

**PACKAGE LEAFLET: INFORMATION OFR THE USER****Spezato<sup>®</sup>**  
**20mg, gastro-resistant capsules, hard**  
Omeprazole**Read all of this leaflet carefully before you start taking this medicine**

- 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 to you only. Do not pass it on to others. It may harm them, even if the signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist or any other healthcare professional, or directly to the National Drug Organization (284 Mesogeion Av., 15562, Chologos Greece, [www.eof.gr](http://www.eof.gr))

**What is in this leaflet:**

1. What **SPEZATO<sup>®</sup>** is and what is used for
2. What you need to know before you start taking **SPEZATO<sup>®</sup>**
3. How to take **SPEZATO<sup>®</sup>**
4. Possible side effects
5. How to store **SPEZATO<sup>®</sup>**
6. Contents of the pack and other information

**1. WHAT SPEZATO<sup>®</sup> IS AND WHAT IS USED FOR**

**Spezato<sup>®</sup>** contains the active substance omeprazole. It belongs to a group of medicines called “proton pump inhibitors”. They act by reducing the amount of acid that your stomach produces.

**Spezato<sup>®</sup>** is used to treat the following conditions:

In adults:

- “Gastro-oesophageal reflux disease” (GORD). This is where acid from the stomach escapes into the gullet (the tube that connects your throat to your stomach) causing pain, inflammation and heartburn.
- Ulcers in the upper part of the intestine (duodenal ulcer) or stomach (gastric ulcer)
- Ulcers which are infected with bacteria called “*Helicobacter pylori*”. If you have this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.
- Ulcers caused by medicines called NSAIDs (Non-Steroidal Anti-Inflammatory Drugs). **Spezato<sup>®</sup>** can also be used to stop ulcers from forming if you are taking NSAIDs.
- Too much acid in the stomach caused by tumor in pancreas (Zollinger-Ellison syndrome).

In children:

*Children over 1 year of age and  $\geq 10$  kg*

- “Gastro-oesophageal reflux disease” (GORD). This is where acid from the stomach escapes into the gullet (the tube which connects your throat to your stomach) causing pain, inflammation and heartburn.

In children, the symptoms of the condition can include the return of stomach contents into the mouth (regurgitation), being sick (vomiting) and poor weight gain.

*Children and adolescents over 4 years of age*

- Ulcers which are infected with bacteria called “*Helicobacter pylori*”. If your child has this condition, your doctor may also prescribe antibiotics to treat the infection and allow the ulcer to heal.

## 2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE SPEZATO<sup>®</sup>

### Do not take **Spezato<sup>®</sup>**

- if you allergic (hypersensitive) to omeprazole or any of the other ingredients of **Spezato<sup>®</sup>**
- if you are allergic to medicines containing other proton pump inhibitors (eg pantoprazole, lansoprazole, rabeprazole, esomeprazole).
- If you are taking a medicine containing nelfinavir (used for HIV infection).

If you are not sure, talk to your doctor or pharmacist before taking **Spezato<sup>®</sup>**.

### Warnings and precautions with **Spezato<sup>®</sup>**

**Spezato<sup>®</sup>** may hide the symptoms of other diseases. Therefore, if any of the following happen to you before you start taking **Spezato<sup>®</sup>** or while you are taking it, talk to your doctor straight away:

- You lose a lot of weight for no reason and have problems swallowing.
- You get stomach pain or indigestion.
- You begin to vomit food or blood.
- You pass black stools (blood-stained feces).
- You experience severe or persistent diarrhea, as omeprazole has been associated with a small increase in infectious diarrhea.
- You have severe liver problems.

If you take **Spezato<sup>®</sup>** on a long-term basis (longer than 1 year) your doctor will probably keep you under regular surveillance. You should report any new and exceptional symptoms and circumstances whenever you see your doctor.

