

# CONTROLOC 40MG TABLETS

Pantoprazole sodium (40mg)

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## What Controloc is used for

Controloc is used in adults and children 12 years and older:

- Treatment of moderate and severe reflux oesophagitis (inflammation or irritation of esophagus caused by a return flow of fluid from stomach)
- In adults:
- Treatment of gastric and intestinal ulcers
  - Hormone producing tumors in the pancreas causing excess acid in the stomach (Zollinger-Ellison Syndrome) and other pathological hypersecretory conditions.
  - Eradication of *H. pylori* in people with peptic ulcer in combination with two appropriate antibiotics

## How Controloc works

Controloc belongs to a medicine group known as proton pump inhibitors (PPIs). Controloc reduces the amount of acid in your stomach. Controloc may help your acid-related symptoms, but you could still have serious stomach problems. Talk with your doctor.

## Before you use Controloc

- When you must not use it
  - You should not take Controloc if you are allergic to

pantoprazole or any of the other ingredients of this medicine.

- You have moderate to severe liver and kidney problems
- You have mild gastrointestinal complain
- Before you start to use it

Before you take Controloc, tells your doctor if you:

  - Are pregnant or plan to become pregnant. It is not known if Controloc can harm your unborn baby.
  - Are breast-feeding or planning to breast-feed. Your doctor should decide if you will take Controloc or breast-feed. You should not do both without first talking with your doctor.
  - Have reduced body stores or risk factors for reduced vitamin B12 absorption
  - Doctor will plan a few tests if you have any alarm symptom (e. g. significant unintentional weight loss, recurrent vomiting, swallowing difficulty vomiting blood, low red blood cells or black, tarry stools) and when gastric ulcer is suspected or present to diagnose cancer.
  - Are due to have a specific blood test (chromogranin A)

## Taking other medicines

Tell your doctor about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Controloc may affect how other medicines work, and other medicines may affect how Controloc works. Especially tell your doctor if you take:

- Atazanavir or nelfinavir (medicines for Human Immunodeficiency Virus (HIV))
- Methotrexate (chemotherapy medication used to treat cancer)
- Tacrolimus (prevent transplant rejection),
- Fluvoxamine (for depression or anxiety disorder)
- Warfarin, phenprocoumon (prevent blood clotting)

## How to use Controloc

- How much to use
  - Take 1 or 2 Controloc 40mg each day for moderate to severe reflux esophagitis.
  - Take 2 Controloc 40mg + combination of any 2 antibiotics for eradication of *H.pylori* twice per day as below:
    - o 1000mg amoxicillin
    - o 500 clarithromycin
    - o 500mg metronidazole
  - Take 1 or 2 Controloc 40mg each day for treatment of gastric and intestinal ulcer
  - Take 2 Controloc 40mg each day for long-term management of Zollinger- Ellison Syndrome. The dose may be titrated up or down
- When to use it

Controloc is taken 1 hour before breakfast. Combination therapy for *H.pylori*, the second dose should be taken before evening meal.
- How long to use it
  - *H.pylori* infection usually lasts 7 days and extended maximum 2 weeks. If a two-week treatment period is not sufficient, healing will

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be achieved in almost all cases within a further 2 weeks.

- 4-weeks for gastric ulcers and reflux esophagitis (inflammation of esophagus). If this should be inadequate, healing will in most cases be achieved within a further 4 weeks.
- Treatment for Zollinger-Ellison is not limited.

- If you forget to use it

If you miss a dose, take it as soon as you remember. If you do not remember until it is time for your next dose, skip the missed dose, and take the next dose at your regular time. Do not take 2 doses of Controloc at the same time.

- If you use too much (overdose)

If you take too much Controloc, call your doctor or go to the nearest hospital emergency room right away.

### While you are using it

- Things you must do

Controloc should be swallowed whole with water

- Things you must not do

Controloc should not be chewed or crushed.

