SUMMARY OF PRODUCT CHARACTERISTICS

1. NAME OF THE VETERINARY MEDICINAL PRODUCT

PRIMAZYM
40000 Ph. Eur. U.
capsules for dogs

2. QUALITATIVE AND QUANTITATIVE COMPOSITION

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

For a full list of excipients, see section 6.1

3. PHARMACEUTICAL FORM

Capsule, hard
Filled with gastro-resistant micro-pellets.

4. CLINICAL PARTICULARS

4.1. Target species

Dogs.

4.2. Indications for use, specifying the target species

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

4.3. Contra-indications

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

4.4. 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.

4.5. Special precautions for use

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.

4.6. Adverse reactions (frequency and seriousness)

The adverse events that have been observed are gastrointestinal in nature and may actually represent symptoms of the underlying disease or associated gastrointestinal 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.

4.7. Use during pregnancy, lactation

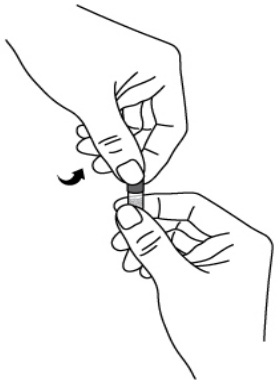
The safety of the veterinary medicinal product has not been established in pregnant and lactating bitches. Laboratory studies (rats and rabbits) have not produced any evidence of teratogenic, foetotoxic, or maternotoxic effects.
Use according to the risk/benefit assessment by the veterinarian.

4.8. Interactions with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

This product is intended for oral 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.

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.

4.10. 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.

4.11. Withdrawal periods

Not applicable.

5. PHARMACOLOGICAL PROPERTIES

Pharmacotherapeutic group: digestive enzymes.

ATCvet code: QA09A A 02.

5.1. Pharmacodynamic properties

This veterinary medicinal product contains standardised pancreatin (pancreas powder from pigs). Pancreatin contains the enzymes excreted by the pancreas: lipase, amylase, trypsin and multiple other enzymes.
Pancreatin hydrolyses fats to glycerol and fatty acids, breaks down protein into peptides and derived substances, and converts starch into dextrins and sugars.

5.2. 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.

6. PHARMACEUTICAL PARTICULARS

6.1. List of excipients

The coating of the micro-pellets consists of
Methacrylic acid - ethyl acrylate -copolymer (1:1),
Triethyl citrate,

Talc
Simethicone emulsion.

The enteric-coated micro-pellets are filled into hard gelatin capsules which consist of
Gelatin,
Red Iron Oxide, E 172,
Titanium dioxide, E171
Sodium laurylsulphate.

The ink consists of:
Titanium dioxide, E171
Shellac
Ethanol, anhydrous
Isopropyl Alcohol
Butyl Alcohol
Propylene Glycol
Sodium Hydroxide
Polyvidone

6.2. Incompatibilities

Not applicable

6.3. Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 3 years
Shelf life after first opening the immediate packaging: 6 months.

6.4. Special precautions for storage

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.

6.5. Nature and contents of immediate packaging

Amber coloured glass bottle (Ph. Eur. type III) with snap-on LDPE caps:
Volume 50 ml containing 20 capsules,
Volume 100 ml containing 50 capsules,
Volume 175 ml containing 100 capsules.

Not all pack sizes may be marketed.

6.6. Special precautions for the disposal of unused veterinary medicinal product or waste materials, derived from the use of such products if appropriate.

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

7. MARKETING AUTHORISATION HOLDER

Eurovet Animal Health BV
Handelsweg 25
5531 AE Bladel
The Netherlands

8. MARKETING AUTHORISATION NUMBER

Vm 16849/4050

9. DATE OF FIRST AUTHORISATION

08 April 2016

10. DATE OF REVISION OF THE TEXT

April 2016

Approved: 08/04/2016