A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton for 60, 91, 100 and 160 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prascend 1 mg tablet for horses (pergolide as pergolide mesylate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 1.0 mg pergolide (as pergolide mesylate 1.31 mg)

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

60 tablets
91 tablets
100 tablets
160 tablets

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

For oral use.
Read the package leaflet before use.

8. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.
Not authorised for use in mares producing milk for human consumption.

9. SPECIAL WARNING(S), IF NECESSARY

Avoid accidental ingestion by humans. See package leaflet for user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

Do not store above 25°C.
Keep the blister in the outer carton.

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

Disposal: read package leaflet.

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, if applicable

For animal treatment only. To be supplied only on veterinary prescription.

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

UK:
Boehringer Ingelheim Animal Health UK Ltd
Bracknell, Berkshire, RG12 8YS,
United Kingdom

FR:
Boehringer Ingelheim Animal Health France SCS
29, avenue Tony Garnier
69007 Lyon
France

AT, BE, DE, DK, FI, IE, IS, IT, LU, NL, NO, SE:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4300

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Outer wrapper label (480 tablets)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prascend 1 mg tablet for horses (pergolide as pergolide mesylate)

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains 1.0 mg pergolide (as pergolide mesylate 1.31 mg)

3. PHARMACEUTICAL FORM

Tablet

4. PACKAGE SIZE

480 tablets

5. TARGET SPECIES

Horses

6. INDICATION(S)

7. METHOD AND ROUTE(S) OF ADMINISTRATION

8. WITHDRAWAL PERIOD(S)

9. SPECIAL WARNING(S), IF NECESSARY

See package leaflet for user warnings.

10. EXPIRY DATE

EXP {month/year}

11. SPECIAL STORAGE CONDITIONS

12. SPECIFIC PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCTS OR WASTE MATERIALS, IF ANY

13. THE WORDS "FOR ANIMAL TREATMENT ONLY" AND CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE, IF APPLICABLE

14. THE WORDS "KEEP OUT OF THE SIGHT AND REACH OF CHILDREN"

Keep out of the sight and reach of children.

15. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

16. MARKETING AUTHORISATION NUMBER(S)

Vm 08327/4300

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

Blister of 7 or 10 tablets

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prascend 1 mg tablets for horses (pergolide as pergolide mesylate)

2. NAME OF THE MARKETING AUTHORISATION HOLDER

Boehringer Ingelheim

3. EXPIRY DATE

EXP {month/year}

4. BATCH NUMBER

Lot {number}

5. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET
Prascend 1 mg tablets for horses

1. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER AND OF THE MANUFACTURING AUTHORISATION HOLDER RESPONSIBLE FOR BATCH RELEASE, IF DIFFERENT

Marketing authorisation holder
UK:
Boehringer Ingelheim Ltd
Bracknell, Berkshire, RG128YS
United Kingdom

FR:
Boehringer Ingelheim Animal Health France SCS
29, avenue Tony Garnier
69007 Lyon
France

Manufacturer responsible for batch release
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Haupt Pharma Amareg GmbH
Donaustaufer Str. 378
93055 Regensburg
Germany

Marketing authorisation holder and manufacturer responsible for batch release
AT, BE, DE, DK, FI, IE , IS, IT, LU, NL, NO, SE:
Boehringer Ingelheim Vetmedica GmbH
55216 Ingelheim/Rhein
Germany

Manufacturer responsible for batch release
Haupt Pharma Amareg GmbH
Donaustaufer Str. 378
93055 Regensburg
Germany

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

Prascend 1 mg tablet for horses (pergolide as pergolide mesylate)

3. STATEMENT OF THE ACTIVE SUBSTANCE(S) AND OTHER INGREDIENTS

Pink, rectangular scored tablet, engraved on one side with the Boehringer Ingelheim logo and the letters “PRD”. The tablets can be divided into 2 equal parts.

Each tablet contains 1.0 mg pergolide (as pergolide mesylate 1.31 mg).

4. INDICATION(S)

Symptomatic treatment of clinical signs associated with Pituitary Pars Intermedia Dysfunction (PPID) (Equine Cushing's Disease).

