above 25°C.

Protect from light.

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

Discard unused material.

14. SPECIAL WARNING(S)

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

Do not administer by intravenous injection.

It is unwise to use the product in young puppies because of the cardio-vascular stimulant effect.

Use with caution in pregnancy.

Overdose: 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.

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

15. EXPIRY DATE

Do not use after the expiry date stated on the label.

16. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Dispose of any unused product and empty containers in accordance with guidance from your local waste regulation authority.

17. DATE ON WHICH THE LABEL WAS LAST APPROVED

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

For animal treatment only.

POM-VPS	Prescription Only Medicine – Veterinarian, Pharmacist, Suitably Qualified Person

To be supplied only on veterinary prescription.

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

Keep out of the sight and reach of children.

20. MARKETING AUTHORISATION NUMBER

Vm 10434/4028

21. MANUFACTURER'S BATCH NUMBER

22. OTHER INFORMATION

Lignol is a local anaesthetic containing lignocaine hydrochloride/lidocaine hydrochloride/ (>2.0% w/v) and adrenaline acid tartrate/epinephrine acid tartrate (0.00198%) w/v. lignocaine hydrochloride/lidocaine hydrochloride produces local anaesthesia with a shorter period of onset, a more intense action and a longer duration then is achieved with procaine hydrochloride.

Adrenaline is added to local anaesthetics, such as lignocaine hydrochloride/ 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.

Local representative:

Dechra Veterinary Products Limited, Sansaw Business Park, Hadnall, Shrewsbury, Shropshire, SY4 4AS, UK

Approved: 04 October 2017

D Austin