

Package leaflet: Information for the user

Micrazym 10000 units, gastro-resistant capsules, hard
Micrazym 25000 units, gastro-resistant capsules, hard
pancreatin

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

1. What Micrazym is and what it is used for
2. What you need to know before you take Micrazym
3. How to take Micrazym
4. Possible side effects
5. How to store Micrazym
6. Contents of the pack and other information

1. What Micrazym is and what it is used for

What Micrazym is

- Micrazym contains an enzyme mixture called “pancreatin”.
- Pancreatin is also called pancreas powder. It helps you digest food. The enzymes are taken from pig pancreas glands.
- Micrazym capsules contain micro pellets which slowly release the pancreatin in your gut (gastro-resistant pellets).

What Micrazym is used for

Micrazym is a replacement therapy indicated for the treatment of exocrine pancreatic insufficiency in adults, adolescents and children. This is when the pancreas gland does not make enough enzymes to digest food.

It is for example often found in people who have:

- Mucoviscidosis (cystic fibrosis), a rare genetic disorder.
- Chronic inflammation of the pancreas (chronic pancreatitis).
- Had a part or the whole of their pancreas removed (partial or total pancreatectomy).
- Pancreatic cancer.

Treatment with Micrazym improves the symptoms of pancreatic exocrine insufficiency including stool consistency (e.g. fatty stools), abdominal pain, flatulence and stool frequency (diarrhoea or constipation), independent of the underlying disease.

You should use this product only if your doctor has confirmed that you or your child suffer from any of these diseases and your doctor has explicitly recommended the treatment with this product to you or your child.

You must talk to a doctor if you do not feel better or feel worse after 5 days.

How Micrazym works

The enzymes in Micrazym work by digesting food as it passes through the gut. You should take Micrazym during or immediately after a meal or a snack. This will allow the enzymes to mix thoroughly with the food.

Micrazym contains gastro-resistant micro pellets which are mixed evenly with the food in the stomach keeping all activity of enzymes and allowing to digest it in a smooth and natural way.

2. What you need to know before you take Micrazym

Do not take Micrazym

- If you are allergic to pancreatin or any of the other ingredients of Micrazym (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking Micrazym.

Patients with cystic fibrosis

A rare bowel condition called “fibrosing colonopathy”, where your gut is narrowed, has been reported in patients with cystic fibrosis taking high dose pancreas powder products. If you have cystic fibrosis and take in excess of 10000 lipase units per kilogram per day and have unusual abdominal symptoms or changes in abdominal symptoms tell your doctor.

The dosing of lipase units is explained in section 3 of this leaflet, “How to take Micrazym”.

Severe allergic reaction

If an allergic reaction occurs, stop your treatment and talk to your doctor. An allergic reaction could include itching, hives or rash. Rarely, a more serious allergic reaction may include a feeling of warmth, dizziness and fainting, trouble breathing; these are symptoms of a severe, potentially life-threatening condition called ‘anaphylactic shock’. If this occurs, call for urgent medical attention straightaway.

Talk to your doctor if you are allergic to pig proteins before taking Micrazym.

Mouth irritation

Oral pain, irritation (stomatitis), bleeding, and ulcer formation in the mouth may occur in case the capsules are chewed and/or kept too long in the mouth. Rinsing the mouth and drinking of a glass of water may help if there are preliminary signs of mouth irritation.

Micrazym can only be sprinkled on certain food (see section 3 of this leaflet, “How to take Micrazym”).

Traceability

In order to improve the traceability of biological medicinal products, the name and the batch number of the administered product should be clearly recorded.

This medicine is essentially 'sodium-free'.

Alcohol

Use of Micrazym concomitantly with heavy alcohol is not recommended for all the proposed strengths.

Other medicines and Micrazym

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines.

Pregnancy, breast-feeding and fertility

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Your doctor will decide whether you can take Micrazym and at what dose. Micrazym can be used while breast-feeding.

Driving and using machines

Micrazym does not affect your ability to drive or operate tools or machines.

Micrazym 10000 units contains Ponceau 4R (E124)

The excipient Ponceau 4R (E124) included in the capsules shell may cause allergic reactions.