- Things to be careful of

- There is increased risk for bone fracture for people who received high-doses, or used more than a year or longer.
- There is an increased risk of bacteria infection.
- Liver enzymes should be monitored for individuals on long-term use.

- Low magnesium level (hypomagnesemia) has been rarely reported in individuals treated with PPIs for at least three months (in most cases after a year of therapy). Serious consequences of hypomagnesemia include muscle spasm, irregular heart beat, and fits. For those expected to be on prolonged treatment or who take PPIs with medications such as digoxin or medicines that may cause hypomagnesemia (e.g. diuretics), doctor may consider measuring magnesium levels before starting PPI treatment and periodically during treatment. Low magnesium level may lead to low calcium level and/ or low potassium level.

### Side Effects

The side effects of Controloc include:

- Sleep disorder
- Headache
- Dizziness
- Diarrhoea
- Nausea
- Vomiting
- Constipation
- Dry mouth, abdominal pain and discomfort
- Liver enzymes increased
- Rash
- Fatigue
- Benign polyps in the stomach
- Inflammation in the large bowel, that causes persistent watery diarrhea

When you are taking this

medicine, your doctor will want to monitor you (especially if you are taking it for long term). Hence, you should report any new and exceptional symptoms and circumstances whenever you see your doctor. Please tell your doctor promptly if you get any of the symptoms below:

- **Subacute Cutaneous Lupus Erythematosus (SCLE).**

Rash (especially in areas exposed to the sun), possibly with pain in the joints. SCLE frequency "not known".

- **Kidney problems (Tubulointerstitial Nephritis)**

Fever that do not go away, extreme tiredness, pus/ blood in urine

- **Hypomagnesaemia.** Involuntary muscle contractions, disorientation, convulsions, dizziness, increased heart rate. Anemic (pale skin, weakness, tiredness or lightheadedness), shortness of breath, a smooth tongue, nerve problems (numbness or tingling, muscle weakness and problems walking), vision loss and mental problems (depression, memory loss or behavioral changes)

Low levels of magnesium can also lead to a reduction in potassium or calcium levels in the blood (hypomagnesaemia). Frequency "not known".

- **Bone fracture.**

People who are taking multiple daily doses of proton pump inhibitor medicines for a long period of time may have an increased risk of fractures of the hip, wrist or spine. Tell your doctor if you have osteoporosis or if you are taking corticosteroids (which can increase the risk of osteoporosis). Frequency "uncommon".

- **Vitamin B-12**

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## **Absorption.**

Malabsorption of vitamin B-12 may happen if you are taking acid-suppressing medications for a long period of time (e.g longer than 3 years).

- ***Clostridium Difficile***  
**Diarrhea**

Watery stool, stomach pain and fever that do not go away. Severe diarrhea which may be caused by an infection (*Clostridium difficile*) in your intestines.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website [npra.gov.my](http://npra.gov.my) [Consumers --> Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

## **Storage and Disposal of Controloc**

### - Storage

Store Controloc below 30°C. Keep Controloc and all medicines out of the reach of children.

### - Disposal

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.

## **Product Description**

### - What it looks like

Controloc is supplied as film-coated tablets that are oval, yellow, biconvex and printed with P40 in brown ink on one side.

### - Ingredients

- Active ingredient

Pantoprazole Sodium

- Inactive ingredients

Sodium carbonate; Mannitol;

Croscopovidone; Povidone K90;

Calcium stearate;

Hypromellose 2910; Povidone

K25; Titanium dioxide E171;

Yellow ferric oxide E172;

Propylene glycol; Triethyl

citrate; Methacrylic acid –

ethyl acrylate Copolymer (1:1);

Polysorbate 80; Sodium

Laurisulfate; Printing ink.

### - MAL Number

MAL19972093ARZ

## **Manufacturer**

Takeda GmbH,  
Production Site Oranienburg  
Lehnitzstrasse 70-98  
D-16515 Oranienburg  
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## **Product Registration Holder**

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## **Date of Revision**

25/03/2021 (CCDS v8)

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