

ANNEX III
LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

Carton box

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trilotab 120 mg chewable tablets

2. STATEMENT OF ACTIVE SUBSTANCES

Each tablet contains
Trilostane 120 mg

3. PACKAGE SIZE

30 tablets
100 tablets

4. TARGET SPECIES

Dogs.

5. INDICATIONS

6. ROUTES OF ADMINISTRATION

For oral use.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

9. SPECIAL STORAGE PRECAUTIONS

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.

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

CP- Pharma Handelsgesellschaft mbH

14. MARKETING AUTHORISATION NUMBERS

Vm 20916/3007

15. BATCH NUMBER

Lot {number}

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

Blister

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Trilotab

2. QUANTITATIVE PARTICULARS OF THE ACTIVE SUBSTANCES

Each tablet contains
Trilostane 120 mg

3. BATCH NUMBER

Lot {number}

4. EXPIRY DATE

Exp. {mm/yyyy}

B. PACKAGE LEAFLET

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Trilotab 120 mg chewable tablets for dogs

2. Composition

Each tablet contains:

Active substance:

Trilostane 120 mg

Off-white to light brown with brown spots, round and convex tablet with a cross-shaped break line on one side. Tablets can be divided into 2 or 4 equal parts.

3. Target species

Dogs.

4. Indications for use

For the treatment of pituitary-dependent and adrenal-dependent hyperadrenocorticism (Cushing's disease and syndrome) in dogs.

5. Contraindications

Do not use in animals suffering from primary hepatic disease and/or renal insufficiency.

Do not use in cases of hypersensitivity to the active substance or to any of the excipients.

6. Special warnings

An accurate diagnosis of hyperadrenocorticism is essential.

Where there is no apparent response to treatment, the diagnosis should be re-evaluated. Dose increases may be necessary.

Veterinarians should be aware that dogs with hyperadrenocorticism are at increased risk of pancreatitis. This risk may not diminish following treatment with trilostane.

Special precautions for safe use in the target species:

As the majority of cases of hyperadrenocorticism are diagnosed in dogs between the ages of 10-15 years, other pathological processes are frequently present. It is particularly important to screen cases for primary hepatic disease and renal insufficiency as the product is contraindicated in these cases.

Subsequent close monitoring during treatment should be carried out. Particular attention should be paid to liver enzymes, electrolytes, urea and creatinine.

The presence of diabetes mellitus and hyperadrenocorticism together requires specific monitoring. If a dog has previously been treated with mitotane, its adrenal function will have been reduced. Experience in the field suggests that an interval of at least a month should elapse between cessation of mitotane and the introduction of

trilostane. Close monitoring of adrenal function is advised, as dogs may be more susceptible to the effects of trilostane.

The product should be used with extreme caution in dogs with pre-existing anaemia as further reductions in packed-cell volume and haemoglobin may occur. Regular monitoring should be undertaken.

The tablets are flavoured. In order to avoid any accidental ingestion, store tablets out of reach of animals.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:

Accidental ingestion of the product can cause gastrointestinal effects, such as nausea and vomiting.

Avoid hand to mouth contact. To avoid accidental ingestion, especially by a child, unused tablet parts should be placed back into the blister and carton and carefully kept away from children. Part used tablets should be used at the time of the next dose.

In case of accidental ingestion, seek medical advice immediately and show the package leaflet or carton to the physician.

Wash hands with soap and water after use.

Trilostane may decrease testosterone synthesis and has anti-progesterone properties.

Women who are pregnant or are intending to become pregnant should avoid handling the product.

The product may cause skin and eye irritation. After contact of the product with eyes or skin, wash with plenty of water. If irritation persists, seek medical advice.

This veterinary medicinal product may cause hypersensitivity reactions. People with known hypersensitivity to trilostane should avoid contact with the product. If you develop allergic symptoms such as a skin rash, swelling of the face, lips or eyes following exposure to the product, seek medical advice and show the package leaflet or label to the physician.

Pregnancy and lactation:

Do not use during pregnancy and lactation.

Fertility:

Do not use in breeding animals.

Interaction with other medicinal products and other forms of interaction:

The possibility of interactions with other medicinal products has not been specifically studied. Given that hyperadrenocorticism tends to occur in older dogs, many will be receiving concurrent medication. In clinical studies, no interactions were observed.

The risk of hyperkalaemia developing should be considered if trilostane is used in conjunction with potassium-sparing diuretics or ACE inhibitors. The concurrent use of such drugs should be subject to a risk-benefit analysis by the veterinary surgeon, as

there have been a few reports of deaths (including sudden death) in dogs when treated concurrently with trilostane and an ACE inhibitor.

Overdose:

Lethargy, anorexia, vomiting, diarrhoea, cardiovascular signs, and collapse are all possible signs of hypoadrenocorticism, and could indicate an overdose. Animals that suffer from hyperadrenocorticism may die in case they are treated with doses over 36 mg of trilostane/kg. If an overdose is suspected, consult your veterinarian.