Micrazym 25000 units contains Sunset yellow FCF (E110)

The excipient Sunset yellow FCF (E110) included in the capsules shell may cause allergic reactions.

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

3. How to take Micrazym

Always take this medicine exactly as described in this leaflet or your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

How much Micrazym to take

- Your dose is measured in 'lipase units'. Lipase is one of the enzymes in pancreatin. Different strengths of Micrazym contain different amounts of lipase.
- Always follow your doctor's advice on how much Micrazym to take. Your doctor will adjust your dose to suit you. It will depend on:
 - the severity of your illness
 - your weight
 - your diet
 - how much fat is in your stool.
- If you still have fatty stools or other stomach or gut problems (gastrointestinal symptoms), talk to your doctor as your dose may need to be adjusted.

Dosing in paediatric and adult patients with cystic fibrosis:

Weight-based enzyme dosing should begin with 1000 lipase units/kg/meal for children less than four years of age and with 500 lipase units/kg/meal for those over age four.

Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status.

Most patients should remain below or should not exceed 10000 lipase units/kg body weight per day or 4000 lipase units/gram fat intake, and the patients should not exceed the dose 2500 lipase units/kg body weight/meal.

Dosing in other conditions associated with exocrine pancreatic insufficiency:

Dosage should be individualized by patients according to the degree of maldigestion and the fat content of the meal. The required dose for a meal ranges from about 25000 to 80000 Ph. Eur. units of lipase and half of the individual dose for snacks.

When to take Micrazym

Always take Micrazym during or immediately after a meal or a snack. This will allow the enzymes to mix thoroughly with the food and digest it as it passes through the gut.

How to take Micrazym

- Micrazym should always be taken with a meal or snack.
- The capsules should be swallowed whole with a drink of water or juice.
- Do not crush or chew the capsules or its contents as this can cause irritation inside your mouth or change the way Micrazym works in your body.
- If it is difficult to swallow the capsules, open them carefully and add the pellets to a small amount of soft acidic food or acidic soft drinks. Examples of acidic soft foods are yogurt and applesauce. Examples of acidic soft drinks could be apple, orange or pineapple juice. Do not mix the pellets with water, milk including flavoured milk, breast milk and formula feeds or with hot food. Swallow the mixture immediately, without crushing or chewing and drink some water or juice.
- Mixing with non-acidic food or liquid, crushing or chewing of the granules may cause irritation inside your mouth or change the way Micrazym works in your body.
- Do not hold Micrazym capsules or its content inside your mouth. Make sure the medicine and food mixture are swallowed completely and no pellets are left in your mouth.
- Do not store the mixture.
- As a general rule, drink plenty of fluids every day.

If you take more Micrazym than you should

If you take more Micrazym than you should, drink plenty of water and talk to a doctor or pharmacist. Very high doses of pancreatin have sometimes caused too much uric acid in the urine (hyperuricosuria) and in the blood (hyperuricaemia).

If you forget to take Micrazym

If you forget a dose, take your next dose at the usual time, with your next meal. Do not take a double dose to make up for a forgotten dose.

If you stop taking Micrazym

Do not stop taking Micrazym without first talking to your doctor. Many patients will need to take the Micrazym for the rest of their lives.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

4. Possible side effects

Like all medicines, Micrazym can cause side effects, although not everybody gets them. The following side effects may happen with this medicine.

The most important serious side effects seen with pancreatic enzyme replacement medicines are ‘anaphylactic shock’ and fibrosing colonopathy. These two side effects have occurred in a very small number of people, but their exact frequency is unknown.

Anaphylactic shock is a severe, potentially life-threatening allergic reaction that can develop rapidly. If you notice any of the following seek urgent medical attention straightaway:

- itching, hives or rash,
- swollen face, eyes, lips, hands or feet,
- feeling lightheaded or faint,
- trouble breathing or swallowing,
- palpitations,
- dizziness, collapse or unconsciousness.

