Issued: April 2016
AN: 00923/2013

PART IB - 2

LABELLING AND PACKAGE LEAFLET

PRIMAZYM 40000 PH. EUR. U. CAPSULE FOR DOGS

LABELLING AND PACKAGE LEAFLET

A. LABELLING

PARTICULARS TO APPEAR ON THE OUTER PACKAGE

outer carton

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMAZYM
40000 Ph. Eur. U.
Capsules
For dogs
Pancreas powder

2. STATEMENT OF ACTIVE AND OTHER SUBSTANCES

1 hard capsule filled with gastro-resistant micro-pellets contains:
Active substances:
Pancreas powder (porcine) 351 -456 mg equivalent to:

lipase	40000	Ph. Eur. Units
amylase	not less than 25000	Ph. Eur. Units
protease	not less than 1500	Ph. Eur. Units

3. PHARMACEUTICAL FORM

Capsule, hard
Filled with gastro-resistant micro-pellets

4. PACKAGE SIZE

20 / 50 / 100 capsules

5. TARGET SPECIES

Dogs

6. INDICATION(S)

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7. METHOD AND ROUTE(S) OF ADMINISTRATION

Read the package leaflet before use.
For oral administration.

8. WITHDRAWAL PERIOD

Not applicable for non-food producing animals

9. SPECIAL WARNING(S), IF NECESSARY

Read the package leaflet before use.

10. EXPIRY DATE

EXP {month/year}
Shelf life after first opening the immediate packaging: 6 months.
Once opened, use by: __/__/__

11. SPECIAL STORAGE CONDITIONS

Do not store above 30°C. After opening: store in a dry place and keep the bottle tightly closed in order to protect from moisture.

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

Any unused product or waste materials should be disposed of in accordance with national requirements.

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

Eurovet Animal Health BV
Handelsweg 25, 5531 AE Bladel
The Netherlands

16. MARKETING AUTHORISATION NUMBER(S)

Vm 16849/4050

17. MANUFACTURER'S BATCH NUMBER

Lot {number}

POM-V

MINIMUM PARTICULARS TO APPEAR ON SMALL IMMEDIATE PACKAGING UNITS

{NATURE/TYPE}

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMAZYM
40000 Ph. Eur. U.
Capsules
For dogs
Pancreas powder

2. QUANTITY OF THE ACTIVE SUBSTANCE(S)

1 hard capsule filled with gastro-resistant micro-pellets contains:
Active substances:
Pancreas powder (porcine) 351 – 456 mg equivalent to:

lipase	40000	Ph.Eur. Units
amylase	not less than 25000	Ph.Eur. Units
protease	not less than 1500	Ph.Eur. Units

3. CONTENTS BY WEIGHT, BY VOLUME OR BY NUMBER OF DOSES

20 / 50 / 100 capsules

4. ROUTE(S) OF ADMINISTRATION

For oral administration

5. WITHDRAWAL PERIOD

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6. BATCH NUMBER

Lot {number}

7. EXPIRY DATE

EXP {month/year}
Once opened, use by: __/__/__

8. THE WORDS "FOR ANIMAL TREATMENT ONLY"

For animal treatment only.

POM-V

B. PACKAGE LEAFLET

PACKAGE LEAFLET FOR:
PRIMAZYM 40000
Ph. Eur. U.
Capsules for dogs

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

Marketing authorisation holder and manufacturer responsible for batch release:
Eurovet Animal Health B.V. Handelsweg 25, 5531 AE Bladel, The Netherlands

2. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMAZYM 40000 Ph. Eur. U. capsules for dogs
Pancreas powder

3. STATEMENT OF THE ACTIVE SUBSTANCES AND OTHER INGREDIENTS

1 hard capsule filled with gastro-resistant micro-pellets contains**:**
Active substances:
Pancreas powder (porcine) 351 – 456 mg equivalent to:

lipase	40000	Ph.Eur. Units
amylase	not less than 25000	Ph.Eur. Units
protease	not less than 1500	Ph.Eur. Units

4. INDICATION(S)

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

5. CONTRAINDICATIONS

Do not use in dogs known to be hypersensitive to pork protein or to any of the excipients of the veterinary medicinal product.

6. ADVERSE REACTIONS

The adverse events that have been observed are gastrointestinal in nature and may actually represent symptoms of the underlying disease or related conditions, such as diarrhoea, greasy stools and flatulence. No serious adverse events have been reported in relation to use of this product, but tolerance has not been evaluated beyond 60 days. If you notice any serious effects or other effects not mentioned in this leaflet, please inform your veterinary surgeon.

7. TARGET SPECIES

Dogs.

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

This product is intended for oral administration.

The following starting doses are recommended based on twice daily feeding:

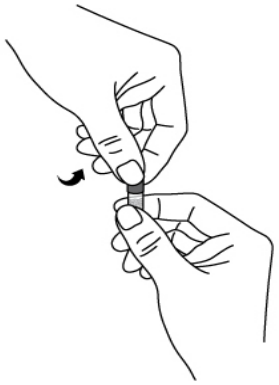
Body weight (kg)	Number of Primazym capsules / meal
≤ 16	1
> 16 - ≤ 40	2
> 40 - ≤ 69	3
> 69 - ≤ 101	4

It is advised to feed dogs suffering from EPI at least twice daily. In-between meals and/or snacks without enzyme substitution must be avoided.

