Package leaflet: Information for the user Co-Tenidone 50/12.5mg Tablets Co-Tenidone 100/25mg Tablets

(Referred to as Co-Tenidone tablets in the leaflet)



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

- What Co-Tenidone tablets are and what they are used for
- 2. What you need to know before you take Co-Tenidone tablets
- 3. How to take Co-Tenidone tablets
- 4. Possible side effects
- 5. How to store Co-Tenidone tablets
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What Co-Tenidone tablets are and what they are used for

Co-tenidone is used to treat high blood pressure (hypertension). It contains two different medicines atenolol and chlortalidone. These medicines work together to lower your blood pressure.

- Atenolol belongs to a group of medicines called beta-blockers. It works by making your heart beat more slowly and with less force.
- Chlortalidone belongs to a group of medicines called diuretics. It works by increasing the amount of urine produced by your kidneys.

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

Do not take Co-Tenidone tablets:

- if you are allergic to atenolol, chlortalidone or to any of the other ingredients in this medicine (listed in section 6)
- if you have ever had any of the following heart problems:
 - heart failure which is not under control (this usually makes you breathless and causes your ankles to swell)
 - second- or third-degree heart block (a condition which may be treated by a pacemaker)
 - very slow or very uneven heart beats, very low blood pressure or very poor circulation
- if you have a tumour called phaeochromocytoma that is not being treated. This is usually near your kidney and can cause high blood pressure
- if you have problems with your kidneys
- if you have been told that you have higher than normal levels of acid in your blood (metabolic acidosis)
- if you are pregnant, are trying to become pregnant or are breast-feeding.

Do not take Co-tenidone tablets if any of the above apply to you. If you are not sure, talk to your doctor or pharmacist before taking Co-tenidone tablets.

Warnings and precautions Talk to your doctor before taking Co-tenidone tablets:

- if you have asthma, wheezing or any other similar breathing problems, or you get allergic reactions, for example to insect stings. If you have ever had asthma or wheezing, do not take this medicine without checking with your doctor.
- if you have a risk of developing gout (sudden to a risk of developing gout)
- unexpected burning pain in the joints)if you have a type of chest pain (angina)called Prinzmetal's angina
- if you have poor blood circulation or controlled heart failure
- if you have first-degree heart block
- if you have diabetes. Your medicine may change how you respond to having low blood sugar. You may feel your heart beating faster
- if you have thyrotoxicosis (a condition caused by an overactive thyroid gland). Your medicine may hide the symptoms of

thyrotoxicosis.

- if you have problems with your adrenal glands.
- if you have liver 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 tablets. 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.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking Co-tenidone tablets.

Children

This medicine is not for use in children.

Other medicines and Co-Tenidone tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. This includes medicines that you buy without a prescription and herbal medicines. This is because Co-tenidone tablets can affect the way some other medicines work and some medicines can have an effect on Co-tenidone tablets.

In particular, tell your doctor if you are taking any of the following medicines:

- clonidine (for high blood pressure or migraine). If you are taking clonidine and Co-tenidone tablets together, do not stop taking clonidine unless your doctor tells you to do so. If you have to stop taking clonidine, your doctor will give you careful instructions on how to do so.
- verapamil, diltiazem and nifedipine (for high blood pressure or chest pain)
- disopyramide or amiodarone (for an uneven heart beat)
- digoxin (for heart problems)
- adrenaline, also known as epinephrine (a medicine that stimulates the heart)
- baclofen (a medicine used for muscle relaxation)
- ibuprofen or indometacin (for pain and inflammation)
- insulin or medicines that you take by mouth for diabetes.
- lithium (for certain mental illnesses)
- medicines to treat nose or sinus congestion or other cold remedies (including those you can buy in the pharmacy)
- betaxolol, carteolol, levobunolol and timolol (eye drops for glaucoma)

Operations

If you go into hospital to have an operation, tell the anaesthetist or medical staff that you are taking Co-tenidone tablets. This is because you can get low blood pressure (hypotension) if you are given certain anaesthetics while you are taking Co-tenidone tablets.

Pregnancy and breast-feeding

- Do not take Co-tenidone tablets if you are pregnant or trying to get pregnant, ask your doctor for advice before using this medicine.
- Do not take Co-tenidone tablets if you are breast-feeding, ask your doctor for advice before using this medicine.

Driving and using machines

- Your medicine is not likely to affect you being able to drive or use any tools or machines. However, it is best to wait to see how your medicine affects you before trying these activities.
- If you feel dizzy or tired when taking this medicine, ask your doctor for advice.