5. CONTRAINDICATIONS

Do not use in horses with known hypersensitivity to pergolide mesylate or other ergot derivatives or to any of the excipients.
Do not use in horses less than 2 years of age.

6. ADVERSE REACTIONS

In rare cases inappetence, transient anorexia and lethargy, mild central nervous system signs (e.g. mild depression and mild ataxia), diarrhoea and colic have been observed in horses. In very rare cases sweating has been reported.

If signs of dose intolerance develop, treatment should be stopped for 2 to 3 days and reinstated at one-half of the previous dose. The total daily dose may then be titrated back up to the desired clinical effect by 0.5 mg increments every 2 to 4 weeks.

The frequency of adverse reactions is defined using the following convention:
- very common (more than 1 in 10 animals treated displaying adverse reaction(s))
- common (more than 1 but less than 10 animals in 100 animals treated)
- uncommon (more than 1 but less than 10 animals in 1,000 animals treated)
- rare (more than 1 but less than 10 animals in 10,000 animals treated)
- very rare (less than 1 animal in 10,000 animals treated, including isolated reports).

If you notice any side effects, even those not already listed in this package leaflet or you think that the medicine has not worked, please inform your veterinary surgeon.

7. TARGET SPECIES

Horses not intended for human consumption

8. DOSAGE FOR EACH SPECIES, ROUTE(S) AND METHOD OF ADMINISTRATION

Starting dose
The starting dose is 2 µg pergolide/kg (dose range: 1.3 to 2.4 µg/kg) body weight. Studies from the published literature cite the most common, average dose as 2 µg pergolide/kg with a range from 0.6 to 10 µg pergolide/kg (0.25 mg to 5 mg total daily dose per horse). The starting dose (2 µg pergolide/kg) should then be titrated according to the individual response as determined by monitoring (see below). Starting doses are recommended as follows:

Horse body weight	Number of tablets	Starting dose	Dosage range
200-400 kg	½	0.5 mg	1.3 – 2.5 µg/kg
401-600 kg	1	1.0 mg	1.7 – 2.5 µg/kg
601-850 kg	1 ½	1.5 mg	1.8 – 2.5 µg/kg
851-1000 kg	2	2.0 mg	2.0 – 2.4 µg/kg

Maintenance dose
Life long treatment is anticipated for this disease.
Most horses respond to therapy and are stabilised at an average dose of 2 µg pergolide/kg body weight. Clinical improvement with pergolide is expected within 6 to 12 weeks. Horses may respond clinically at lower or varying doses; it is therefore recommended to titrate to the lowest effective dose per individual based on response to therapy, whether it is effectiveness or signs of intolerance. Some horses may require doses as high as 10 µg pergolide/kg body weight per day. In these rare situations, appropriate additional monitoring is advised.

Following initial diagnosis, repeat endocrinologic testing for dose titration and monitoring of treatment at intervals of 4 to 6 weeks until stabilisation or improvement of clinical signs and/or diagnostic testing occurs.

Clinical signs are: hirsutism, polyuria, polydipsia, muscle wasting, abnormal fat distribution, chronic infections, laminitis, sweating, etc.

The approach to treatment is the dose titration to the lowest effective dose per individual, based on response to therapy, whether it is effectiveness or signs of intolerance. Depending on the severity of the disease, time to treatment response may vary among individuals.

If clinical signs or diagnostic testing have not yet improved at the first 4 to 6 week interval, the total daily dose may be increased by 0.5 mg. In case clinical signs have improved but are not yet normalised, the veterinarian may decide to titrate or not to titrate the dose, considering the individual’s response/tolerance to the dose.

In case clinical signs are not adequately controlled (clinical evaluation and/or diagnostic testing) it is recommended to increase the total daily dose by 0.5 mg increments every 4 to 6 weeks until stabilisation occurs and if the drug is tolerated at that dose. If signs of dose intolerance develop, treatment should be stopped for 2 to 3 days and reinstated at one-half of the previous dose. The total daily dose may then be titrated back up to the desired clinical effect by 0.5 mg increments every 2 to 4 weeks. If a dose is missed, the next scheduled dose should be administered as prescribed.

