Package leaflet: Information for the user

Crezanta 10,000 Ph. Eur. units, gastro-resistant hard capsules

pancreatin

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

Always take this medicine exactly as described in this leaflet or as your doctor, pharmacist or nurse has told you.

- Keep this leaflet. You may need to read it again.
- Ask your pharmacist if you need more information or advice.
- If you get any side effects, talk to your doctor, or pharmacist or nurse. This includes any possible side effects not listed in this leaflet. See section 4.
- You must talk to a doctor if you do not feel better or if you feel worse after 5 days.

What is in this leaflet

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

1 What Crezanta is and what it is used for

What Crezanta is

- This medicine 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.
- Crezanta capsules contain micro pellets which slowly release the pancreatin in your gut (gastro-resistant pellets).

What Crezanta is used for

Crezanta 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.

Treatment with Crezanta 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 Crezanta works

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

Crezanta 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 Crezanta

Do not take Crezanta

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

Warnings and precautions

Talk to your doctor or pharmacist before taking Crezanta.

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 10,000 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 Crezanta".

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 Crezanta.

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

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 Crezanta concomitantly with heavy alcohol is not recommended for all the proposed strengths.

Other medicines and Crezanta

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 Crezanta and at what dose.

This medicine can be used while breast-feeding.

Driving and using machines

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

Crezanta and sodium

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

3 How to take Crezanta

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.

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.

How much Crezanta to take

- Your dose is measured in 'lipase units'. Lipase is one of the enzymes in pancreatin. Different strengths of Crezanta contain different amounts of lipase.
- Always follow your doctor's advice on how much Crezanta 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.

The recommended dose is initially one or two capsules during or immediately after each meal.

When to take Crezanta

Always take this medicine 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 Crezanta

- 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 Crezanta works in your body.
- Do not hold Crezanta capsules or its content in your mouth.
- Do not store the mixture.

If you take more Crezanta than you should

If you take more Crezanta 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 Crezanta

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 Crezanta

Do not stop taking this medicine without first talking to your doctor. Many patients will need to take Crezanta 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, Crezanta 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 light-headed 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 Crezanta 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 or nurse. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme Website: www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store. By reporting side effects you can help provide more information on the safety of this medicine.

5 How to store Crezanta

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 Crezanta contains

The active substance in this medicine is pancreatin. Each Crezanta 10,000 capsule contains pancreatin corresponding to (Ph. Eur. units)

- Lipase 10,000
- Amylase 8,000
- Protease 600

The other ingredients are:

Pellets:
- Cetyl alcohol
- Poloxamer

Gastro-resistant coating:
- Methacrylic acid - ethyl acrylate copolymer (1:1) dispersion 30%
- Macrogol-4000
- Talc
- Simeticone
- Methyl cellulose
- Sorbic acid

Gelatin hard capsules:
- gelatin, yellow iron oxide (E172), black iron oxide (E172), red iron oxide (E172), titanium dioxide (E171).

What Crezanta 10,000 looks like and contents of the pack

Hard gelatin capsules of size 2 (length 17.8 ± 0.4mm) 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.

Crezanta is available in a 75ml 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 over-packed in a carton box.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

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