There is no specific antidote for trilostane. In case of overdose treatment should be withdrawn and supportive therapy, including corticosteroids, correction of electrolyte imbalances and fluid therapy may be indicated depending on the clinical signs.

In cases of acute overdosage, induction of emesis followed by administration of activated charcoal may be beneficial.

In case an overdose causes (signs of) hypoadrenocorticism, symptoms are usually quickly reversed following cessation of treatment. However in a small percentage of dogs, effects may be prolonged. Following a one week withdrawal of trilostane treatment, treatment should be reinstated at a reduced dose rate.

Special restrictions for use and special conditions for use:

Not applicable.

Major incompatibilities:

Not applicable.

7. Adverse events

Target species: Dogs.

Rare (1 to 10 animals / 10,000 animals treated):	Ataxia, Muscle tremor Hypersalivation, Bloated Generalised skin reaction
Undetermined frequency (cannot be estimated from the available data)	Adrenal gland disorders, Hypoadrenocorticism ^{1,2} and Addison disease ³ Sudden death Lethargy ⁴ , Anorexia ⁴ Vomiting ⁴ , Diarrhoea ⁴

1: Signs associated with iatrogenic hypoadrenocorticism, including weakness, lethargy, anorexia, vomiting and diarrhoea (particularly if monitoring is not adequate, see section 'Dosage for each species, routes and method of administration'. Signs are generally reversible within a variable period following withdrawal of treatment.).

2: possible result from adrenal necrosis

3 : Acute Addisonian crisis (collapse) (see section 'Special warnings' under 'Overdose').

4 : in the absence of evidence of hypoadrenocorticism.

Corticosteroid withdrawal syndrome or hypocortisolaemia should be distinguished from hypoadrenocorticism by evaluation of serum electrolytes.

Subclinical renal dysfunction may be unmasked by treatment with the product.

Treatment may unmask arthritis due to a reduction in endogenous corticosteroid levels.

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 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.

Administer once daily with a meal.

The starting dose for treatment is approximately 2 mg trilostane /kg bodyweight, based on available combinations of (divided) tablet sizes. This tablet strength is therefore not appropriate for dogs weighing less than 15 kg.

The veterinarian should titrate the dose according to individual response, as determined by monitoring (see below). If a dose increase is required, use combinations of (divided) tablet sizes to slowly increase the once daily dose. A wide range of divisible tablet sizes enables optimum dosing for the individual dog. The veterinarian should prescribe the lowest dose necessary to control the clinical signs. Ultimately, if symptoms are not adequately controlled for an entire 24 hour inter-dose period, the veterinarian should consider increasing the total daily dose by up to 50% and dividing it equally between morning and evening doses.

A small number of animals may require doses significantly in excess of 10 mg per kg body weight per day. In these situations appropriate additional monitoring should be implemented by the prescribing veterinarian.

Monitoring:

Samples should be taken by the veterinarian for biochemistry (including electrolytes) and an ACTH stimulation test pre-treatment and then at 10 days, 4 weeks, 12 weeks, and thereafter every 3 months, following initial diagnosis and after each dose adjustment. It is imperative that ACTH stimulation tests are performed 4 – 6 hours post-dosing to enable accurate interpretation of results. Dosing in the morning is preferable as this will allow your veterinary surgeon to perform monitoring tests 4-6 hours following administration of the dose. Regular assessment of the clinical progress of the disease should also be made at each of the above time points. In the event of a non-stimulatory ACTH stimulation test during monitoring, treatment should be stopped for 7 days and then re-started at a lower dose. The veterinarian should repeat the ACTH stimulation test after a further 14 days. If the result is still non-stimulatory, the veterinarian should stop treatment until clinical signs of hyperadrenocorticism recur. The veterinarian should repeat the ACTH stimulation test one month after re-starting treatment.

9. Advice on correct administration

Do not mix tablets or parts of tablets in a bowl with pelleted food.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.

Do not use this veterinary medicinal product after the expiry date which is stated on the carton after Exp. The expiry date refers to the last day of that month.

Any remaining portions of divided tablets should be returned to the opened blister and given at the next administration.

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 20916/3007

Aluminium-PVC/Aluminium/oPA blisters, containing 10 tablets.

Cardboard box of 3 blister of 10 tablets

Cardboard box of 10 blisters of 10 tablets

Not all pack sizes may be marketed.

15. Date on which the package leaflet was last revised

{DD/MM/YYYY}

Detailed information on this veterinary medicinal product is available in the Union Product Database (<https://medicines.health.europa.eu/veterinary>).