### Other medicine and **Spezato<sup>®</sup>**

Tell your doctor or pharmacist If you take, have recently taken or might take any other medicines, including those you take without medicinal prescription. This is because **Spezato<sup>®</sup>** can affect the way some medicines work and some medicines can have effect on **Spezato<sup>®</sup>**.

Do not take **Spezato<sup>®</sup>** if you are taking a medicine containing **nelfinavir** (used to treat HIV infection)

Tell your doctor or pharmacist if you are taking any of the following medicines:

- Ketoconazole, itraconazole, or voriconazole (used to treat infections caused by fungus)
- Dogoxin (used to treat heart problems)
- Diazepam (used to treat anxiety, relax muscle or in epilepsy).
- Phenytoin (used in epilepsy). If you are taking phenytoin, your doctor will need to monitor you when you start or stop taking **Spezato<sup>®</sup>**.
- Medicines that are used to thin your blood, such as warfarin or other vitamin K blockers. Your doctor may need to monitor you when you start or stop taking **Spezato<sup>®</sup>**.
- Rifampicin (used to treat tuberculosis)
- Atazanavir (used to treat HIV infection)
- Tacrolimus (in cases of organ transplantation)
- St John's wort (*Hypericum perforatum*) (used to treat mild depression)
- Cilostazol (used to treat intermittent claudication)
- Saquinavir (used to treat HIV infection)
- Clopidogrel (used to prevent blood clots)

If your doctor has prescribed the antibiotics amoxicillin and clarithromycin as well as **Spezato<sup>®</sup>** to treat ulcers caused by *Helicobacter pylori* infection, it is very important that you tell your doctor about any other medicines you are taking.

### **Spezato<sup>®</sup>** with food and drink

You may take the capsules with food or in empty stomach.

**Pregnancy and Breast-feeding**

Before you take **Spezato**<sup>®</sup>, inform your doctor if you are pregnant or are planning to have a baby. Your doctor will decide whether you can take **Spezato**<sup>®</sup> during this time. Your doctor will decide whether you can take **Spezato**<sup>®</sup> if you are breast-feeding..

**Driving and using machines**

**Spezato**<sup>®</sup> is not likely to affect your ability to drive or use any tools or machines. Side effects such as dizziness and visual disturbances may occur (see section 4). If affected, you should not drive or operate machinery.

**3. HOW TO TAKE SPEZATO<sup>®</sup>**

Always take **Spezato**<sup>®</sup> exactly as your doctor instructed you. Check with your doctor or pharmacist if you are not sure. Your doctor will tell you how many capsules to take and how long to take them for. This will depend on your condition and how old you are. The recommended dose is given below.

Adults:

To treat symptoms of GORD such as **heartburn and acid regurgitation:**

- If your doctor has found that your food pipe (gullet) has been slightly damaged, the recommended dose is 20 mg once a day for 4-8 weeks. Your doctor may tell you to take a dose of 40 mg for a further 8 weeks if your gullet has not yet healed.
- The recommended dose once the gullet is healed is 10 mg once a day.
- If your gullet has not been damaged, the usual dose is 10 mg once a day.

To treat **ulcers in the upper part of the intestine** (duodenal ulcer):

- The recommended dose is 20 mg once a day for 2 weeks. Your doctor may tell you to take the same dose for a further 2 weeks if your ulcer has not yet healed.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day for 4 weeks.

To treat **ulcers in the stomach** (gastric ulcers):

- The recommended dose is 20 mg once a day for 4 weeks. Your doctor may tell you to take the same dose for a further 4 weeks if your ulcer has not yet healed.
- If the ulcers do not fully heal, the dose can be increased to 40 mg once a day for 8 weeks.

**To prevent recurrence of duodenal and stomach ulcers:**

- The recommended dose is 10 mg or 20 mg once a day. Your doctor may increase the dose to 40 mg once a day.

To treat **duodenal and stomach ulcers caused by NSAIDs:**

- The recommended dose is 20 mg once a day for 4-8 weeks.

