

Sputolosin Oral Powder 5 mg/g

Authorised

- Dembrexine hydrochloride monohydrate

Product identification

Medicine name:

Sputolosin Oral Powder 5 mg/g

Active substance:

Dembrexine hydrochloride monohydrate

Target species:

Horse

Route of administration:

Oral use

Product details

Active substance and strength:

Dembrexine hydrochloride monohydrate
5.00 milligram(s) / 1.00 gram(s)

Pharmaceutical form:

Oral powder

Withdrawal period by route of administration:

Oral use:

-

Horse

- Meat and offal. 1 day

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QR05CB90

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Ireland

Package description:

The product is packaged in a polyethylene container with a push-fit polyethylene cap and a measuring spoon (5 g powder). The container is filled with 420 g powder.

Additional information

Entitlement type:

Marketing Authorisation

Legal basis of product authorisation:

Full application (Article 12(3) of Directive No 2001/82/EC)

Marketing authorisation holder:

Boehringer Ingelheim Vetmedica GmbH

Marketing authorisation date:

1/10/1990

Manufacturing sites for batch release:

Klocke Pharma-Service GmbH

Responsible authority:

Health Products Regulatory Authority

Authorisation number:

VPA10454/014/001

Date of authorisation status change:

1/10/1990

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

Documents

Summary of Product Characteristics