PARTICULARS TO APPEAR ON THE OUTER PACKAGE (CARTON BOX)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doktyl 30 000 Ph. Eur. Units granules in capsules for opening for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Pancreas powder (porcine) 310.8 – 398.8 mg equivalent to:
Lipase 30,000 Ph.Eur. Units
Amylase not less than 21,750 Ph.Eur. Units
Protease not less than 1,275 Ph.Eur. Units

3. PACKAGE SIZE

50 capsules
100 capsules
200 (2x100) capsules

4. TARGET SPECIES

Dogs.

5. INDICATIONS

Enzyme supplementation to aid in the treatment of maldigestion in dogs with exocrine pancreatic insufficiency (EPI).

6. ROUTES OF ADMINISTRATION

Oral route.

7. WITHDRAWAL PERIODS

8. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by.

9. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C.
Store in a dry place.
Keep the container tightly closed in order to protect from moisture.

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

Nordmark Pharma GmbH

14. MARKETING AUTHORISATION NUMBERS

Vm 55789/5000
Vm 55789/3000

15. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE IMMEDIATE PACKAGE (MULTI-DOSE GLASS BOTTLE)

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

Doktyl 30 000 Ph. Eur. Units granules in capsules for opening for dogs

2. STATEMENT OF ACTIVE SUBSTANCES

Pancreas powder (porcine) 310.8 – 398.8 mg equivalent to:
Lipase 30,000 Ph.Eur. Units
Amylase not less than 21,750 Ph.Eur. Units
Protease not less than 1,275 Ph.Eur. Units

3. TARGET SPECIES

Dogs.

4. ROUTES OF ADMINISTRATION

Oral route. Read the package leaflet before use.

5. WITHDRAWAL PERIODS

Not applicable

6. EXPIRY DATE

Exp. {mm/yyyy}

Once opened, use by.

7. SPECIAL STORAGE PRECAUTIONS

Do not store above 25 °C
Store in a dry place.
Keep the container tightly closed in order to protect from moisture.

8. NAME OF THE MARKETING AUTHORISATION HOLDER

Nordmark Pharma GmbH

9. BATCH NUMBER

Lot {number}

PARTICULARS TO APPEAR ON THE PACKAGE LEAFLET:

PACKAGE LEAFLET

1. Name of the veterinary medicinal product

Doktyl 30 000 Ph. Eur. Units granules in capsules for opening for dogs

2. Composition

Pancreas powder (porcine) 310.8 – 398.8 mg equivalent to:
- Lipase 30,000 Ph.Eur. Units
- Amylase not less than 21,750 Ph.Eur. Units
- Protease not less than 1,275 Ph.Eur. Units

White-coloured capsules filled with gastro-resistant micro-pellets.

3. Target species

Dogs.

4. Indications for use

Enzyme supplementation to aid in the treatment of maldigestion in dogs with exocrine pancreatic insufficiency (EPI).

5. Contraindications

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

6. Special warnings

Special warnings:
Should hypersensitivity occur, discontinue medication and treat the hypersensitivity symptomatically.

Dogs with EPI can have reduced bicarbonate secretion. The veterinary medicinal product may not be fully efficacious in dogs with reduced bicarbonate secretion as this is essential to reach a pH which ensures pancreatic enzyme activity.

Hypocobalaminaemia can be seen in a large proportion of dogs with EPI and negatively impacts long-term survival. Diagnosed cobalamin deficiency should be addressed appropriately.

Appropriate diet is important for the successful management of patients with EPI. High fibre diets should be avoided as published studies have shown they can impair fat absorption and interfere with pancreatic enzyme action. When changing diet, the effect of the veterinary medicinal product should be monitored, as a change in dosing may be necessary.

Several other associated pathophysiological changes can occur in EPI patients and should be addressed as appropriate.

In cases of inadequate response to therapy, further clinical investigations may be required to determine the clinical status of the patient, and it may be necessary to consider other causes of poor response.

As EPI is often progressive and lifelong, dogs should be re-examined at adequate intervals to ensure proper clinical response and dosing.

The veterinary medicinal product consists of a capsule filled with gastro-resistant micro pellets containing the active substance pancreatin. The concurrent use of gastric pH modifying drugs, such as proton pump inhibitors and H2 receptor antagonists may reduce the effectiveness of the gastro-resistant coating leading to degradation and reduction of enzyme activity.

Special precautions for safe use in the target species:
The diagnosis of exocrine pancreatic insufficiency can be confirmed with appropriate laboratory tests such as serum trypsin-like immunoreactivity.

Alterations to the intestinal microbiome (dysbiosis) can occur in dogs with exocrine pancreatic insufficiency, before and during enzyme replacement treatment. Appropriate management may be required.

