**The content of this leaflet was updated according to the Ministry of health guidelines on January 2020.**

**Patient leaflet in accordance with the Pharmacists' Regulations (Preparations) - 1986**

This medicine is to be supplied upon physician's prescription only

# Controloc 20 mg tablets
# Controloc 40 mg tablets

Each tablet of Controloc 20 mg contains 20 mg Pantoprazole

Each tablet of Controloc 40 mg contains 40 mg Pantoprazole

Inactive ingredients and allergens - see section 6.

**Read the entire leaflet carefully before you start using this medicine**. This leaflet contains summary information about this medicine. If you have any further questions, refer to the physician or the pharmacist.

This medicine has been prescribed for your treatment. Do not pass it on to others. It may harm them, even if it seems to you that their medical condition is similar.

## 1. What is this medicine intended for?

Controloc inhibits the secretion of acid from cells in the digestive system walls, and helps reduce gastric acidity.

**Controloc 20 mg:**

This medicine is intended for treating reflux oesophagitis that is associated with symptoms such as heartburn, acid regurgitation, pain on swallowing. This medicine is intended for long-term treatment and preventing reflux oesophagitis from recurring.

To prevent duodenal and stomach ulcers that are a result of using non-selective non-steroidal anti-inflammatory drugs (NSAIDs) in patients at risk with a need for continuous NSAIDs treatment.

**Controloc 40 mg:**

This medicine is intended for short-term treatment of acute duodenal and gastric ulcers and moderate to severe reflux oesophagitis.

To eradicate bacteria called Helicobacter pylori (present in the digestive system) in combination with clarithromycin and amoxycillin or clarithromycin and metronidazole/tinidazole or amoxycillin and metronidazole/tinidazole in cases of duodenal ulcer and gastric ulcer with the objective of reducing the recurrence of duodenal and gastric ulcers caused by this microorganism.

To treat Zollinger-Ellison Syndrome.

**Therapeutic group:** proton pump inhibitors (PPIs).

## 2. Before using this medicine

**☒. Do not use this medicine if:**

- You are sensitive (allergic) to the active ingredient or to any of the other ingredients that this medicine contains (see section 6).
- You are sensitive (allergic) to other medicines that contain proton pump inhibitors.

**! Special warnings regarding the use of this medicine**

**Before taking Controloc, tell your physician:**

- If you have severe liver problems. Please tell your physician if you have ever had problems with your liver. The physician will perform liver enzymes tests more frequently, especially when you are taking Controloc as a long-term treatment. In any case of a rise of liver enzymes the treatment should be stopped.
- If you need to take medicines called non-steroidal-anti-inflammatory drugs (NSAIDs) continuously and take Controloc because you have an increased risk of developing stomach and intestinal complications. Any increased risk will be assessed according to your own personal risk factors such as your age (65 years old or more), a history of stomach or duodenal ulcers or of stomach or intestinal bleeding.
- If your body's stores of vitamin B12 are reduced or there is a risk to suffer from a reduced amount of vitamin B12 and you receive Controloc as a long-term treatment. As with all acid reducing agents, Controloc may lead to a reduced absorption of this vitamin.
- If you are taking medicines to treat an HIV infection, such as atazanavir, and at the same time are treated with Controloc, refer to the physician for medical advice.
- Taking proton pump inhibitors like Controloc, especially over a period of more than one year, may slightly increase your risk of fracture in the hip, wrist or spine.
- Tell your physician if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis).
- If you are on Controloc for more than three months, it is possible that the levels of magnesium in your blood may decrease. Low levels of magnesium can manifest as fatigue, involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate.

  If you experience any of these symptoms, contact your physician as soon as possible. Low levels of magnesium can also lead to reduced potassium or calcium levels in your blood. Your physician may refer you to perform regular blood tests to monitor your levels of magnesium.
- If you have ever had a skin reaction after treatment with a medicine similar to Controloc that reduces stomach acid.
- If you get a rash on your skin, especially in areas exposed to the sun, tell your physician as soon as you can, as you may need to stop your treatment with Controloc. Remember to also mention any other side effects like pain in your joints.
- If you are due to have a specific blood test (Chromogranin A).

  **Tell your physician immediately, before or after taking this medicine, if** you notice any of the following symptoms, which could be a sign of another, more serious, disease:

  - an unintentional loss of weight
  - vomiting, particularly if repeated
  - vomiting blood; this may look like dark solids in your vomit
  - blood in your stools; which may be black in appearance
  - difficulty in swallowing or pain when swallowing
  - you look pale and feel weak (anaemia)
  - chest pain
  - stomach pain
  - severe and/or persistent diarrhea; using this medicine is associated with a small increase in frequency of infectious diarrhea.
- Your physician may decide that you need some tests to rule out malignant disease because Controloc also alleviates the symptoms of cancer and could cause delay in diagnosing it. If your symptoms continue in spite of your treatment, further investigations will be considered.
- If you are taking Controloc as a long-term treatment (longer than 1 year), your physician will probably monitor you regularly. Report any symptoms and unusual conditions you experience after using Controloc whenever you see your physician.

