ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pergocoat 1 mg film-coated tablets

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

Pergolide 1.0 mg (equivalent to 1.31 mg pergolide mesilate)

3. PACKAGE SIZE

10 tablets
30 tablets
60 tablets
90 tablets
100 tablets
120 tablets
160 tablets
240 tablets

4. TARGET SPECIES

Horse (non food-producing)

5. INDICATION(S)

6. ROUTES OF ADMINISTRATION

Oral use.

7. WITHDRAWAL PERIOD(S)

Withdrawal period(s):
Not authorised for use in horses intended for human consumption.
Treated horses may never be slaughtered 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.

8. EXPIRY DATE

Exp {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

Store in the original package, in order to protect from light.

10. THE WORDS "READ THE PACKAGE LEAFLET BEFORE USE"

Read the package leaflet before use

11. THE WORDS "FOR ANIMAL TREATMENT ONLY"

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

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

Keep out of the sight and reach of children.

13. NAME AND ADDRESS OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

14. MARKETING AUTHORISATION NUMBER

Vm 36408/5023

15. BATCH NUMBER

Lot {number}

16. SPECIAL WARNING(S), IF NECESSARY

User warnings:
People with known hypersensitivity to pergolide and pregnant or lactating women should avoid contact with the product.

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

Disposal: read package leaflet

18. CONDITIONS OR RESTRICTIONS REGARDING SUPPLY AND USE IF APPLICABLE

MINIMUM PARTICULARS TO APPEAR ON BLISTERS OR STRIPS

ALUMINIUM BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pergocoat

2. QUALITATIVE AND QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCE(S)

Pergolide 1 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp {mm/yyyy}

5. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V

6. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

B. PACKAGE LEAFLET

PACKAGE LEAFLET:

Pergocoat 0.5 / 1 / 2 mg film-coated tablets for horses

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pergocoat 0.5/1/2 mg film-coated tablets for horses

2. COMPOSITION

Each tablet contains:

Active substance:
Pergolide 0.5/1.0/2.0 mg
equivalent to 0.66/1.31/2.62 mg pergolide mesilate

Excipients:
0.5 mg tablet
Core:

Iron oxide yellow (E172)	0.064 mg

Coating:

Iron oxide yellow	22 µg
Titanium dioxide (E171)	1.5 mg

1 mg tablet
Core:

Iron oxide yellow (E172)	0.12 mg

Coating:

Iron oxide yellow (E172)	0.11 mg
Titanium dioxide (E171)	2.86 mg
Ferrosofferic oxide	25 µg
Iron oxide red (E172)	6 µg

2 mg tablet
Core:

Iron oxide yellow (E172)	0.24 mg

Coating:

Iron oxide yellow (E172)	0.66 mg
Titanium dioxide (E171)	5.06 mg
Ferrosofferic oxide	0.28 mg

Film-coated tablet
0.5 mg tablet: Off-white sphere shaped, film-coated tablet
1 mg tablet: Beige sphere shaped, film-coated tablet
2 mg tablet: Green sphere shaped, film-coated tablet

3. TARGET SPECIES

Horses (non food-producing)

4. INDICATIONS FOR USE

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 mesilate or other ergot derivatives or to any of the excipients.
Do not use in horses less than 2 years of age.

6. SPECIAL WARNING(S)

Special warnings for each target species:
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 8.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause hypersensitivity (allergy) reactions. People with known hypersensitivity to pergolide or other ergot derivatives should avoid contact with the veterinary medicinal product.

This product may cause adverse effects due to decreased prolactin levels, which poses a particular risk to pregnant and lactating women. Pregnant or lactating women should avoid dermal contact or hand-to-mouth contact and wear gloves when administering the product.

Accidental ingestion, especially by children, may cause adverse reactions such as emesis, dizziness, lethargy or low blood pressure. To avoid accidental ingestion, the blister should be replaced into the carton and carefully kept away from children. Avoid hand-to-mouth contact. Do not eat, drink or smoke when using this product. In case of accidental ingestion, seek medical advice immediately and show the package leaflet or the label to the physician.

This product may cause eye irritation. Avoid contact with the eyes including hand-to-eye contact when handling the tablets. Minimize exposure risks when dissolving the tablets, e.g. tablets should not be crushed. In case of contact of the dissolved product

with skin, wash exposed skin with water. In the event of eye exposure, flush the affected eye immediately with water and seek medical advice.
Wash hands after use.

Pregnancy:
Use only according to the benefit/ risk assessment by the responsible veterinarian. The safety of this veterinary medicinal product 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 veterinary medicinal 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 veterinary medicinal 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):
No information available.

7. ADVERSE EVENTS

Horses:

Rare (1 to 10 animals / 10,000 animals treated):	Inappetence, anorexia[1], lethargy[1]. Central nervous system signs[2] (e.g. depression[2], ataxia[2]). Diarrhoea, colic.
Very rare (<1 animal / 10,000 animals treated, including isolated reports):	Sweating.

[1] transient
[2] mild

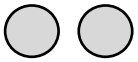
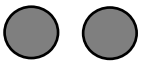
Reporting adverse events is important. It allows continuous safety monitoring of a veterinary medicinal product. Reports should be sent, preferably via a veterinarian, to either the marketing authorisation holder or its local representative or the national competent authority via the national reporting system. See also section ‘contact details’ of the package leaflet for respective contact details.
Alternatively you can report via your national reporting system {national system details}

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

Oral use, once daily.

Starting dose
The starting dose is about 2 µg pergolide/kg (dose range: 1.3 to 2.5 µg/kg; see table below) . The maintenance dose should then be titrated according to the individual response as determined by monitoring (see below), resulting in an average maintenance dose of 2 µg pergolide/kg bodyweight with a dose range of 0.6 to 10 µg pergolide/kg bodyweight.

Starting doses are recommended as follows:

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

Maintenance dose
Lifelong 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.

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 0.50 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 (if the drug is tolerated at that dose) every 4 to 6 weeks until stabilisation occurs. 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

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, see section 6.

10. WITHDRAWAL PERIOD(S)

Not authorised for use in horses intended for human consumption.
Treated horses may never be slaughtered 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.
Store in the original package, in order to protect from light. Do not use this veterinary medicinal product after the expiry date which is stated on the blister and carton after "EXP". The expiry date refers to the last day of that month.

12. SPECIAL PRECAUTIONS FOR THE DISPOSAL

Medicines should not be disposed of via wastewater.
Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal product should be disposed of in accordance with local requirements.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required. These measures should help to protect the environment.

13. CLASSIFICATION OF VETERINARY MEDICINAL PRODUCTS

14. MARKETING AUTHORISATION NUMBER AND PACK SIZES

Vm 36408/5023

Carton box of 10, 30, 60, 90, 100, 120, 160 or 240 tablets.
Not all pack sizes may be marketed.

15. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

August 2023

16. CONTACT DETAILS

Marketing authorisation holder and manufacturer responsible for batch release:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands

Manufacturer responsible for batch release:
Lelypharma BV
Zuiveringsweg 42
8243 PZ Lelystad
The Netherlands

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

Local representatives and contact details to report suspected adverse reactions:

Dechra Veterinary Products Ltd
Sansaw Business Park
Hadnall, Shrewsbury
Shropshire, SY4 4AS
United Kingdom
Tel: 01939 211 200

17. OTHER INFORMATION

Approved: 18 August 2023