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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:
Sweden

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:

28/04/2022

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

Responsible authority:
Swedish Medical Products Agency

Authorisation number:
62633

Date of authorisation status change:
28/04/2022

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

This document does not exist in this language (English). You can find it in another language below.

Package Leaflet

This document does not exist in this language (English). You can find it in another language below.

Labelling

This document does not exist in this language (English). You can find it in another language below.

Final PuAR_Subestin NLV0362001_122025.pdf