

# Odasol®

## PATIENT INFORMATION LEAFLET

### ODASOL/GENEPHARM Omeprazole 20mg/CAP

#### Name of the medicinal product:

ODASOL/GENEPHARM

#### Composition

Active substance: Omeprazole

Excipients: Core: Sucrose, Starch maize, lactose anhydrous, dextrose (glucose) anhydrous, sodium lauryl sulfate, sodium phosphate dibasic dehydrate. Pellets coating: Hypromellose, mannitol. Enteric Coating: Hypromellose phthalate, cetyl alcohol, diethylphthalate. Composition of empty capsule: Titanium dioxide E171, gelatin.

**Pharmaceutical form:** Gastro –resistance hard capsules.

**Content in active substance:** Omeprazole 20mg/CAP

**Description – Packaging:** Carton box containing plastic vial with 14 or 28 capsules

**Pharmacotherapeutic group:** Drug for peptic ulcer and gastro –oesophageal reflux disease (proton pump inhibitors).

#### Marketing Authorization Holder:

GENEPHARM SA, 18th km., Marathon Avenue 15351 Pallini Greece

**Manufacturer (Pellets):** Natco Pharma Ltd. India

**Manufacturer (Filling of capsules with pellets):** GENEPHARM SA, 18th km. Marathon Avenue 15351 Pallini Greece

#### WHAT YOU SHOULD KNOW ABOUT THE DRUG PRESCRIBED TO YOU BY YOUR DOCTOR

**General:** Odasol reduces the amount of acid produced in the stomach.

**Indications:** Odasol is used for the treatment of the following diseases:

- Duodenal ulcer (ulcer in the upper part of the intestine)

- Gastric ulcer (benign gastric ulcer)

- Duodenal and/or stomach ulcers, associated with a microbe called "Helicobacter pylori". If you have this condition, your doctor may also prescribe other medicines.

- 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.

- Too much acid in the stomach caused by a growth in the pancreas (Zollinger-Ellison syndrome).

- Aspiration of acidic gastric contents during general anesthesia (Prophylaxis of aspiration)

- Maintenance treatment (prevention of relapse in patients with refractory to the usual treatment, peptic ulcer or severe reflux oesophagitis).

- Ulcers caused by medicines called NSAIDs

- (Non-Steroidal Anti-Inflammatory Drugs).

- Odasol can also be used to stop ulcers from forming if you are taking NSAIDs, specifically in the following cases:

1. In asymptomatic patients recently diagnosed with ulcer regardless of age and particularly in those over 70 years.

2. In women older than 70 years without a history of ulcers due to 5times higher relative risk of developing peptic ulcer compared to males of the same age.

3. In patients with a history of ulcers, when the long-term use of nonsteroidal anti-inflammatory drugs is necessary.

**Contraindications:** Medications can help the sick people, but they can cause problems when they are not taken according to instructions. Before you take this medicine you should inform your doctor for the following cases: If you had ever experienced an allergic reaction or an unusual reaction to this medicine or to any of the substances contained in the product or any other medications.

**Special warnings and precautions for use**

**General:** Patients with severe liver disease rarely

need more than 20mg Odasol a day. No adjustment to the dose of Odasol should be made to the patients with impaired renal function.

**Elderly:** There is no need for dosage adjustment in the elderly.

**Pregnancy:** Odasol should not be used during pregnancy unless its use is deemed necessary. For this reason you should tell your doctor immediately if during treatment with Odasol you become pregnant. **Lactation:** Odasol should not be used during breastfeeding.

**Children:** It is not proven the safety and efficacy in children, except for the use of severe esophagitis gastroesophageal reflux in children older than 2 years (See gastroesophageal reflux / children).

**Effect on the ability to drive and use machines:** Odasol is safe and has no effect at all on the ability to drive and use machines.

**Drug interaction with other medicinal products and other forms of interaction:**

Before starting treatment with Odasol, make sure you tell your doctor about all other medicines you are taking, including those bought without a prescription.

Treatment results can be affected if you use Odasol concomitantly with drugs anxiolytics (diazepam), anticoagulants (warfarin) and anticonvulsants (phenytoin). In this case your doctor may reduce the dose of these drugs.