16. Contact details

Marketing authorisation holder and manufacturer responsible for batch release and contact details to report suspected adverse reactions:

CP- Pharma Handelsgesellschaft mbH
Ostlandring 13
31303 Burgdorf
+49 5136 60660
Germany

Local representatives and contact details to report suspected adverse reactions:

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

België/Belgique/Belgien

{Nom/Naam/Name}
<{Adresse/Adres/Anschrift }
BE-0000 {Localité/Stad/Stadt}>
Tél/Tel: + {N° de
téléphone/Telefoonnummer/
Telefonnummer}
<{E-mail}>

Република България

{Наименование}
<{Адрес}
BG {Град} {Пощенски код}>
Тел: + 359 {Телефонен номер}
<{E-mail}>

Česká republika

{Název}
<{Adresa}
CZ {město}>
Tel: +{telefonní číslo}
<{E-mail}>

Danmark

{Navn}
<{Adresse}
DK-0000 {by}>
Tlf: + {Telefonnummer}
<{E-mail}>

Deutschland

{Name}
<{Anschrift}
DE-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Lietuva

{pavadinimas}
<{adresas}
LT {pašto indeksas} {miestas}>
Tel: +370{telefono numeris}
<{E-mail}>

Luxembourg/Luxemburg

{Nom}
<{Adresse}
L-0000 {Localité/Stadt}>
Tél/Tel: + {N° de
téléphone/Telefonnummer}
<{E-mail}>

Magyarország

{Név}
<{Cím}
HU-0000 {Város}>
Tel.: + {Telefonszám}
<{E-mail}>

Malta

{Isem}
<{Indirizz}
MT-0000 {Belt/Raħal}>
Tel: + {Numru tat-telefon}
<{E-mail}>

Nederland

{Naam}
<{Adres}
NL-0000 XX {stad}>
Tel: + {Telefoonnummer}
<{E-mail}>

Eesti

{Nimi}
<{Aadress}>
EE - {Postiindeks} {Linn}>
Tel: +{Telefoninumber}
<{E-mail}>

Ελλάδα

{Όνομα}
<{Διεύθυνση}>
EL-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

España

{Nombre}
<{Dirección}>
ES-00000 {Ciudad}>
Tel: + {Teléfono}
<{E-mail}>

France

{Nom}
<{Adresse}>
FR-00000 {Localité}>
Tél: + {Numéro de téléphone}
<{E-mail}>

Hrvatska

{Ime}
<{Adresa}>
{Poštanski broj} {grad}>
Tel: + {Telefonski broj}
<{e-mail}>

Ireland

{Name}
<{Address}>
IE - {Town} {Code for Dublin}>
Tel: + {Telephone number}
<{E-mail}>

Ísland

{Nafn}
<{Heimilisfang}>
IS-000 {Borg/Bær}>
Sími: + {Símanúmer}
<{Netfang}>

Norge

{Navn}
<{Adresse}>
N-0000 {poststed}>
Tlf: + {Telefonnummer}
<{E-mail}>

Österreich

{Name}
<{Anschrift}>
A-00000 {Stadt}>
Tel: + {Telefonnummer}
<{E-mail}>

Polska

{Nazwa/ Nazwisko:}
<{Adres:}>
PL – 00 000{Miasto:}>
Tel.: + {Numer telefonu:}
<{E-mail}>

Portugal

{Nome}
<{Morada}>
PT-0000–000 {Cidade}>
Tel: + {Número de telefone}
<{E-mail}>

România

{Nume}
<{Adresă}>
{Oraș} {Cod poștal} – RO>
Tel: + {Număr de telefon}
<{E-mail}>

Slovenija

{Ime}
<{Naslov}>
SI-0000 {Mesto}>
Tel: + {telefonska številka}
<{E-mail}>

Slovenská republika

{Meno}
<{Adresa}>
SK-000 00 {Mesto}>
Tel: + {Telefónne číslo}
<{E-mail}>

Italia

{Nome}
<{Indirizzo}
IT-00000 {Località}>
Tel: + {Numero di telefono}>
<{E-mail}>

Suomi/Finland

{Nimi/Namn}
<{Osoite/Adress}
FI-00000 {Postitoimipaikka/Stad}>
Puh/Tel: +
{Puhelinnumero/Telefonnummer}
<{E-mail}>

Κύπρος

{Όνομα}
<{Διεύθυνση}
CY-000 00 {πόλη}>
Τηλ: + {Αριθμός τηλεφώνου}
<{E-mail}>

Sverige

{Namn}
<{Adress}
SE-000 00 {Stad}>
Tel: + {Telefonnummer}
<{E-mail}>

Latvija

{Nosaukums}
<{Adrese}
{Pilsēta}, LV{Pasta indekss }>
Tel: + {Telefona numurs}
<{E-mail}>

United Kingdom (Northern Ireland)

{Name}
<{Address}
{Town} {Postal code} – UK>
Tel: + {Telephone number}
<{E-mail}>>

17. Other information

Approved 03 October 2023