**To prevent duodenal and stomach ulcers if you are taking NSAIDs:**

- The recommended dose is 20 mg once a day.

To treat **ulcers caused by *Helicobacter pylori* infection** and to stop them coming back:

- The recommended dose is 20 mg **Spezato**<sup>®</sup> twice a day for one week.
- Your doctor will also tell you to take two antibiotics among amoxicillin, clarithromycin and metronidazole.

To treat too much acid in the stomach caused by **a tumor in pancreas (Zollinger-Ellison syndrome):**

- The recommended dose is 60 mg daily.
- Your doctor will adjust the dose depending on your needs and will also decide how long you need to take the medicine for.

Children:

To treat symptoms of GORD such as **heartburn and acid regurgitation:**

- Children over 1 year of age and with a body weight of more than 10 kg may take **Spezato<sup>®</sup>**. The dose for children is based on the child's weight and the doctor will decide the correct dose.

To treat **ulcers caused by *Helicobacter pylori* infection** and to stop them coming back:

- Children over 4 years may take **Spezato<sup>®</sup>**. The dose for children is based on the child's weight and the doctor will decide the correct dose.
- Your doctor will also prescribe two antibiotics called amoxicillin and clarithromycin for your child.

### Taking this medicine

- It is recommended that you take the capsules in the morning.
- You can take your capsules with food or on an empty stomach.
- Swallow your capsules whole with half a glass of water. Do not chew or crush the capsules. This is because the capsules contain coated pellets which stop the medicine from being broken down by the acid in your stomach. It is important not to damage the pellets..

### What to do if you or your child have trouble swallowing the capsules

If you or your child have trouble swallowing the capsules:

- Open the capsules and swallow the contents directly with half a glass of water or put the contents into a glass of still (non-fizzy) water, any acidic fruit juice (e.g. apple, orange or pineapple) or apple sauce.
- Always stir the mixture just before drinking it (the mixture will not be clear). Then drink the mixture straight away or within 30 minutes.
- To make sure that you have drunk all of the medicine, rinse the glass very well with half a glass of water and drink it. The solid pieces contain the medicine – do not chew or crush them.

### If you take more Spezato<sup>®</sup> than you should

If you take more **Spezato<sup>®</sup>** than prescribed by your doctor, talk to your doctor or pharmacist straight away.

### If you forget to take Spezato<sup>®</sup>

If you forget to take a dose, take it as soon as you remember it. However, it is almost the time for your next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

## 4. POSSIBLE SIDE EFFECTS

Like all medicines, **Spezato<sup>®</sup>** can cause side effects, although not everybody gets them.

**If you notice any of the following rare but serious side effects, stop taking Spezato<sup>®</sup> and contact a doctor immediately:**

- Sudden wheezing, swelling of your lips, tongue and throat or body, rash, fainting or difficulties in swallowing (severe allergic reaction).
- Reddening of the skin with blisters or peeling. There may also be severe blisters and bleeding in the lips, eyes, mouth, nose and genitals. This could be “Stevens-Johnson syndrome” or “toxic epidermal necrolysis”.
- Yellow skin, dark urine and tiredness which can be symptoms of liver problems.

Side effects may take place in frequencies that are determined as follows:

Very Common:	May affect more than 1 patient out of 10
Common:	May affect 1 to 10 patients out of 100
Uncommon:	May affect 1 to 10 patients out of 1.000
Rare:	May affect 1 to 10 patients out of 10.000
Very Rare:	May affect less than 1 patient out of 10.000
Unknown:	The frequency cannot be determined on the current data.

Other side effects include:

**Common side effects**

- Headache.
- Effects on your stomach or gut: diarrhea, stomach pain, constipation, gas (flatulence).
- Feeling sick (nausea) or vomiting.

