Revised: December 2019 AN: 01138/2019

# MINIMUM PARTICULARS TO APPEAR ON THE LABEL WHERE THERE IS NO PACKAGE LEAFLET

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

Dorwest Herbs Ltd, Parkway Farm Business Park, Middle Farm Way, Poundbury, Dorchester, Dorset, DT1 3AR

#### 2. NAME OF THE VETERINARY MEDICINAL PRODUCT

SCULLCAP & VALERIAN SUGAR COATED TABLETS

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

Valerian Dry Extract Ph.Eur. 5:1	50mg
Mistletoe Dry Extract 3:1	50mg
Scullcap	30mg
Gentian Dry Extract Ph.Eur 2:1	24mg

#### 4. PHARMACEUTICAL FORM

Sugar coated tablet

#### 5. PACKAGE SIZE

100, 200, 500 (as appropriate)

#### 6. INDICATION(S)

A herbal medicine for the symptomatic relief of anxiety, nervousness, excitability and travel sickness, and an adjunct in the treatment of epilepsy.

#### 7. CONTRAINDICATIONS

Not recommended for pregnant or lactating animals.

#### 8. ADVERSE REACTIONS

Based on post marketing experience and complementary data, behavioural disorders as hyperactivity, anxiety have been observed very rarely. On very rare occasion diarrhoea, lethargy and malaise have been reported.

#### 9. TARGET SPECIES

For dogs and cats (infographic)

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

Recommended dosage:

1-2 tablets per 5kgs bodyweight daily.

#### 11. ADVICE ON CORRECT ADMINISTRATION

Can be used on a daily basis or as required for specific occasions or situations.

#### 12. WITHDRAWAL PERIOD

#### 13. SPECIAL STORAGE PRECAUTIONS

Store in a dry place, below 25°C

### 14. SPECIAL WARNING(S)

If condition fails to improve consult a veterinary surgeon. Epilepsy should only be treated in conjunction with your veterinary surgeon.

#### 15. EXPIRY DATE

As designated during assembly

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

Dispose of packaging and unused product in household refuse

#### 17. DATE ON WHICH THE LABEL WAS LAST APPROVED

Label revised: November 2019

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

For animal treatment only Wash hands after use

AVM-GSL

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

KEEP OUT OF THE REACH OF CHILDREN

#### 20. MARKETING AUTHORISATION NUMBER(S)

Vm 00866/4021

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### 21. MANUFACTURER'S BATCH NUMBER

## 22. OTHER INFORMATION

Approved: 05 December 2019