ANNEX II

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

CARTON BOX

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pergosafe 2 mg film-coated tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Pergolide 2 mg (equivalent to 2.62 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

Horses (non food-producing)

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

Oral use

7. WITHDRAWAL PERIODS

Withdrawal periods:
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 animals 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. Avoid accidental ingestion by humans. See package leaflet for user warnings.

11. THE WORDS “FOR ANIMAL TREATMENT ONLY”

For animal treatment only.

12. THE WORDS “KEEP OUT OF THE SIGHT AND REACH OF CHILDREN”

Keep out of the sight and reach of children.

13. NAME OF THE MARKETING AUTHORISATION HOLDER

Alfasan Nederland B.V.

14. MARKETING AUTHORISATION NUMBERS

Vm 36408/3028

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

ALUMINIUM BLISTER

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Pergosafe

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Pergolide 2 mg (equivalent to 2.62 mg pergolide mesilate)

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Pergosafe 0.25 / 0.5 / 1 / 2 mg film-coated tablets for horses

2. Composition

Each tablet contains:

Active substance:
Pergolide 0.25/0.5/1.0/2.0 mg
equivalent to 0.33/0.66/1.31/2.62 mg pergolide mesilate

Excipients:
0.25 mg tablet
Core:
Iron oxide yellow 30 µg

Coating:
Titanium dioxide (E171) 0.708 mg
Ferrosoferric oxide 42 µg

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
Ferrosoferric 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
Ferrosoferric oxide 0.28 mg

Film-coated tablet
0.25 mg tablet: Grey sphere shaped, 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 cases of hypersensitivity to the active substance or other ergot derivatives or to any of the excipients.
Do not use in horses less than 2 years of age.

6. Special warnings

Special warnings:
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 safe use in the target species:
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 for each species, routes and method of administration.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
Pergolide, like other ergot derivatives, may cause emesis, dizziness, lethargy or low blood pressure. Severe adverse events such as collapse have been observed. Ingestion may be harmful and associated with severe adverse events, especially in children or people with pre-existing heart conditions. Take utmost care to avoid accidental ingestion of the veterinary medicinal product.

In order to reduce the risk of accidental ingestion:
-Avoid hand-to-mouth contact. Do not eat, drink or smoke when using this product.
- Store and handle this veterinary medicinal product separately away from human medicinal products and handle this product with great care. Replace the blister into the carton and keep it carefully away from children.

- Tablets prepared for administration should be administered immediately and not left unattended.
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 veterinary medicinal product.

This veterinary medicinal product may cause eye irritation. Avoid contact with the eyes including hand-to-eye contact when handling the tablets. Minimise 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.

This veterinary medicinal 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 veterinary medicinal 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.

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:
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):	Sudation (sweating).

[1] transient
[2] mild

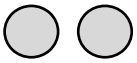
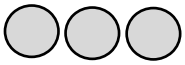
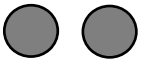
Reporting adverse events is important. It allows continuous safety monitoring of a product. If you notice any side effects, even those not already listed in this package leaflet, or you think that the medicine has not worked, please contact, in the first instance, your veterinarian. You can also report any adverse events to the marketing authorisation holder or the local representative of the marketing authorisation holder using the contact details at the end of this leaflet, or via your national reporting system.

8. Dosage for each species, routes 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	*0.25 mg tablet*		*0.5 mg tablet*		*1 mg tablet*	*2 mg tablet*	*Starting dose*	*Dosage range*
100 – 200 kg							*0.25 mg*	*1.3 - 2.5 µg/kg*
201 - 300 kg							*0.50 mg*	*1.7 – 2.5 µg/kg*
301 - 400 kg		+					*0.75 mg*	*1.9 – 2.5 µg/kg*
or								
301 - 400 kg							*0.75 mg*	*1.9 – 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 0.25 - 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 0.25 - 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 0.25 - 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 Special warnings.

10. Withdrawal periods

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 animals producing milk for human consumption.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 30 °C (only for the 0.25 mg tablet). 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 disposal

Medicines should not be disposed of via wastewater or household waste.

Use take-back schemes for the disposal of any unused veterinary medicinal product or waste materials derived thereof in accordance with local requirements and with any applicable national collection systems. These measures should help to protect the environment.
Ask your veterinary surgeon or pharmacist how to dispose of medicines no longer required.

13. Classification of veterinary medicinal products

Veterinary medicinal product subject to prescription.

14. Marketing authorisation numbers and pack sizes

Vm 36408/3028
Carton box of 10, 30, 60, 90, 100, 120, 160 or 240 tablets.
Not all pack sizes may be marketed.

15. PID LINK (Do not print heading)

[The following statement must be included where reference to the European Union Product Database is included on the product information. This statement is relevant to both UK(GB) and UK(NI) products:]

Find more product information by searching for the 'Product Information Database' on www.gov.uk.

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Alfasan Nederland B.V.
Kuipersweg 9
3449 JA Woerden
The Netherlands
Tel: +31 348 416945
E-mail: pharmacovigilance@alfasan.nl

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

Local representatives and contact details to report suspected adverse reactions :
Dechra Veterinary Products
Sansaw Business Park
Hadnall, Shrewsbury
Shropshire, SY4 4AS
United Kingdom

Tel: 01939 211 200

17. Other information

POM-V

Gavin Hall
Approved: 24 March 2026