

**Package leaflet: Information for the patient**  
**CO-TENIDONE 50 mg/12.5 mg and 100 mg/25 mg TABLETS**

**Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.**

- 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 for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

**What is in this leaflet**

1. What Co-Tenidone is and what it is used for
2. What you need to know before you take Co-Tenidone
3. How to take Co-Tenidone
4. Possible side effects
5. How to store Co-Tenidone
6. Contents of the pack and other information

**1. What Co-Tenidone is and what it is used for**

Co-Tenidone is a combination of two drugs. Atenolol is a beta blocker and chlortalidone is a diuretic. Beta blockers have an action on the heart; to slow the pulse rate and reduce the force of contraction of the heart muscle. Diuretics increase urine output and so reduce fluid retention. This combined action leads to a lowering of your blood pressure.

Co-Tenidone is used to treat people with high blood pressure.

**2. What you need to know before you take Co-Tenidone**

**Do not take Co-Tenidone:**

- if you are allergic to the active substances or any of the other ingredients of this medicine (listed in section 6)
- if you are pregnant or breast-feeding
- if you have an unusually slow heart beat or low blood pressure sometimes causing dizziness, faintness or lightheadness on standing
- if you have a phaeochromocytoma (adrenal gland tumor) unless adequately controlled by medication
- if you have metabolic acidosis (acidification of the blood)
- if you have a second or third degree heart block (a conduction defect of the heart) or a weak heart (cardiogenic shock)
- if you have sick-sinus syndrome (slow and irregular heart beat due to sino-atrial block)
- if you have unstable/uncontrolled heart failure
- if you have severe hardening of the arteries affecting the circulation in your legs or feet
- if you have severe kidney failure.

**Warnings and precautions**

Talk to your doctor or pharmacist before taking Co-Tenidone

- if you have a history of asthma, wheezing or have other problems with your breathing
- if you have liver or kidney problems
- if you have gout
- if you have first degree heart block, controlled heart failure or Prinzmetal's angina (chest pain) or any type of heart disease

- if you have history of allergic reactions (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives)
- if you have diabetes as your low blood sugar “hypo” warning signs may be less obvious than usual. Your doctor may want to test your blood sugar level at the beginning of this treatment
- if you have thyroid problems
- if you are elderly
- if you have a diet low in potassium
- if you suffer from stomach problems.
- if you experience a decrease in vision or eye pain. These could be symptoms of fluid accumulation in the vascular layer of the eye (choroidal effusion) or an increase of pressure in your eye and can happen within hours to a week of taking co-Tenidone. This can lead to permanent vision loss, if not treated. If you earlier have had a penicillin or sulfonamide allergy, you can be at higher risk of developing this.

Tell your doctor or dentist you are taking Co-Tenidone tablets if you are to have an operation requiring an anaesthetic.

Your doctor may test the level of potassium in your blood if you are taking digoxin or digitoxin, are on a low potassium diet or if you have any stomach complaints.

If you take Co-Tenidone for a long time your urine will be tested regularly for sugar.

Co-Tenidone can affect or be affected by other medicines you are using, including eye drops for the treatment of glaucoma.

### **Other medicines and Co-Tenidone**

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. Talk to your doctor if you are taking any of the following:

- insulin or tablets to treat diabetes
- digoxin or digitoxin (used to treat heart problems)
- non-steroidal anti-inflammatory drugs (NSAIDs) e.g. indometacin or ibuprofen
- sympathomimetic (heart stimulating) drugs such as dopamine, terbutaline, salmeterol, salbutamol, ephedrine, adrenaline and phenylpropranolamine. Ephedrine and phenylpropranolamine may be present in medicines for colds and nasal stuffiness
- lithium (use to treat manic depression)
- calcium channel blockers e.g. diltiazem, verapamil or nifedipine
- medication to treat an irregular heart beat such as disopyramide, amiodarone
- clonidine (another drug used to treat high blood pressure)
- baclofen (used for relaxation of muscle)
- anaesthetics (medicines used for temporary loss of bodily sensation).

### **Co-Tenidone with food, drink and alcohol**

Do not drink alcohol while taking Co-Tenidone.

### **Pregnancy, breast-feeding and fertility**

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

### **Driving and using machines**

Co-Tenidone may cause dizziness or tiredness, if affected do not drive or operate machinery.

### **Information about ingredient of Co-Tenidone**

This medicine contains less than 1 mmol sodium (23 mg) per Tablet, that is to say essentially ‘sodium-free’.

### **3. How to take Co-Tenidone**

Always take this medicine exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

The recommended dose is:

#### **Adults**

One Co-Tenidone 50 mg/12.5 mg tablet daily. This may be increased to 100 mg/25 mg daily.

#### **Elderly**

Dosage may be reduced.

#### **Kidney problems**

You may be prescribed a lower dose or you may need to take your medicine less frequently. Please speak to your doctor before taking this medicine if you have severe kidney problems.

#### **Children and adolescents < 18 years**

Co-Tenidone is not recommended for use in children and adolescents < 18 years.