Co-Tenidone tablets contain sodium

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

3. How to take Co-Tenidone tablets

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

- Your doctor will tell you how many tablets to take each day and when to take them. Read the label on the carton to remind you what the doctor said.
- Swallow your Co-tenidone tablets with a drink of water.

Adults

The recommended dose for an adult is one tablet each day.

People with kidney problems

If you have problems with your kidneys, your doctor may give you a lower dose or ask you to take this medicine less often.

Use in Children

Your medicine must not be given to children

If you take more Co-Tenidone tablets than you should

If you take more Co-tenidone tablets than prescribed by your doctor, talk to a doctor or go to a hospital straight away. Take the medicine pack with you so that the tablets can be identified.

If you forget to take Co-Tenidone tablets

If you forget to take a dose, take it as soon as you remember. However, if it is almost time for the next dose, skip the missed dose. Do not take a double dose to make up for a forgotten dose.

If you stop taking Co-tenidone tablets

Do not stop taking Co-tenidone tablets without talking to your doctor. In some cases, you may need to stop taking it gradually.

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

4. Possible side effects

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

Allergic reactions:

If you have an allergic reaction, see a doctor straight away. The signs may include raised lumps on your skin (weals) or swelling of your face, lips, mouth, tongue or throat.

Other possible side effects: Common (may affect up to 1 in 10 people)

- cold hands and feet
- you may notice that your pulse rate becomes slower while you are taking the tablets. This is normal, but if you are concerned please tell your doctor about it.
- diarrhoea
- · feeling sick (nausea)
- · feeling tired
- changes in the amount of certain substances in your blood.

It can cause:

- higher levels of sugar (glucose) than normal
- low levels of sodium, which may cause weakness, being sick (vomiting) and cramps
- low levels of potassium, which can cause muscle weakness, twitching or abnormal heart rhythm
- an increase in the amount of uric acid

Your doctor may take blood samples every so often to check on these levels.

Uncommon (may affect up to 1 in 100 people)

disturbed sleep

Rare (may affect up to 1 in 1,000 people)

- heart block (which can cause an abnormal heart beat, dizziness, tiredness or fainting)
- · numbness and spasm in your fingers which is followed by warmth and pain (Raynaud's disease)
- dizziness (particularly when standing up)
- headache
- feeling confused
- · changes in personality (psychoses) or hallucinations
- · mood changes
- nightmares · dry mouth
- · thinning of your hair
- dry eyes
- skin rash
- · tingling of your hands
- disturbances of vision
- · bruising more easily or purplish marks on
- being unable to get an erection (impotence)
- jaundice (causing yellowing of the skin or the whites of your eyes)
- pancreatitis (inflammation of a large gland behind the stomach)
- a reduced number of white blood cells. You may get more infections than usual.

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

Changes to some of the cells or other parts of your blood. Your doctor may take blood samples every so often to check whether

Not known (frequency cannot be estimated

Co-tenidone has had any effect on your blood.

constipation

from the data available)

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

 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)

Conditions that may get worse

If you have any of the following conditions, they may get worse

when you start to take your medicine. This happens rarely affecting up to 1 in 1,000 people:

- psoriasis (a skin condition)
- being short of breath or having swollen ankles (if you have heart failure)
- asthma or breathing problems
- · poor circulation

Reporting of side effects

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

Keep out of the sight and reach of children.

- · Co-Tenidone tablets should be stored below 25°C. Store in the original package to protect from light and moisture.
- do not use this medicine after the expiry date on the label. 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 protect the environment.

Contents of the pack and other information

What Co-tenidone Tablets contain

The active ingredients are: atenolol and chlortalidone.

The other ingredients are: maize starch, calcium hydrogen phosphate, microcrystalline cellulose, povidone K30, sodium starch glycollate, magnesium stearate, purified water. Film coating: opadry OY-6954

What Co-Tenidone tablets look like and the contents of the pack

Co-Tenidone tablets are brownish pink, round, biconvex film-coated tablets marked CTE 50 or CTE 100 on one side and CP on the other.

These tablets are available in blister packs of white opaque PVC film and hard tempered aluminium foil. They are available in the pack size of 28, 30, 56 and 60. Not all pack sizes may be marketed.

Marketing Authorisation Holder:

Wockhardt UK Ltd,

Ash Road North, Wrexham, LL13 9UF, UK.

Manufacturer:

CP Pharmaceuticals Ltd, Ash Road North, Wrexham, LL13 9UF, UK.

Other formats:

To listen to or request a copy of this leaflet in Braille, large print or audio please call, free of charge: 0800 198 5000 (UK Only).

Please be ready to give the following information:

Reference number
29831/0056 29831/0057

This is a service provided by the Royal National Institute of Blind People.

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