

Summary of Product Characteristics

1 NAME OF THE VETERINARY MEDICINAL PRODUCT

Tryplase 500mg capsules

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains :

Active Substance

*Pancreas Powder 500 mg

* to provide:

Amylase not less than 9,000 Ph. Eur. units

Lipase not less than 12,600 Ph. Eur. units

Protease not less than 450 Ph. Eur. units

Excipients

Indigotin 238 mg

Tartrazine 114 mg

Titanium dioxide 1.0 mg

For a full list of excipients, see section 6.1

3 PHARMACEUTICAL FORM

Capsules, hard.

4 CLINICAL PARTICULARS

4.1 Target Species

Dogs and cats

4.2 Indications for use, specifying the target species

Tryplase is indicated in cases of indigestion and diarrhoea caused by deficiencies in pancreatic exocrine secretion. Administration may also be indicated in cases of diarrhoea where persistent hyper-motility of the intestine prevents adequate utilisation of pancreatic enzymes.

4.3 Contraindications

None.

4.4 Special warnings for each target species

None.

4.5 Special precautions for use**Special precaution(s) for use in animals**

None.

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

Wash hands after use.

4.6 Adverse reactions (frequency and seriousness)

None known.

4.7 Use during pregnancy, lactation or lay

May be used during pregnancy and lactation.

4.8 Interaction with other medicinal products and other forms of interaction

None known.

4.9 Amounts to be administered and administration route

Dogs: The contents of 2-5 capsules per day, sprinkled on food or milk. 5 capsules are sufficient to digest the declared fat, protein and carbohydrate content of a 1 lb tin of dog food.

Cats: The contents of 1-2 capsules per day, sprinkled on food or milk. 2 capsules are sufficient to digest the declared fat, protein and carbohydrate content of a ½ lb tin of cat food.

4.10 Overdose (symptoms, emergency procedures, antidotes), if necessary

No specific treatment or antidote recommended.

4.11 Withdrawal Period(s)

Not applicable.

5 PHARMACOLOGICAL or IMMUNOLOGICAL PROPERTIES

Pharmacotherapeutic group: Multi-enzymes.

ATCvet code: QA09AA02

5.1 Pharmacodynamic properties

Trypsin contains the three major pancreatic enzymes responsible for the digestion of fat, protein and starch in the small intestine. The capsules contain a concentrated extract of pig pancreas, standardised to provide the following activity:

Lipase	- sufficient to digest 17 g of dietary fat
Trypsin	- sufficient to digest 34 g of dietary protein
Amylase	- sufficient to digest 40 g of dietary starch

5.2 Pharmacokinetic properties

The product is administered orally and acts locally in the digestive tract, therefore pharmacokinetic data is not applicable.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Calcium Carbonate
Magnesium Stearate
Talc purified
Lactose monohydrate
Indigotin (E132)
Tartrazine (E102)
Titanium dioxide (E171)
Gelatin

6.2 Incompatibilities

None known

6.3 Shelf-life

Shelf life of the veterinary medicinal product as packaged for sale: 1 year.

6.4 Special precautions for storage

Do not store above 25°C. Protect from light.
Store in tightly closed original container. Store in a dry place.
Keep container in outer carton.

6.5 Nature and composition of immediate packaging

Opaque, white polypropylene securitainers with a polyethylene lid containing 100 or 250 capsules.
Not all pack sizes may be marketed.

6.6 Special precautions for the disposal of unused veterinary medicinal products or waste materials

Unused product or waste material should be disposed of in accordance with current practice for pharmaceutical waste under national waste disposal regulations.

7 MARKETING AUTHORISATION HOLDER

Intervet Ireland Ltd.
Magna Drive
Magna Business Park
Citywest Road
Dublin 24

8 MARKETING AUTHORISATION NUMBER(S)

VPA: 10996/043/001

9 DATE OF THE FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

28th August 2009

10 DATE OF REVISION OF THE TEXT

January 2013