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Adrestan 60 mg hard capsules

Not authorised

- Trilostane

Product identification

Medicine name:
Adrestan 60 mg hard capsules

Active substance:
Trilostane

Target species:
Dog

Route of administration:
Oral use

Product details

Active substance and strength:
Trilostane
60.00 milligram(s) / 1.00 Capsule

Pharmaceutical form:
Capsule, hard

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QH02CA01

Legal status of supply:
Veterinary medicinal product subject to veterinary prescription

Authorisation status:
Surrendered

Authorised in:
Netherlands

Package description:
Three PVC-PVdc/aluminium foil blister strips each containing 10 capsules.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Informed consent application (Article 13c of Directive No 2001/82/EC)

Marketing authorisation holder:
Dechra Regulatory B.V.

Marketing authorisation date:
7/04/2016

Manufacturing sites for batch release:
Dales Pharmaceuticals Limited
Genera d.d.

Responsible authority:
Medicines Evaluation Board

Authorisation number:
REG NL 117140

Date of authorisation status change:
21/05/2024

Reference member state:

Ireland

Procedure number:
IE/V/0503/003

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Documents

Combined File of all Documents

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Summary of Product Characteristics