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Subestin 25 microgram/ml oral solution for horses

Authorised

- Clenbuterol hydrochloride

Product identification

Medicine name:
Subestin 25 microgram/ml oral solution for horses

Active substance:
Clenbuterol hydrochloride

Target species:
Horse

Route of administration:
Oral use

Product details

Active substance and strength:
Clenbuterol hydrochloride
25.00 microgram(s) / 1.00 millilitre(s)

Pharmaceutical form:
Oral solution

Withdrawal period by route of administration:

Oral use:

- **Horse**
  - Meat and offal. 28 day

Not authorised for use in animals producing milk for human consumption

Anatomical therapeutic chemical veterinary (ATCvet) codes:
QR03CC13

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

Authorisation status:
Valid

Authorised in:
Denmark

Package description:
White HDPE bottle with white polypropylene child-resistant screw cap and LDPE syringe inlay. The product is supplied in a carton box with a measuring device, a 25 ml syringe with polypropylene body and polyethylene plunger, capable of delivering 4 to 24 ml of the product. Each bottle contains 360 ml.

Additional information

Entitlement type:
Marketing Authorisation

Legal basis of product authorisation:
Generic application (Article 13(1) of Directive No 2001/82/EC)

Marketing authorisation holder:
Floris Holding B.V.

Marketing authorisation date:

2/05/2022

Manufacturing sites for batch release:
Floris Veterinaire Producten B.V.

Responsible authority:
Danish Medicines Agency

Authorisation number:
65631

Date of authorisation status change:
2/05/2022

Reference member state:
Netherlands

Procedure number:
NL/V/0362/001

Concerned member states:
Austria Belgium Denmark France Germany Ireland Italy Sweden United Kingdom (Northern Ireland)

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

Documents

Combined File of all Documents

Summary of Product Characteristics

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Final PuAR_Subestin NLV0362001_122025.pdf