**Uncommon side effects**

- Swelling of the feet and ankles.
- Disturbed sleep (insomnia).
- Dizziness, tingling feelings such as “pins and needles” feeling sleepy.
- Spinning feeling (vertigo).
- Changes in the blood tests that check how the liver is functioning.
- Skin rash, lumpy rash (hives) and itchy skin.
- Generally feeling unwell and lacking energy.

**Rare side effects**

- Blood problems such as a reduced number of white cells or platelets. This can cause weakness, bruising or make infections more likely.
- Allergic reactions, sometimes very severe, including swelling of the lips, tongue and throat, fever, wheezing.
- Low levels of sodium in the blood. This may cause weakness, being sick (vomiting) and cramps.
- Feeling agitated, confused or depressed.
- Taste changes.
- Eyesight problems such as blurred vision.
- Suddenly feeling wheezy or short of breath (bronchospasm).
- Dry mouth.
- An inflammation of the inside of the mouth.
- An infection called “thrush” which can affect the gut and is caused by a fungus.
- Liver problems, including jaundice which can cause yellow skin, dark urine, and tiredness.
- Hair loss (alopecia).
- Skin rash on exposure to sunshine.
- Joint pains (arthralgia) or muscle pains (myalgia).
- Severe kidney problems (interstitial nephritis).
- Increased sweating.

**Very rare side effects**

- Changes in blood count including agranulocytosis (lack of white blood cells).
- Aggression.
- Seeing, feeling or hearing things that are not there (hallucinations).
- Severe liver problems leading to liver failure and inflammation of the brain.
- Sudden onset of a severe rash or blistering or peeling skin. This may be associated with a high fever and joint pains (Erythema multiforme, Stevens-Johnson syndrome, toxic epidermal necrolysis).
- Muscle weakness.
- Enlarged breasts in men.
- Hypomagnesaemia

**Spezato<sup>®</sup>** may in very rare cases affect the white blood cells leading to immune deficiency. If you have an infection with symptoms such as fever with a **severely** reduced general condition or fever with symptoms of a local infection such as pain in the neck, throat or mouth or difficulties in urinating, you must consult your doctor as soon as possible so that a lack of white blood cells (agranulocytosis) can be ruled out by a blood test. It is important for you to give information about your medicine at this time.



Do not be disturbed with this list of possible side effects. You may not experience any of them. If you get any side effect, talk to your doctor or pharmacist or any other health care professional or directly to the National Drug Organization (284 Mesogeion Av., 15562, Cholargos, Greece [www.eof.gr](http://www.eof.gr)).

## 5. HOW TO STORE SPEZATO<sup>®</sup>

- Keep this medicine out of sight and reach of children.
- Do not use **Spezato<sup>®</sup>** after the expiry date which is stated on the carton after the word “EXP”. The expiry date refers to the last day of that month.
- Do not throw away any medicine 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 Spezato<sup>®</sup> contains

- The active substance is omeprazole. Each capsule contains 20 mg omeprazole.
- The other ingredients are: Hypromellose, Disodium hydrogen phosphate dihydrate, Sodium lauryl sulphate, Low substituted hydroxypropyl cellulose, Sugar spheres, Titanium dioxide E171 CI 77891, Magnesium carbonate light, Talc, Methacrylic acid copolymer, PEG 6000, Polysorbate 80, Sodium hydroxide pellets. Composition of the capsule: Patent blue V E131 CI 42051, Quinoline yellow E104 CI 47005, Titanium dioxide E171 CI 77891, Iron oxide (yellow) E172 CI 77492, Gelatin.

### What Spezato<sup>®</sup> look like and contents of the pack

Each carton contain 28 gastro-resistant hard capsules, in four alu/alu blisters of 7 caps each and a leaflet.

### Marketing Authorization Holder

TARGET PHARMA Ltd, 54 Menandrou st. Athens, Greece

### Manufacturer

KLEVA S.A., 189 Parnithos Av. Acharnai, Attica, 13671, Greece

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