- **Children and adolescents:**

This medicine is not recommended for use in children below 12 years of age due to limited data on safety and efficacy regarding the use of this medicine in this age group.

**If you are taking or have recently taken other medicines, including nonprescription medications and nutritional supplements, inform your physician or pharmacist.** This is because Controloc may influence the effectiveness of other medicines.

In particular inform the physician or the pharmacist if you are taking medicines such as:

- Itraconazole, ketoconazole, and posaconazole (used for treatment of fungal infections) or erlotinib (used for treatment of certain types of cancer), since Controloc may stop these and other medicines from working properly.
- Warfarin and phenprocoumon, which affect the thickening or thinning of the blood. You may need further testing.
- Medicines used for treatment of HIV-infection, such as atazanavir.
- Methotrexate (used for treatment of rheumatoid arthritis, psoriasis and cancer). Your physician may temporarily stop your Controloc treatment because Controloc can increase levels of methotrexate in the blood.
- Fluvoxamine (used for treatment of depression and other psychiatric conditions), your physician may consider reducing your dose of Controloc.
- Rifampicin (for treatment of infections).
- Hypericum perforatum (St John's wort) (for treatment of mild depression).

**Pregnancy and breastfeeding**

If you are pregnant or breast-feeding, consult your physician or pharmacist before taking medicines.

There are no adequate data regarding use of Controloc in pregnant women. Excretion into human milk has been reported.

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, consult your physician before taking this medicine. Your physician will weigh the benefit of this treatment against the potential risk to your unborn child or baby.

**Driving and using machines**

There is a possibility that Controloc may affect your ability to drive and operate machines.

If you experience side effects such as dizziness or visual disturbances, you should not drive or operate dangerous machines.

## 3. How should you use the medicine?

Always use according to the physician's instructions. You should check with the physician or the pharmacist if you are unsure.

The dosage and manner of treatment will be determined by the physician only.

**This medicine is not intended for children under the age of 12 years.**

**Do not exceed the recommended dose**.

Take the tablets one hour before the meal. Swallow the medicine with water.

Do not crush, halve or chew the tablets.

Swallow the tablets whole as they have an enteric coating.

**Special patient groups:**

– If you suffer from severe liver problems, you should not take more than one 20 mg tablet a day.

- If you suffer from kidney problems or moderate or severe liver problems, you should not take Controloc 40 mg as a treatment for eradication of Helicobacter pylori.

**If you have accidentally taken a higher dose** you should consult the physician or the pharmacist. There are no known symptoms of overdose.

If you have taken an overdose, or if a child has accidentally swallowed the medicine, immediately refer to a physician or to a hospital emergency room and bring the medicine package with you.

**If you forgot to take the medicine** at the required time, do not take a double dose to make up for a forgotten dose.

Take the next dose at the usual time and consult your physician.

Adhere to treatment as recommended by your physician.

Even if there is an improvement in your health, do not stop the treatment with this medicine without consulting your physician.

Do not take medicines in the dark! Check the label and the dose each time you take the medicine. Wear glasses if you need them.

If you have any further questions regarding the use of this medicine, consult the physician or the pharmacist.

## 4. Side effects

As with any medicine, use of Controloc may cause side effects in some patients. Do not be alarmed by reading the list of side effects. You may not experience any of them.

**Stop the treatment and contact the physician immediately or refer to the emergency room of the nearest hospital if you get any of the following side effects:**

*Rare side effects (occur at most in 1 out of 1000 patients):*

**Serious allergic reactions**: swelling of the tongue and/or throat, difficulty swallowing, hives, difficulties in breathing, allergic facial swelling (uvula's edema (Quincke's oedema) / subcutaneous swelling (angioedema)), severe dizziness with rapid heartbeat and heavy sweating.

*Side effects of unknown frequency (frequency was not determined yet)*

**Serious skin reactions:** blistering of the skin and rapid deterioration of your general condition, erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals (Stevens-Johnson-Syndrome, Lyell-Syndrome, erythema multiforme) and sensitivity to light.

**Other serious conditions:** yellowing of the skin or whites of the eyes (severe damage to liver cells, jaundice) or fever, rash and enlarged kidneys sometimes with painful urination and lower back pain (serious inflammation of the kidneys), possibly leading to kidney failure.