Based on published human literature, very high doses of pancreatin may be associated with increased risk of hyperuricosuria and hyperuricaemia, especially in dogs with a genetic predisposition to hyperuricosuria including German shepherd dogs.

The enteric coating of the micropellets is designed to prevent contact of the enzymes with the oral mucosa, therefore preventing local irritation. However, it is theoretically possible that mastication (chewing) may affect the integrity of the enteric coating, which could lead to exposure of the oral mucosa to the enzymes, potentially resulting in oral mucosal damage. Although this is considered an unlikely event, if signs of oral discomfort, ulceration, or other adverse reactions are observed, consult a veterinarian.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
The contents of capsules may cause contact dermatitis and/or hypersensitivity reactions, including anaphylaxis.. People with a known hypersensitivity to pancreatin should avoid contact with the product.

Personal protective equipment consisting of gloves should be worn by people with protein contact dermatitis when handling this product or food to which the product has been added.
Do not crush the contents of capsules.
In case of dermal contact, wash hands with soap and water.
Ingestion of this product may cause gastrointestinal effects such as nausea, vomiting, and diarrhoea, dizziness, and allergy-type reactions. Accidental ingestion, particularly by a child should be avoided.
Irritation of oral mucosa may occur following contact with partially chewed medication in dog food. Any uneaten medicated food should be disposed of immediately and the bowl washed thoroughly.
In case of accidental ingestion, seek medical advice and show the package leaflet or the label to the physician.
Wash hands after use.

Pregnancy and lactation:
The safety of the veterinary medicinal product has not been established during pregnancy or lactation.
Laboratory studies in rats and rabbits have not produced any evidence of teratogenic, foetotoxic, or maternotoxic effects.
Use only accordingly to the benefit-risk assessment by the responsible veterinarian.

Interaction with other medicinal products and other forms of interaction
None known.

Overdose:
Administration of non-enteric coated pancreatin at up to 24,060 Ph.Eur. Units/kg/day (lipolytic activity) for four weeks in healthy dogs (with a functioning pancreas) resulted in no significant clinical signs that could be attributed to treatment.

Special restrictions for use and special conditions for use:
Not applicable.

Major incompatibilities:
Not applicable.

7. Adverse events

Dogs:

Common (1 to 10 animals / 100 animals treated):	Digestive tract disorders (e.g. diarrhoea and vomiting)*

*Diarrhoea and vomiting may be observed, although these signs may also be related to the disease condition exocrine pancreatic insufficiency.

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 at:
Website: https://www.gov.uk/report-veterinary-medicine-problem/animal-reacts-medicine
e-mail: adverse.events@vmd.gov.uk

8. Dosage for each species, routes and method of administration

To ensure a correct dosage, body weight should be determined as accurately as possible.
This veterinary medicinal product is intended for oral administration.

The following starting doses are based on twice daily feeding:

Body weight (kg)	Number of capsules/meal	Lipolytic activity (Ph.Eur. Units)/meal	Max. lipolytic activity/kg/meal	Min. lipolytic activity/kg/meal
6 - 15	*1*	*30,000*	*5,000*	*2,000*
15.1 - 30	*2*	*60,000*	*3,974*	*2,000*
30.1 - 45	*3*	*90,000*	*2,990*	*2,000*
45.1 - 60	*4*	*120,000*	*2,661*	*2,000*
60.1 - 75	*5*	*150,000*	*2,496*	*2,000*
75.1 - 90	*6*	*180,000*	*2,397*	*2,000*
>90	*7*	*210,000*	*2,331*	

It is not possible to accurately dose dogs by dividing the contents of one capsule between more than one meal. Therefore, due to the presentation of the capsules, accurate dosing of dogs below 6 kg cannot be determined.

The effect of in-between meal snacks and treats (i.e. without enzyme substitution) on the stability of EPI patients has not been determined for this veterinary medicinal product and the addition of such feed items should be made only under the direction of a veterinarian.

An adjustment of the dose (increase or decrease) to the individual degree of maldigestion may be necessary. Dose adjustments must be carried out under the direction of a veterinarian. Reassessment after initiation of therapy should include clinical status, body weight, appetite, food intake, characteristics and quantity of stools and defaecation frequency. Time to improvement can vary, but changes are typically noticed within 2-4 weeks. The dose should be adjusted at time points appropriate to the individual.

The dose can be adjusted in increments or decrements of one or more capsules from the starting dose. The recommended maximum incremental dose increase is outlined in the table below.

