

SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Scullcap and Valerian Sugar Coated Tablets

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

Active substance: Each tablet contains;
Mistletoe Dry Ext (Powdered) 3:1 50mg
Valerian Dry Ext Powdered) 5:1 50mg
Scullcap herb (Powdered) 30mg
Gentian Dry Ext (Powdered) 2:1 24mg

Excipients

Ferric oxide, yellow (E172) 0.1mg
Titanium dioxide (E171) 0.8mg

For full list of excipients, see section 6.1.

3. PHARMACEUTICAL FORM

Coated tablet
Yellow tablet, 8.73mm diameter

4. CLINICAL PARTICULARS

4.1 Target species

Dogs and cats

4.2 Indications for use

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

4.3 Contra-indications

None

4.4 Special warnings for each target species

Dogs – None necessary
Cats – None necessary

4.5 Special precautions for use

i) Special precautions for use in animals:

Epilepsy should only be treated in conjunction with a veterinary surgeon

ii) Special precautions to be taken by the person administering the medicinal product to animals:

Wash hands after use

4.6 Adverse reactions (frequency and seriousness)

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.

The frequency of adverse reactions is defined using the following convention:

- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

4.7 Use during pregnancy and lactation

No data is available to support the use of this product in pregnant or lactating animals. Therefore the use of this product in pregnant or lactating animals is not recommended.

4.8 Interaction with other medicinal products and other forms of interaction

None known

4.9 Amounts to be administered and administration route

1-2 tablets per 5kgs of bodyweight daily.

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

Oral administration

4.10 Overdose

No treatment specified

4.11 Withdrawal periods

Not applicable

5. PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Not known

5.2 Pharmacokinetic properties

Not known

6. PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Ferric oxide, yellow (E172)

Titanium dioxide (E171)

Asafoetida

Talc, purified

Magnesium stearate

Sodium starch glycollate

Sucrose, compressible

Syrup

6.2 Incompatibilities

None known

6.3 Shelf life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years

6.4 Special precautions for storage

Do not store above 25°C. Store in a dry place

6.5 Nature and composition of immediate packaging

White high density polyethylene bottle

White high density polyethylene cap (tamper evident)

Available in bottles of 50, 100, 200 and 500 tablets

Not all pack sizes may be marketed

6.6 Special precautions for the disposal of unused veterinary medicinal product

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

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

8. MARKETING AUTHORISATION NUMBER

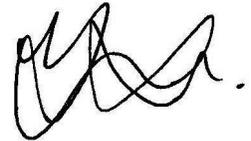
Vm 00866/4021

9. DATE OF FIRST AUTHORISATION

01 September 1992

10. DATE OF REVISION OF THE TEXT

December 2019

A handwritten signature in black ink, consisting of several loops and a final horizontal stroke.

Approved: 05 December 2019