**Additional side effects:**

*Common side effects (occur at most in 1 out of 10 patients):*

Benign polyps in the stomach

*Uncommon side effects (occur at most in 1 out of 100 patients):*

Headache, dizziness, diarrhea, feeling sick, vomiting, bloating and flatulence (wind), cconstipation, dry mouth, abdominal pain and discomfort, rash, exanthema, itching, feeling weak, exhausted or generally unwell, sleep disorders, hip, wrist or spinal fracture.

*Rare side effects (occur at most in 1 out of 1,000 patients):*

Distortion or complete lack of the sense of taste, disturbances in vision such as blurred vision, hives, pain in the joints, muscle pains, weight changes, raised body temperature, high fever, swelling of the extremities (peripheral oedema), allergic reactions, depression, breast enlargement in men.

*Very rare side effects (occur at most in 1 out of 10,000 patients):*

Disorientation.

*Side effects of unknown frequency (frequency was not determined yet):*

Hallucinations, confusion (especially in patients with a history of these symptoms), decreased sodium level in blood, decreased magnesium level in blood (see section 2, Special warnings regarding the use of this medicine), feeling of tingling, prickling, pins and needles, burning sensation or numbness, rash, possibly with pain in the joints , inflammation in the large bowel, that causes persistent watery diarrhoea.

**Side effects identified through blood tests:**

*Uncommon side effects (occur at most in 1 out of 100 patients):*

An increase in liver enzymes.

*Rare side effects (occur at most in 1 out of 1,000 patients):*

An increase in bilirubin, high fat levels in blood, sharp drop in granular white blood cells, associated with high fever.

*Very rare side effects (occur at most in 1 out of 10,000 patients):*

A reduction in the number of blood platelets, which may cause you to bleed or bruise more than normal; a reduction in the number of white blood cells, which may lead to more frequent infections; coexisting abnormal reduction in the number of red and white blood cells and platelets.

If a side effect occurs, if any of the side effects worsens or if you suffer from a side effect not mentioned in the leaflet, you should consult the physician.

Side effects can be reported to the Ministry of Health (MoH) by clicking on the "Report on side effects due to medication therapy" link on the MoH home page (www.health.gov.il) which refers to the online form for side effects reporting, or by entering the link:

https://sideeffects.health.gov.il

## 5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine should be kept in a closed place out of the sight and reach of children and/or infants in order to avoid poisoning. Do not induce vomiting without explicit instruction from the physician.
- Do not use the medicine after the expiry date (exp. date) appearing on the package. The expiry date refers to the last day of that month.
- Storage conditions: Store at a temperature below 25˚C.
- Do not throw away medicines via wastewater or household waste. Ask your pharmacist how to dispose of medicines you no longer need. Taking these measures will help to protect the environment.

## 6. Additional information

In addition to the active ingredient the medicine also contains:

Sodium carbonate (anhydrous), Mannitol, Crospovidone, Povidone K90, Calcium stearate (vegetable), Hypromellose 2910, Povidone K25, Titanium dioxide (E171), Propylene glycol, Methacrylic acid-ethyl acrylate copolymer (1:1), Sodium laurylsulfate, Polysorbate 80, Triethyl citrate, , Shellac, Red Ferric Oxide (E-172), Black ferric oxide (E-172), Yellow ferric oxide (E172), Ammonia solution concentrated.

The amount of sodium in each Controloc 20 mg tablet: 5 mg.

The amount of sodium in each Controloc 40 mg tablet: less than 10 mg.

- **What does the medicine look like and what are the contents of the package**

Controloc 20 mg:

Yellow, oval, biconvex, gastro-resistant tablet with 'P 20' imprinted on one side.

The package contains 30 tablets in 2 blisters. Each blister contains 15 tablets.

Controloc 40 mg:

Yellow, oval, biconvex, gastro-resistant tablet with 'P 40' imprinted on one side.

The package contains 14 tablets in 1 blister, or 28 tablets in 2 blisters (each blister pack contains 14 tablets).

Not all pack sizes may be marketed.

- **Registration holder and address:**

  Takeda Israel Ltd., Efal 25, P.O.B 4140 Kiryat Arie, Petach Tikva 4951125.

- **Manufacturer name:** Takeda GmbH, Oranienburg, Germany.

- Registration number of the medicine in the National Drug Registry of the Ministry of Health:

  Controloc 20 mg: 116-36-29745-00

  Controloc 40 mg: 104-40-28684-00

The format of this leaflet was determined by the ministry of health and its content was checked and approved by the ministry of health on 07.2016, and was updated according to the guidelines of the ministry of health on 01.2020.