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

This medicine is dispensed with a 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 2 "Before using this medicine" and section 6 "Additional information".

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

This medicine has been prescribed to treat you. 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 and gastric ulcers caused by this microorganism, with the objective of reducing the recurrence of these ulcers.

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. Please contact your physician if you notice any of the following symptoms, which could indicate low levels of Vitamin B12:
  - extreme tiredness or lack of energy
  - pins and needles
  - sore or red tongue, mouth ulcers
  - muscle weakness
  - disturbed vision
  - problems with memory, confusion, depression.

- If you are taking protease inhibitor 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 (reduced bone density) or if you have been told that you are at risk of getting osteoporosis (for example, if you are taking steroids).
- 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 or 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.
  Serious skin reactions including Stevens-Johnson syndrome, drug reaction with eosinophilia and systemic symptoms (DRESS), erythema multiforme, and toxic epidermal necrolysis (TEN) have been reported in association with Controloc treatment. Stop using Controloc and

seek medical attention immediately if you notice any of the symptoms related to these serious skin reactions described in section 4.
- 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 diarrhoea; using this medicine is associated with a small increase in frequency of infectious diarrhoea.
- 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 with Controloc, 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 new unusual conditions you experience whenever you see your physician.

Children and adolescents:
This medicine is not recommended for use in children below 12 years of age because of limited data on safety and efficacy in this age group.

Drug interactions:
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 tests.
- Medicines used for treatment of HIV-infection, such as atazanavir.
- Methotrexate (used for treatment of rheumatoid arthritis, psoriasis and cancer). If you are taking methotrexate, 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). If you are taking fluvoxamine your physician may reduce the dose.
- Rifampicin (for treatment of infections).
- Hypericum perforatum (St John's wort) (for treatment of mild depression).

Talk to your doctor before taking Controloc if you are due to have a specific urine test for THC; Tetrahydrocannabinol.

Pregnancy, breast-feeding and fertility
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 or pharmacist 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
Controloc has no or negligible influence on the ability to drive and use machines.

If you experience side effects such as dizziness or disturbed vision, you should not drive or operate machines.

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

3. How should you use the medicine?

Always use the medicine according to the physician's instructions. You should check with the physician or the pharmacist if you are not sure about your dose or about how to take this medicine.
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.

Take the medicine 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 populations:

- If you suffer from severe liver problems, you should not take more than one Controloc 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.

Do not exceed the recommended dose.

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 some 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 in up to 1 in 1,000 users):
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 (the frequency of these effects has not been established yet):
Serious skin reactions: you may notice one or more of the following: blistering of the skin and rapid deterioration of your general condition, skin erosion (including slight bleeding) of eyes, nose, mouth/lips or genitals, or skin sensitivity/rash, particularly in areas of skin exposed to light/the

sun. You may also have joint pain or flu-like symptoms, a fever, swollen glands (e.g. in the armpit) and blood tests may show changes in certain white blood cells or liver enzymes.

- reddish non-elevated, target-like or circular patches on the trunk, often with central blisters, skin peeling, ulcers of mouth, throat, nose, genitals and eyes.
  These serious skin rashes can be preceded by fever and flu-like symptoms (Stevens-Johnson syndrome, toxic epidermal necrolysis (TEN)).
- widespread rash, high body temperature and enlarged lymph nodes (DRESS syndrome or drug hypersensitivity syndrome).

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 in up to 1 in 10 users):
Benign polyps in the stomach.
Uncommon side effects (occur in up to 1 in 100 users):
Headache, dizziness, diarrhoea, feeling sick, vomiting, bloating and flatulence, constipation, dry mouth, abdominal pain and discomfort, rash, exanthema, eruption, itching, feeling weak, exhausted or generally unwell, sleep disorders, hip, wrist or spinal fracture.
Rare side effects (occur in up to 1 in 1,000 users):
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 in up to 1 in 10,000 users):
Disorientation.
Side effects of unknown frequency (the frequency of these effects has not been established yet):
Hallucinations, confusion (especially in patients with a history of these symptoms), 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 in up to 1 in 100 users):
An increase in liver enzymes.

Rare side effects (occur in up to 1 in 1,000 users):
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 in up to 1 in 10,000 users):
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.

Side effects of unknown frequency (the frequency of these effects has not been established yet):
Decreased level of sodium, magnesium, calcium or potassium in blood (see section 2, Special warnings regarding the use of this medicine).

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 "Reporting side effects of drug treatment" 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 reach and sight 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:
Core: crospovidone, mannitol, sodium carbonate (anhydrous), povidone K90, calcium stearate (vegetable).
Sub coating: hypromellose 2910, propylene glycol, povidone K25, titanium dioxide (E171), yellow ferric oxide (E172).
Enteric coating: methacrylic acid-ethyl acrylate copolymer (1:1), triethyl citrate, polysorbate 80, sodium laurylsulfate.
Printing ink: shellac, black ferric oxide (E172), red ferric oxide (E172), 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 the medicine looks like and contents of the pack**
  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.

- **Name and address of Registration holder and importer:**
  Takeda Israel Ltd., Efal 25, P.O.B 4140, Petach Tikva 4951125.

- **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

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