Once the target clinical status has been reached, the dose may be reduced until the minimum effective dose is identified. As in rare cases spontaneous cure may be possible, treated animals should be monitored regularly to reassess the needed individual dosage.

The safety of the veterinary medicinal product at doses above 5000 Ph.Eur. Units/kg/meal (lipolytic activity) (10,000 Ph.Eur.Units/kg/day (lipolytic activity)) has not been determined. Increasing beyond the starting dose for dogs of between 6 and 11.9kg or between 15.1 and 17.9kg bodyweight would lead to the maximum recommended lipolytic activity per kg per meal (5000 Ph.Eur. Units/kg/meal) being exceeded and is therefore not recommended.

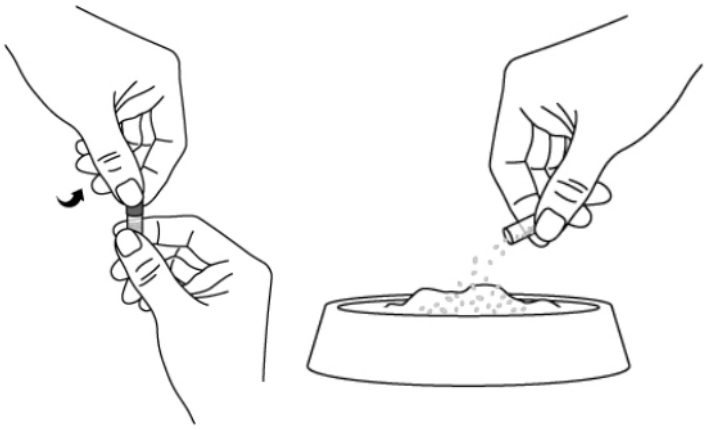
Body weight (kg)	Number of capsules/meal	
	Starting dose	Recommended maximum increment for dose increase*
6 - 11.9	*1*	*Not recommended*
12 - 15	*1*	*1*
15.1 - 17.9	*2*	*Not recommended*
18 - 24.9	*2*	*1*
25 - 39.9	*2 - 3 (see above table)*	*2*
40 - 49.9	*3 - 4 (see above table)*	*3*
50 - 65.9	*4 - 5 (see above table)*	*4*
66 - 79.9	*5 - 6 (see above table)*	*5*
80 - 99.9	*6 - 7 (see above table)*	*6*
>100	*7*	*7*

*For certain weights it is possible to perform additional dose increases, in most cases using smaller increments, and still remain below the recommended maximum dose of 5000 Ph.Eur. Units/kg/meal (lipolytic activity) (10,000 Ph.Eur.Units/kg/day (lipolytic activity)).

9. Advice on correct administration

Administer by opening the capsule and sprinkling the contents onto food intended for immediate consumption. Food containing the veterinary medicinal product must be

consumed within 15 minutes, after this the effectiveness of the enzymes may be reduced.
Hold the bottom half of the capsule vertically and remove the cap by twisting it slightly upwards.



Evenly sprinkle the contents onto the dog's food.

After addition of the veterinary medicinal product, the meal should be given to the dog straight away. Due to the formulation, do not pre-incubate the veterinary medicinal product with meals before administration.

10. Withdrawal periods

Not applicable.

11. Special storage precautions

Keep out of the sight and reach of children.
Do not store above 25 °C.
Store in a dry place.
Keep the container tightly closed in order to protect from moisture.

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

Shelf life after first opening the immediate packaging: 6 months.

Once the jar is opened, using the shelf-life after first opening, calculate the discard date and record in the space provided on the label.

12. Special precautions for disposal

Medicines should not be disposed of via wastewater.
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 55789/5000
Vm 55789/3000

50 capsules.
100 capsules.
200 (2x100) capsules.
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, manufacturer responsible for batch release and contact details to report suspected adverse reactions:
Nordmark Pharma GmbH
Pinnauallee 4
25436 Uetersen
Germany

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

17. Other information

POM-V

This veterinary medicinal product for oral administration consists of hard gelatin capsules containing pure pancreatin in the form of micro-pellets. These micro-pellets

are covered by an enteric coating. Native pancreas lipase is not stable in an acid environment and is inactivated at pH-values below 4. The film-coating of the veterinary medicinal product protects the active ingredient from digestion by gastric juice during passage through the stomach. The enzyme activity has been shown to remain unaffected by pH 1 and pH 4 for at least 120 minutes. The rising pH values encountered during transit through the small intestine results in rapid dissolution of the gastro-resistant coating.
Targeted release of the active ingredient from the micro-pellets occurs in the small intestine. In this way, each single enteric-coated micro-pellet represents an independent, pH-controlled release system.

Gavin Hall
Approved: 26 August 2026