#### **If you take more Co-Tenidone than you should**

If you (or someone else) take too many tablets all together, or if you think a child has swallowed any of the tablets, contact your nearest hospital casualty department or your doctor immediately.

An overdose is likely to cause low blood pressure (feeling faint, dizzy, shaky and weak), slow heart beat, difficulty in breathing and heart failure/attack. Please take this leaflet, any remaining tablets and the container with you to the hospital or doctor so that they know which tablets were consumed.

#### **If you forget to take Co-Tenidone**

If you forget to take a tablet, take one as soon as you remember, unless it is nearly time to take the next one. Do not take a double dose to make up for a forgotten tablet.

#### **If you stop taking Co-Tenidone**

Do not suddenly stop taking your tablets as side effects can occur. If your treatment is to be stopped your doctor will gradually reduce your dose.

If you have any further questions on the use of this product, ask your doctor or pharmacist.

### **4. Possible side effects**

Like all medicines, this medicine can cause side effects, although not everybody gets them.

If the following happens, stop taking the tablets and tell your doctor immediately or go to the casualty department at your nearest hospital:

- an allergic reaction (swelling of the lips, face or neck leading to severe difficulty in breathing; skin rash or hives).

This is a very serious but rare side effect. You may need urgent medical attention or hospitalisation.

If you have a history of asthma or psoriasis (patches of flaky, thickened and sore skin) you may experience a worsening of the symptoms of these conditions.

Decrease in vision or pain in your eyes due to high pressure (possible signs of fluid accumulation in the vascular layer of the eye (choroidal effusion) or acute angle-closure glaucoma)

Tell your doctor if you experience any of the following:

Common: may affect up to 1 in 10 people

- slow heart beat
- cold hands and feet
- stomach upset
- feeling unwell
- tiredness
- high uric acid in blood (this can be detected from a blood test)
- low blood levels of potassium which can cause muscle weakness, twitching or abnormal heart rhythm
- low blood levels of sodium which can cause tiredness and confusion, muscle twitching, fits and coma
- sugar intolerance.

Uncommon: may affect up to 1 in 100 people

- sleep disturbances
- elevated liver function test.

Rare: may affect up to 1 in 1,000 people

- low white blood cell and platelet count in blood
- bleeding underneath the skin
- unusual bleeding or unexplained bruising
- mood changes
- nightmares
- confusion
- abnormal condition of mind
- seeing and hearing things that are not real
- dizziness
- headache
- abnormal sensation of skin
- dry eyes
- disturbed vision
- heart failure deterioration
- heart block
- rapid fall of blood pressure when standing up
- feeling faint
- asthma
- difficulty in breathing or wheezing
- dry mouth
- liver disease
- inflammation of the pancreas that may cause intense, persistent pain in the upper abdomen.  
Symptoms may include nausea, constipation, and jaundice
- hair loss
- skin rash
- patchy inflamed skin
- inability to develop or maintain an erection of the penis.

Very rare: may affect up to 1 in 10,000 people

- increase in anti-nuclear antibody.

Not known: frequency cannot be estimated from the available data

- constipation
- Lupus-like syndrome (a disease where the immune system produces antibodies that attacks mainly skin and joints)

### **Reporting of side effects**

If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the Yellow Card Scheme at:

[www.mhra.gov.uk/yellowcard](http://www.mhra.gov.uk/yellowcard) or search for MHRA Yellow Card in the Google Play or Apple App Store.

By reporting side effects you can help provide more information on the safety of this medicine.

## **5. How to store Co-Tenidone**

Keep this medicine out of the sight and reach of children

Store in a cool dry place at or below 25°C. Protect from light.

Do not use this medicine after the expiry date which is stated on the carton after EXP. The expiry date refers to the last day of that month.

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 to protect the environment.

## **6. Contents of the pack and other information**

### **What Co-Tenidone contains:**

- The active substances are atenolol and chlortalidone.  
Each tablet of Co-Tenidone 50 mg/12.5 mg contains atenolol 50 mg and chlortalidone 12.5 mg.  
Each tablet of Co-Tenidone 100 mg/25 mg contains atenolol 100 mg and chlortalidone 25 mg.
- The other ingredients are magnesium carbonate, maize starch, povidone (E1201), sodium starch glycolate and magnesium stearate (E572). The tablet coating contains hypromellose (E464), purified talc (E553b), polyethylene glycol (E1520), yellow, red and black iron oxides (E172) and titanium dioxide (E171).

### **What Co-Tenidone looks like and contents of the pack:**

- The 50 mg/12.5 mg are brown, film-coated, round, biconvex tablets, engraved: 3H2.
- The 100 mg/25 mg are brown, film-coated, round, biconvex tablets, engraved: 4H2.
- The product comes in packs of 10, 20, 28, 30, 56, 60, 100, 250, 500 and 1000 tablets.  
Not all pack sizes may be marketed.

## **Marketing Authorisation Holder and Manufacturer**

### **Marketing Authorisation Holder**

Teva UK Limited, Ridings Point, Whistler Drive, Castleford, WF10 5HX, United Kingdom

### **Manufacturer**

TEVA UK Limited, Eastbourne, BN22 9AG

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