

Prascend 1 mg tablets for horses

Authorised

- Pergolide mesilate

Product identification

Medicine name:

Prascend 1 mg tablets for horses

Active substance:

Pergolide mesilate

Target species:

Horse (non food-producing)

Route of administration:

Oral use

Product details

Active substance and strength:

Pergolide mesilate

1.31 milligram(s) / 1.00 Tablet

Pharmaceutical form:

Tablet

Withdrawal period by route of administration:

Oral use:

-

Horse (non food-producing)

- Meat and offal. no withdrawal period

Not authorised for use in horses intended for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation. Not authorised for use in mares producing milk for human consumption.

- Milk. no withdrawal period

Not authorised for use in horses intended for human consumption. The horse must have been declared as not intended for human consumption under national horse passport legislation. Not authorised for use in mares producing milk for human consumption.

Anatomical therapeutic chemical veterinary (ATCvet) codes:

QN04BC02

Legal status of supply:

Veterinary medicinal product subject to veterinary prescription

Authorisation status:

Valid

Authorised in:

Norway

Available in:

Norway

Package description:

(ID1) 100 Tablet: Box (cardboard) with 1 Blister (aluminium; polyvinyl chloride; nylon) with 100 Tablet

(ID2) 60 Tablet: Box (cardboard) with 1 Blister (aluminium; polyvinyl chloride; nylon) with 60 Tablet

(ID3) 160 Tablet: Box (cardboard) with 1 Blister (aluminium; polyvinyl chloride; nylon) with 160 Tablet

(ID4) 91 Tablet: Box (cardboard) with 13 Blister (nylon; aluminium; polyvinyl chloride) each with 7 Tablet, closed with Foil (vinyl, aluminium)

(ID5) 480 Tablet: Box (cardboard) with 3 Box (cardboard) each with 16 Blister (nylon; aluminium; polyvinyl chloride) each with 10 Tablet, closed with Foil (vinyl, aluminium)

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:

20/06/2012

Manufacturing sites for batch release:

Boehringer Ingelheim Vetmedica GmbH

Haupt Pharma Amareg GmbH

Responsible authority:

Norwegian Medical Products Agency

Authorisation number:

11-8625

Date of authorisation status change:

29/07/2014

Reference member state:

Germany

Procedure number:

DE/V/0130/001

Concerned member states:

Austria Belgium Denmark Finland France Iceland Ireland Italy Luxembourg
Netherlands Norway Sweden United Kingdom (Northern Ireland)

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

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.

Combined File of all Documents

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