If you are taking antacids at the beginning of the treatment with Odasol, there will not be a problem as it does not affect its activity.

**Dosage and administration:** Route of administration: Oral

**It is recommended to take Odasol in the morning**

**Duodenal ulcer:** usual dose is 20mg once daily.

The treatment in patients with duodenal ulcer is usually completed within 2 weeks otherwise treatment is prolonged for another 2 weeks. In patients resistant to other treatment regimens, the daily dose for Odasol is 40mg once a day and the healing of duodenal ulcer is usually achieved within 4 weeks.

To prevent relapses in patients with duodenal ulcer the recommended dose is 10mg once daily. The dose may be increased to 20mg once daily if symptoms reappear.

**Benign Gastric ulcer:** usual dose is 20mg once daily. The relief from the symptoms is rapid and most patients healing occur within four weeks. For those patients not achieve complete healing after initial treatment, it is usually seen after another 4 weeks of treatment.

In patients resistant to other treatment regimens, the daily dose for Odasol is 40mg once a day and the healing of gastric ulcer is usually achieved within 8 weeks.

To prevent relapses in patients with benign gastric ulcer the recommended dose is 20mg once a day. The dose may be increased to 40mg once daily if symptoms reappear.

**Treatment or prevention of gastric and duodenal ulcers or erosions associated with the use of nonsteroidal anti-inflammatory drugs (NSAIDs):**

For the treatment of gastric and duodenal ulcers or erosions associated with the use of NSAIDs in patients on continuous or intermittent treatment with NSAIDs, the recommended dosage is 20mg Odasol once a day. In most patients healing is achieved within 4 weeks, otherwise treatment is prolonged for another 4 weeks. For the prevention of gastric and duodenal ulcers or erosions associated with the use of NSAIDs, the recommended dosage is 20mg Odasol once a day.

**Esophagitis due to esophageal regurgitation**

**Adults:** The recommended dosage is 20 mg once daily. In most patients healing is achieved within 4 weeks, otherwise treatment is prolonged for another 4 weeks.

In patients with severe esophagitis gastroesophageal reflux, not responding to other treatments, 40mg is given daily for 8 weeks.

For long-term maintenance treatment suggested dosage is 10mg once a day (it can be increased to 20-40mg daily in case of relapse).

**Children older than 2 years with severe gastroesophageal reflux oesophagitis:**

Clinical experience in children is limited. In children, Odasol should be used only in cases of resistant to other medication severe esophagitis caused by gastroesophageal reflux. Treatment should be initiated by hospital pediatrician.

For the monitoring of patients, the determination of dosage and duration of treatment in order to achieve the optimal therapeutic effect is recommended; where necessary, 24 hours periodically count is followed to maintain pH above 4. Where feasible, molecular or acquired disorders of CYP 2C19 should be considered during treatment.

Dosage 0.7-1.4mg/kg of body weight.

Duration of treatment 4 to 8 weeks, and should not exceed 12 weeks.

In resistant cases increase of dose to 2.5mg/kg.

**Treatment of gastroesophageal reflux disease**

**symptoms:** The recommended dosage is 20mg Odasol once a day. The relief from the symptoms is rapid. Several patients may respond adequately to a dosage of 10 mg Odasol once daily, so it should be taken into consideration that the dosage depends on individual patient's response. If control of the symptoms is not achieved after 4 weeks of treatment with 20mg Odasol daily, a further check is recommended.

**Zollinger-ellison syndrome:** The recommended initial dose is 60mg Odasol once daily. But treatment period and dosage must depend on each case individually. Most patients respond to doses of 20-120mg daily. When daily dose exceeds 80mg it should be divided in two doses per day.

**Healing from helicobacter pilori in duodenal and benign gastric ulcer**

**Example of triple dosage regimens (one week treatment):**

Amoxicilline 500mg, 3 times daily and Metronidazole 400mg, 3 times daily and Odasol 20mg, 2 times daily or 40mg once daily for 7 days. Clarithromycine 250mg, 2 times daily and Metronidazole 400mg, 2 times daily and Odasol 20mg, 2 times daily or 40mg once daily for 7 days. Amoxycilline 1g, 2 times daily and Clarithromycine 500mg, 2 times daily and Odasol 20mg, 2 times daily or 40mg once daily for 7 days.

