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MRAbit

Authorised

- Alarelin

Product identification

Medicine name:

MRAbit

Active substance:

Alarelin

Target species:

Rabbit (female for reproduction)

Route of administration:

Vaginal use

Product details

Active substance and strength:

Alarelin

1.50 milligram(s) / 1.00 gram(s)

Pharmaceutical form:

Powder for vaginal solution

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QH01CA

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Portugal

Package description:

cardboard box with 5 sachets of 4 g (210 doses)
cardboard box with 5 sachets of 12 g (630 doses)
cardboard box with 5 sachets of 40 g (2.100 doses)
cardboard box with 25 sachets of 4 g (210 doses)
cardboard box with 25 sachets de12 g (630 doses)
cardboard box with 25 sachets of 40 g (2.100 doses)

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application - Known active substance (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Kubus Lab S.A.

Marketing authorisation date:

14/08/2020

Manufacturing sites for batch release:

Kubus Lab S.A.

Responsible authority:

Directorate General For Food And Veterinary

Authorisation number:

1361/01/20DFVPT

Date of authorisation status change:

14/08/2020

Reference member state:

Spain

Procedure number:

ES/V/0286/001

Concerned member states:

Italy Portugal

To consult adverse reactions on veterinary medicinal products please go to www.adrreports.eu/vet

Documents

Summary of Product Characteristics

Combined File of all Documents

eu-PUAR-mrabit-1.5-mg-g-powder-for-vaginal-solution-en.pdf