The initial recommended dose is merely a starting point. Reassessment is recommended 2-4 weeks after initiation of therapy and should include clinical status, body weight, appetite, food intake, characteristics and quantity of stools and defaecation frequency. An adjustment of the dosage (increase or decrease) to the individual degree of maldigestion may be necessary. The dose can be adjusted in increments or decrements of 1 capsule per meal. As in rare cases spontaneous cure may be possible, treated animals should be monitored regularly to reassess the needed individual dosage. It is recommended to consult a veterinarian for advice.

9. ADVICE ON CORRECT ADMINISTRATION

The preferred method of administration is to open the capsule and sprinkle the contents onto the dog`s food.



Hold the transparent bottom half of the capsule vertically and remove the coloured cap by twisting it slightly upwards.

Evenly sprinkle the contents onto the dog´s food.

After addition of the product, the meal should be given to the dog straight away. To secure optimal efficacy the veterinary medicinal product should be added to every meal.

10. WITHDRAWAL PERIOD

Not applicable.

11. SPECIAL STORAGE PRECAUTIONS

Keep out of the sight and reach of children.
Do not store above 30°C. After opening: store in a dry place and keep the bottle tightly closed in order to protect from moisture.
Do not use this veterinary medicinal product after the expiry date which is stated on the bottle after EXP. Shelf life after first opening the bottle: 6 months.

12. SPECIAL WARNING(S)

Special warnings for each target species:
Should hypersensitivity occur, discontinue medication and treat symptomatically. The 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.
Since hypocobalaminaemia can be seen in the majority of dogs with EPI and negatively impacts long term survival, cobalamin insufficiency should be treated concurrently. Additional dietary control may be essential for the successful management of patients responding unsatisfactorily to the product. When changing diet the effect of the veterinary medicinal product should be monitored, as a change in dosing may be necessary.

In case of maldigestion caused by EPI, life-long treatment is required. As EPI is often progressive, dogs should be re-examined at adequate intervals to ensure proper clinical response and dosing.

Special precautions for use in animals:
The diagnosis of exocrine pancreatic insufficiency can be confirmed with appropriate laboratory tests such as serum trypsin-like immunoreactivity. Small intestinal bacterial overgrowth is common in dogs with exocrine pancreatic insufficiency, before and during enzyme replacement treatment, and therefore treatment for this condition may be required. The capsule is suitable for consumption.

Special precautions to be taken by the person administering the veterinary medicinal product to animals:
This product may cause contact dermatitis in susceptible people. It is recommended that those people who know that they have protein contact dermatitis wear protective gloves when handling the product, or food to which the product has been added. Wash hands after use.
Ingestion of the product may cause gastrointestinal disturbance and/or mild allergy-type reactions. In case of accidental ingestion and when symptoms do not resolve soon afterwards, seek medical advice and show the package leaflet or label to the physician.

Use during pregnancy and lactation:
The safety of the veterinary medicinal product has not been established in pregnant and lactating bitches. Laboratory studies (rats and rabbits) have not produced any evidence of teratogenic, foetotoxic, or maternotoxic effects. Use according to the risk/benefit assessment by the veterinarian.

Overdose (symptoms, emergency procedures, antidotes, if necessary):
Overdoses of two to three times the label recommended starting dose for four weeks in healthy dogs resulted in no significant clinical signs that could be attributed to treatment.

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

Any unused veterinary medicinal product or waste materials derived from such veterinary medicinal products should be disposed of in accordance with local requirements.

14. DATE ON WHICH THE PACKAGE LEAFLET WAS LAST APPROVED

February 2016

15. OTHER INFORMATION

Vm 16849/4050

POM-V

Prescription Only Medicine – Veterinarian

Pack sizes: 20, 50 and 100 capsules.
Not all pack sizes may be marketed.

Information for the treating veterinarian:

The diagnosis of exocrine pancreatic insufficiency can be confirmed with appropriate laboratory tests such as serum trypsin-like immunoreactivity. Small intestinal bacterial overgrowth is common in dogs with exocrine pancreatic insufficiency, before and during enzyme replacement treatment, and therefore treatment for this condition may be required.

Pharmacodynamic properties:
Pancreatin hydrolyses fats to glycerol and fatty acids, breaks down protein into peptides and derived substances, and converts starch into dextrins and sugars.

Pharmacokinetic particulars:
Pancreatin is not absorbed to a clinically relevant amount by the gastrointestinal tract. The non-absorbed part of pancreatin is either digested or eliminated in faeces.

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 product protects the active ingredient from digestion by gastric juice during passage through the stomach. The enzyme activity remains unaffected by 0.1 N hydrochloric acid (pH = 1) for at least 120 minutes.

Entering the duodenum, the abrupt rise of pH-value causes a quick 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.

Due to the special formulation of the product, it is not necessary, nor recommended, to incubate the food with the product to allow predigesting.

Approved: 08/04/2016