**Example of double dosage regimens (2 weeks treatment):**

Clarithromycin 500mg, 3 times daily and Odasol 20mg, 2 times daily or 40mg once daily for 14 days. Amoxycilline 750mg (or 1g), 2 times daily and Odasol 20mg, 2 times daily or 40mg once daily for 14 days.

In order for the healing to be secure in patients with active peptic ulcer, see above mentioned dosage for benign gastric ulcer and duodenal ulcer.

If, after the treatment with some of the above regimens, patient is still positive to Helicobacter pilori, treatment could be repeated according to the physician's instructions.

**Prevention of gastric acid ingestion:** 40 mg the night before surgery followed by 40mg 1-4 hours before surgery.

**Use in renal impairment:** There is no need for dose adjustment in patients with renal impairment.

**Use in hepatic impairment:** Because the bioavailability and the half-life of Omeprazole in plasma are increased in patients with hepatic impairment, a daily dose of 20mg is usually sufficient.

**Children:** The safety and efficacy of Odasol is not demonstrated in children, except for the cases of severe esophagitis gastroesophageal reflux in children older than 2 years (See gastroesophageal Reflux / children).

**Elderly:** There is no need for dosage adjustment in the elderly.

**Overdosage - Treatment:** although no symptoms were observed in patients receiving high doses of

Odasol, we advise you to contact your doctor or pharmacist in case of overdose.

**Undesirable effects:** Odasol is usually well tolerated and the side effects are generally mild and reversible. The following adverse reactions have been reported although in most cases are not relevant to the treatment with Odasol: headache, diarrhea, constipation, abdominal pain, nausea / vomiting, and flatulence.

In rare cases the following have been reported: skin rashes, itchy, burning or numbness, dizziness, sleeping difficulty, drowsiness, dizziness and malaise.

In few isolated cases, the following have been reported: increase skin sensitivity to sunlight (photosensitivity), severe skin reactions, hair loss, joint pain, muscle pain, muscle weakness, dry mouth, inflammation of the mouth, yeast infection of the gastrointestinal tract, aggression, impaired orientation, confusion, reduced level of consciousness (if pre-existing severe liver disease), kidney problems and liver (such as kidney inflammation, liver inflammation and / or without jaundice, liver dysfunction), blood disorders (decreased number of cellular components of white blood cells or platelets in the blood for example leukopenia, thrombocytopenia, agranulocytosis and pancytopenia), gynecomastia, edema, fever, chest discomfort, severe allergic reaction (anaphylactic shock), nephritis, increased sweating, blurred eyes, impaired taste and reduce sodium levels in the blood. In critically ill patients: mental confusion, agitation, depression and hallucinations.

Other adverse effects may occur. If any of the above mentioned side effects arises and continue, or if you notice anything unusual while taking Odasol, consult your doctor.

**Missed dose:** If you need to take the drug constantly and you miss a dose, you should take the missed dose as soon as possible. If, however, it is almost time for your next dose do not take the missed dose but continue normally the treatment.

**Expiry date of product:** Do not use Odasol after the expiration date printed on the outer and inner package of the product.

**Storage:** Store at temperature below 25°C, protected from moisture.

**Date of last revision of the text:** 30-05-2005

#### INFORMATION ON THE RATIONAL USE OF MEDICINES

- This drug was prescribed to you by your doctor only for your specific medical problem. You should not give it to other people or use it for any other disease without first consulting your doctor.
- If any problem with the medicine is experienced during the treatment, tell your doctor or your pharmacist immediately.
- If you have any questions regarding the information concerning the medicine you are taking or if you need to be better informed about your medical problem, do not hesitate to request this information from your doctor or your pharmacist.
- In order for the drug that has been prescribed to you to be effective and safe, it must be taken according to the instructions given to you.
- For your safety and good health, it is necessary to read carefully any information concerning the medicine that was administered to you.
- Do not keep medicines in bathroom cabinets, because heat and humidity may spoil the medicine and render it harmful for your health.
- Do not keep medicines that you do not need any more or that have already expired.
- For increased safety, keep all medicines in a safe place away from children.

**This medicine is given only under physician's prescription.**

 **genepharma**

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