Following stabilisation, regular clinical assessment and diagnostic testing should be performed every 6 months to monitor treatment and dose. Where there is no apparent response to treatment, the diagnosis should be re-evaluated.

9. ADVICE ON CORRECT ADMINISTRATION

The product should be administered orally, once daily. To facilitate administration, the required daily dose should be placed in a small amount of water and/or mixed with molasses or other sweetener and agitated until dissolved. In this case, the dissolved tablets should be administered with a syringe. The whole amount should be administered immediately. Tablets should not be crushed.
Do not use Prascend if you notice visible signs of deterioration or if the blister is breached.

10. WITHDRAWAL PERIOD(S)

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.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 25°C.
Keep the blister in the outer carton.
Do not use this veterinary medicinal product after the expiry date (EXP) which is stated on the blister or the carton.

12. SPECIAL WARNING(S)

Appropriate endocrinologic laboratory tests should be conducted as well as evaluation of clinical signs in order to establish a diagnosis of PPID.

Special precautions for use in animals
As the majority of cases of PPID are diagnosed in aged horses, other pathological processes are frequently present. For monitoring and frequency of testing, see section “Dosage, method and route of administration”.

Special precautions to be taken by the person administering the veterinary medicinal product to animals
This product may cause eye irritation, an irritating smell, or headache after splitting. Minimise exposure risks when splitting tablets. Tablets should not be crushed.

Avoid contact with the eyes and inhalation when handling the tablets.
Wash hands after use.
People with known hypersensitivity to pergolide or other ergot derivatives should avoid contact with the veterinary medicinal product and should not administer it.
Pregnant or lactating women should wear gloves when administering the product.

In case of contact with skin, wash exposed skin with water. In the event of pergolide exposure to the eye, flush the affected eye immediately with water and get medical

advice. For nasal irritation, move to fresh air and seek for medical attention if breathing difficulty develops.

Pergolide, like other ergot derivatives, may cause emesis, dizziness, lethargy or low blood pressure.
Do not ingest the product.
Store this product separately away from human medicinal products and handle this product with great care to avoid accidental ingestion.
In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.
Avoid driving or operating machinery following ingestion of this product.

Children should not come into contact with the veterinary medicinal product.
Accidental ingestion, especially by children, may cause adverse reactions.

Pregnancy and lactation
Pregnancy: Use only according to the benefit/ risk assessment by the responsible veterinarian. The safety has not been demonstrated in pregnant mares. Laboratory studies in mice and rabbits have not produced any evidence of teratogenic effects. Reduced fertility was seen in mice at a dose of 5.6 mg/kg body weight per day.

Lactation: The use is not recommended in lactating horses, in which the safety of this product has not been demonstrated. In mice, reduced body weights and survival rates in the progeny were attributed to the pharmacological inhibition of prolactin secretion resulting in lactation failure.

Interaction with other medicinal products and other forms of interaction
Use with caution in case the product is co-administered with other drugs known to affect protein binding.
Do not administer concurrently with dopamine antagonists, such as neuroleptics (phenothiazines– e.g. acepromazine), domperidone, or metoclopramide, as these agents may reduce the effectiveness of pergolide.

Overdose (symptoms, emergency procedures, antidotes)
There is no clinical experience with massive overdose.

13. SPECIAL PRECAUTIONS FOR THE DISPOSAL OF UNUSED PRODUCT OR WASTE MATERIAL, IF ANY

Medicines should not be disposed of via wastewater or household waste.
Ask your veterinary surgeon how to dispose of medicines no longer required. These measures should help to protect the environment.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

November 2020

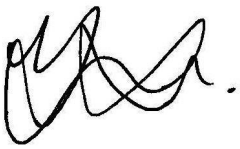
15. OTHER INFORMATION

Package sizes:
Cardboard box containing 60, 100, 160 or 480 (3 x 160) tablets (blisters of 10 tablets).
Cardboard box containing 91 tablets (blisters of 7 tablets).
Not all pack sizes may be marketed.

Prascend is a registered trademark of Boehringer Ingelheim Vetmedica GmbH, used under licence.

For any information about this veterinary medicinal product, please contact the local representative of the marketing authorisation holder.

[To be completed nationally, if different to MAH.]



Approved: 01 December 2020