Summary of Product Characteristics

1 NAME OF THE MEDICINAL PRODUCT

Nutrizym 22,000 Capsules.

2 QUALITATIVE AND QUANTITATIVE COMPOSITION

Each capsule contains Pancreas Powder 313mg with not less than the following activities: Lipase 22,000 FIP Units, Protease 1,100 FIP Units and Amylase 19,800 FIP Units.

For a full list of excipients, see section 6.1.

3 PHARMACEUTICAL FORM

Capsule.
Hard gelatin capsule, yellow with a red cap and containing white enteric coated pancreas powder minitablets.

4 CLINICAL PARTICULARS

4.1 Therapeutic Indications

For the symptomatic relief of pancreatic exocrine insufficiency such as in fibrocystic disease of the pancreas and chronic pancreatitis.

4.2 Posology and method of administration

Since the individual response to pancreatic supplements is variable, the number of capsules taken may need to be titrated to the individual according to symptoms. Capsules should be swallowed whole with water. Where the swallowing of capsules is difficult, the capsule may be opened, the pellets or minitablets removed and swallowed with fluid or mixed with soft food which does not require chewing. In the latter case the food should be swallowed unchewed and it should be used straight away.

The suggested starting dose is as follows:
Adults (including the elderly) and children: 1 - 2 capsules with meals

Further dose increases, if required, should be added slowly, with careful monitoring of response and symptomatology. If food is taken without Nutrizym 22,000 inadvertently, the next meal should be taken with the capsules at the recommended dose.

Colonic damage has been reported in children with cystic fibrosis taking in excess of 10,000 units of lipase /kg/day. The daily dose of pancreatic enzymes for most patients should remain below 2500 units of lipase per kg per meal (10,00 units per kg per day). Higher doses should be used with caution and only if quantitative measures demonstrate substantially improved absorption with such treatment. This applies particularly to young children.

It is important to ensure adequate hydration of patients at all times whilst treating with Nutrizym 22,000.

4.3 Contraindications

In children aged 15 years and under with cystic fibrosis. Known hypersensitivity to the active ingredient (porcine pancreatin) or any of the excipients.

4.4 Special warnings and precautions for use

Hyperuricaemia and hyperuricosuria have been reported to occur in cystic fibrosis patients; pancreatin extracts contain a very small amount of purine which might, in high doses, contribute to this condition.
Patients who are taking or have been given in excess of 10,000 units of lipase/kg/day are at risk of developing colon damage. Abdominal symptoms (which are not usually experienced by the patient) or changes in abdominal symptoms should be reviewed to exclude the possibility of colonic damage - especially if the patient is taking in excess of 10,000 units of lipase/kg/day. All patients should be reviewed regularly.

4.5 Interaction with other medicinal products and other forms of interaction

None known.

4.6 Fertility, pregnancy and lactation

Animal studies are insufficient with respect to effects on pregnancy, embryonal foetal developments parturition and postnatal development. The potential risk for humans is unknown. Nutrizym 22,000 should not be used during pregnancy unless clearly necessary. There is insufficient/limited information on the excretion of pancreatic enzymes in human or animal breast milk. A risk to the suckling child cannot be excluded. A decision on whether to continue/discontinue breast feeding or to continue/discontinue therapy with Nutrizym 22,000 should be made taking into account the benefit of breast feeding to the child and the benefit of Nutrizym 22,000 therapy to the woman.

4.7 Effects on ability to drive and use machines

No studies on the effects on the ability to drive and use machines have been performed.

4.8 Undesirable effects

The most frequently occurring undesirable effects are gastrointestinal.
Hypersensitivity reactions may occur. As with any pancreatin extract, high doses may cause buccal and perianal irritation, in some cases resulting in inflammation.

Stricture of the ileo-caecum and large bowel, and colitis have been reported in children with cystic fibrosis taking pancreatic enzymes. Abdominal symptoms (those not usually experienced by the patient) or changes in abdominal symptoms should be reviewed to exclude the possibility of colonic damage - especially if the patient is taking in excess of 10,000 units of lipase/kg/day.

4.9 Overdose

Inappropriately large doses could result in abdominal discomfort, nausea, vomiting and perianal irritation or inflammation.

5 PHARMACOLOGICAL PROPERTIES

5.1 Pharmacodynamic properties

Pharmacotherapeutic group: Enzyme preparation.
ATC code: A09AA02

The active ingredient is a preparation of porcine pancreas with lipase, amylase and protease activity. Lipase enzymes hydrolyse fats to glycerol and fatty acids. Amylase converts starch into dextrins and sugars and protease enzymes change proteins into proteoses and derived substances.

5.2 Pharmacokinetic properties

The active ingredient of Nutrizym 22000 contains enzymes involved in the digestive process. During the enzymatic degradation of food substances the enzymes themselves are degraded. Any breakdown products are those that would be expected to appear following normal digestion.

5.3 Preclinical safety data

Preclinical data are not available.

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Uncoated minitablets:
Castor Oil (hydrogenated)
Colloidal anhydrous silica
Magnesium stearate
Croscarmellose sodium
Microcrystalline cellulose

Minitablet coating:
Simethicone emulsion 30%
Methacrylic acid - ethyl acrylate copolymer (1:1) 30% dispersion
Talc
Triethyl citrate

Gelatin capsules:
Titanium dioxide
Iron oxide, red (E172)
Iron oxide, yellow (E172)
Gelatin

6.2 Incompatibilities

Not applicable.

6.3 Shelf Life

Twenty months.

6.4 Special precautions for storage

Store below 25°C.
Store in the tightly closed original container.

6.5 Nature and contents of container

Polyethylene or polypropylene containers with polyethylene tamper evident closures containing 50, 100, 200 or 500 capsules.

Not all pack sizes may be marketed.

6.6 Special precautions for disposal of a used medicinal product or waste materials derived from such medicinal product and other handling of the product

No special requirements.

7 MARKETING AUTHORISATION HOLDER

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8 MARKETING AUTHORISATION NUMBER

PA 54/64/3

9 DATE OF FIRST AUTHORISATION/RENEWAL OF THE AUTHORISATION

Date of first authorisation: 23 June 1993

Date of last renewal: 23 June 2008

10 DATE OF REVISION OF THE TEXT

November 2010