

# PACKAGE LEAFLET: INFORMATION FOR THE USER

## Pancreote 10000 capsules pancreatin

### User Information Leaflet

#### Pancreote 10000 throughout the following:

- Pancreote 10000 is a pancreatic enzyme supplement for people whose bodies do not make enough enzymes to digest their food.
- Take the number of capsules as prescribed by your doctor or dietician.
- Take Pancreote 10000 during or immediately after a meal or a snack and drink plenty of water.
- Do not take Pancreote 10000 if you are allergic to pork or any pig product.
- If you experience severe abdominal pain while taking Pancreote 10000, contact your doctor immediately.
- Most people do not have problems taking Pancreote 10000 but side effects can occur (see section 4).

Please read the rest of this leaflet carefully before you start taking these capsules. It includes other important information on the safe and effective use of this medicine that might be especially important for you

#### How to find the information you need

1. About Pancreote 10000 What Pancreote 10000 is and how it works.
2. Before you take Pancreote 10000 Who can take Pancreote 10000? Can you take Pancreote 10000 if you are pregnant or breast-feeding? Driving or operating machinery
3. How to take Pancreote 10000 How much Pancreote 10000 you should take. When you should take Pancreote 10000. How you should take Pancreote 10000. What to do if you take too much Pancreote 10000. What to do if you forget a dose.
4. Possible side effects Abdominal symptoms (such as abdominal pain). Side effects and what to do if you get them.
5. How to store Pancreote 10000 How and where to keep your capsules.
6. Further information The ingredients in Pancreote 10000. More information about cystic fibrosis and pancreatitis.

This medicine has been prescribed for you personally. Don't offer it to other people, even if their symptoms seem to be the same as yours.

1. About Pancreote 10000

#### What is Pancreote 10000

- Pancreote 10000 is a pancreatic enzyme supplement.
- Pancreatic enzyme supplements are used by people whose bodies do not make enough of their own enzymes to digest their food.
- Pancreote 10000 capsules contain a mixture of the natural enzymes which are used to digest food.
- The enzymes are taken from pig pancreas glands.

#### How does Pancreote 10000 work?

The enzymes in Pancreote 10000 work by digesting food as it passes through the gut. So, you must take Pancreote 10000 at the same time as eating a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

2. Before you take Pancreote 10000

#### Do not take Pancreote 10000 if:

- You are allergic to pork, any pig product, or to any of the other ingredients (see section 6).

If the above applies to you do not take Pancreote 10000 Talk to your doctor or dietician again.

#### When you need to take special care with Pancreote 10000

A rare bowel condition called "fibrosing colonopathy", where your gut is narrowed, has been reported in patients with cystic fibrosis taking high dose pancreatin products.

If you have cystic fibrosis and take in excess of 10,000 lipase units per kilogram per day and have unusual abdominal symptoms or changes in abdominal symptoms tell your doctor.

#### Talk to your doctor if:

- you are pregnant or trying to get pregnant (Pancreote 10000 can be used while breast feeding)

Please tell your doctor dietician or pharmacist if you think that you should not take Pancreote 10000 for any other reason.

#### If you drive or use machines

It is unlikely that Pancreote 10000 will affect your ability to drive or operate tools or machines.

#### Sodium content

This medicine contains less than 1 mmol sodium (23 mg) per dosage unit, that is to say essentially 'sodium-free'

3. How to take Pancreote 10000

#### How much Pancreote 10000 to take

- Always follow your doctor or dietician's advice on how many capsules to take.
- If your doctor advises you to increase the number of capsules you take, you should do so slowly. If you still have fatty stools or abdominal pain, talk to your doctor or dietician.

#### When to take Pancreote 10000

- Always take Pancreote 10000 during or immediately after eating a meal or a snack and drink plenty of water (see section 1).

#### How to take Pancreote 10000

- Swallow the capsules whole or
- Open the capsules and mix the granules (without crushing) with acidic liquid (e.g. apple, orange or pineapple juice) or soft food (e.g. apple sauce or yoghurt). Swallow the mixture straight away, without chewing.
- Drink plenty of liquid every day.
- Mixing with non-acidic food or liquid, crushing or chewing of the pellets may cause irritation in your mouth or change the way Pancreote 10000 works in your body.
- Do not hold Pancreote 10000 capsules or its content in your mouth.
- Do not store the mixture.

#### How long to take Pancreote 10000 for

You should take your medicine until your doctor tells you to stop. Many patients will need to take pancreatic enzyme supplements for the rest of their lives.

If you take too much Pancreote 10000

If you take too much Pancreote 10000 you should drink plenty of water and see your doctor immediately.

#### If you forget a dose

If you forget to take your medicine, wait until your next meal and take your usual number of capsules. Do not try to make up for the number of capsules that you have missed. Just take your next dose at the usual time.

#### 4. Possible side effects

Like all medicines, Pancreote 10000 can cause side effects (unwanted effects or reactions), but not everyone gets them.

If you have severe or long-lasting abdominal pain, contact your doctor immediately.

If you notice any unusual abdominal symptoms while taking Pancreote 10000 – contact your doctor.

#### Very common side effects (affect more than 1 in 10 patients):

- stomach pains

#### Common side effects (affect 1 -10 patients out of 100):

- diarrhoea
- constipation
- feeling or being sick
- bloating

#### Uncommon side effects (affect 1 -10 patients out of 1000):

- Skin reactions, such as a rash.

During use, some patients have also experienced the following, the frequency of which is unknown:

- itching with or without a rash
- allergic reactions (which may be severe)
- severe or long-lasting abdominal pain (Fibrosing colonopathy).

At extremely high doses, some patients have had high levels of uric acid in their blood and urine.

#### Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist or nurse.

#### 5. How to store Pancreote 10000

##### How and where to keep your capsules

Keep this medicine out of the sight and reach of children.

Do not store above 25° C and keep in the original container. After opening do not store above 25 °C and use within 6 months. Keep the container tightly closed. The enzymes in Pancreote 10000 are natural products and their ability to digest food decreases over time. If the container is left in warm conditions (e.g. the glove compartment of a car), the digestive activity decreases faster.

Do not take Pancreote 10000 capsules after the expiry date on the bottle. Return all unused medicine to your pharmacist.

#### 6. Further information

##### The ingredients in Pancreote 10000

The active ingredient in Pancreote 10000 is pancreatin.

Each capsule contains enteric coated brownish-coloured granules (minimicrospheres) containing pancreatin 150 mg, equivalent to:

##### List of Enzymes : (USP units per capsule)

Lipase	10,000
Amylase	33,200
Protease	37,500

The granules are coated with a mixture of the following ingredients: macrogol 4000, hypromellose phthalate, dimeticone, triethyl citrate and cetyl alcohol.

The capsules contain: gelatin, iron oxides (E172), titanium dioxide (E171) and sodium lauryl sulfate.

Pancreote 10000 is available in 150 capsule packs. Not all pack sizes may be marketed.

#### Manufactured by :

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