Repeated high doses of pancreatic enzyme replacement medicines can also cause scarring or thickening of the bowel wall that can lead to blockage of the intestines, a condition called fibrosing colonopathy. If you

have severe stomach pain, trouble passing stools (constipation), nausea or vomiting, tell your doctor straightaway.

Very common side effects (may affect more than 1 in 10 people)

- pain in your stomach (abdomen).

Common side effects (may affect up to 1 in 10 people)

- feeling sick (nausea),
- being sick (vomiting),
- constipation,
- bloating (abdominal distention),
- diarrhoea.

These may be due to the condition you are taking Micrazym for.

Uncommon side effects (may affect up to 1 in 100 people)

- rash.

Not known: frequency cannot be estimated from the available data

- allergic reactions (hypersensitivity),
- sudden, severe allergic reaction, with breathing difficulty, swelling, light-headedness, fast heartbeat, sweating and loss of consciousness (anaphylactic reactions),
- scarring or thickening of the bowel wall that can lead to blockage of the intestines (fibrosing colonopathy),
- itching (pruritus),
- itchy rash (urticaria).

Reporting of side effects

If you get any side effects, talk to your doctor, pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via HPRC Pharmacovigilance Website: www.hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Micrazym

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

Do not use this medicine after the expiry date which is stated on the pack. The expiry date refers to the last day of that month.

Store below 25 °C. After opening use within 3 months.

Keep the bottle tightly closed in order to protect it from moisture.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Micrazym contains

The active substance in Micrazym is pancreatin.

Each Micrazym 10000 capsule contains pancreatin corresponding to (Ph. Eur. units)

- Lipase 10000
- Amylase 8000
- Protease 600

Each Micrazym 25000 capsule contains pancreatin corresponding to (Ph. Eur. units)

- Lipase 25000
- Amylase 18000
- Protease 1000

The other ingredients are:

Pellets: cetyl alcohol, poloxamer (contains butylated hydroxytoluene).

Gastro-resistant coating: methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30 % (contains sodium lauryl sulphate, polysorbate 80), macrogol-4000, talc, simeticone emulsion 30 % (contains methyl cellulose, sorbic acid).

Gelatin capsules, hard:

- *10000 units*: gelatin, ponceau 4R (E124), patent blue (E131), titanium dioxide (E171), quinoline yellow (E104).
- *25000 units*: gelatin, sunset yellow FCF (E110), titanium dioxide (E171).

What Micrazym 10000, 25000 looks like and contents of the pack

Micrazym 10000 Ph. Eur. units

Hard gelatin capsules of size 2 (length 17.8 ± 0.4 mm) with a brown cap and transparent body, filled with cylindrical, spherical or irregularly shaped gastro-resistant pellets (micro pellets) of light brown to brown colour.

Micrazym is available in a 75 ml white HDPE bottle with a white PP screw cap containing a coloured white insert block made of low-density polyethylene with desiccant inside (silica gel). Each bottle contains 100 capsules and is overpacked in a carton box.

Micrazym 25000 Ph. Eur. units

Hard gelatin capsules of size 00 (length 23.5 ± 0.4 mm) with an orange cap and transparent body, filled with cylindrical, spherical or irregularly shaped gastro-resistant pellets (micro pellets) of light brown to brown colour.

Micrazym is available in a 150 ml white HDPE bottle with a white PP screw cap containing a coloured white insert block made of low-density polyethylene with desiccant inside (silica gel). Each bottle contains 100 capsules and is overpacked in a carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Azure Pharmaceuticals Ltd.
12 Hamilton Drive, The Rock Road,

Blackrock, Co. Louth, A91 T997, Ireland

Manufacturer:

AVVA Pharmaceuticals Ltd.,
23A Spyrou Kyprianou, 4001, Limassol, Cyprus

SIA “Unifarma”
Vangazu street 23, Riga, LV-1024, Latvia

**This medicine is authorised in the Member States of the European Economic Area
under the following names:**

Austria, Cyprus, Denmark, Finland, Netherlands, Norway, Slovakia, Sweden	Micrazym
Spain, Czech Republic	Mekrazym
Belgium, Luxembourg	Ankreta
Germany	Pankreatin Klinge

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