

PATIENT INFORMATION LEAFLET

Triamterene/Chlortalidone 50mg/50mg film-coated tablets

Read all of this leaflet carefully before you start taking this medicine.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.
- If any of the side effects gets serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist.
- The full name of this product is Triamterene/Chlortalidone 50mg/50mg film-coated tablets but in this leaflet it will be referred to as Triamterene/Chlortalidone tablets.

In this leaflet:

1. What Triamterene/Chlortalidone tablets are and what they are used for
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3. How to take Triamterene/Chlortalidone tablets
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1. WHAT TRIAMTERENE/CHLORTALIDONE TABLETS ARE AND WHAT THEY ARE USED FOR

Triamterene/Chlortalidone tablets contain the active ingredients triamterene and chlortalidone. The tablets increase the amount of urine passed while limiting the amount of potassium lost into the urine.

They are used to treat mildly or moderately raised blood pressure or to reduce swelling of the feet and legs when this is due to fluid collecting under the skin, or to reduce fluid which has collected in the abdomen because of damage to the liver (this is called ascites).

2. BEFORE YOU TAKE TRIAMTERENE/CHLORTALIDONE TABLETS

Do not take Triamterene/Chlortalidone tablets if you:

- are **allergic** (hypersensitive) to chlortalidone, triamterene, other sulfonamide based drugs or any of the other ingredients of this medicine (see section 6).
- have **worsening kidney failure**
- are taking **lithium** (anti-depressant)
- have **high blood potassium** levels (hyperkalaemia)
- are taking other **potassium sparing drugs**, such as spironolactone or amiloride

This medicine should not be used in children.

Take special care with Triamterene/Chlortalidone tablets

Tell your doctor, pharmacist or nurse before taking Triamterene/Chlortalidone tablets if you:

- have severe **kidney disease**
- have worsening **liver disease** or reduced liver function
- are taking **potassium supplements** (for treatment of low blood potassium)
- suffer from **diabetes**

- are **allergic to penicillin**. If you have had a penicillin or sulfonamide allergy you could be at higher risk of developing serious side effects affecting the eyes.
- are **pregnant or breastfeeding**
- are about to undergo **surgery** (these tablets may interact with surgery medicines)

Triamterene/Chlortalidone tablets may cause a reaction affecting the eyes in some people. Talk to your doctor 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 Triamterene/Chlortalidone 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.

Your doctor will monitor your blood salt levels during your treatment.

Taking other medicines

You should tell your doctor if you are taking or have taken any of the following medicines as they may interact with Triamterene/Chlortalidone tablets:

- potassium supplements
- lithium, (used in the management of manic depression, mania, some types of depression, aggressive behaviour and intentional self-harm)
- barbiturates (sleeping medicine)
- narcotics or alcohol (strong painkillers)
- tubocurarine (medicines used during surgery)
- other high blood pressure medication (antihypertensive)
- other diuretics (increase urine production)

Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, including medicines obtained without a prescription.

Taking Triamterene/Chlortalidone tablets with food and drink

Do not drink alcohol when taking this medicine.

Triamterene/Chlortalidone tablets should be taken after breakfast.

Pregnancy and breast-feeding

If you are pregnant, likely to become pregnant or are breast-feeding, you **must inform your doctor**. Some ingredients of Triamterene/Chlortalidone tablets may harm your unborn child or your breastfeeding baby. Your doctor will prescribe this medicine for you only if it is essential.

Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

This medicine should not affect your ability to drive or operate machinery.

Important information about some of the ingredients of Triamterene/Chlortalidone tablets

This medicine contains **lactose**. If you have been told that you have intolerance to some sugars, contact your doctor before taking this medicine.

This medicine contains the colouring agent sunset yellow, which may cause allergic reactions.

This medicine contains sodium propyl hydroxybenzoate which may cause allergic reactions (possibly delayed).

3. HOW TO TAKE TRIAMTERENE/CHLORTALIDONE TABLETS

Always take your medicine as your doctor has instructed.

Do not give these tablets to children

Dosage

A typical dose is one tablet daily after breakfast.

If necessary the dose may be increased to two tablets once daily after breakfast.

Elderly patients may require lower dosage.

If you take more Triamterene/Chlortalidone tablets than you should

If you suspect that you or someone else has taken an overdose of these tablets, contact your doctor or go to the emergency department of your local hospital **immediately**. Always take the container with you, even if empty.

If you forget to take Triamterene/Chlortalidone tablets

Take that dose as soon as you remember unless it is time for your next dose. Do not take a double dose to make up for a forgotten 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.

Triamterene/Chlortalidone tablets can rarely cause metabolic acidosis which causes rapid breathing and reduced heart function. If you believe this is happening to you then **inform your doctor immediately**.

These tablets may rarely cause allergic reactions. Symptoms may include swelling of the hands, feet, ankles, face, lips, mouth or throat, difficulty in swallowing or difficulty breathing. You should contact a doctor immediately if you experience any of these side effects.

The following side effects have been reported:

- nausea
- mouth dryness
- constipation
- leg cramps
- headache
- dizziness
- fatigue
- 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)
- onset or aggravation of gout
- onset or aggravation of diabetes
- decreased blood iodine

- anaemia (resulting in shortness of breath, weakness and fatigue)
- jaundice (yellowing of the skin and whites of the eyes)
- allergic reaction causing inflammation of the kidney

Triamterene/Chlortalidone tablets may lead to increased blood potassium (hyperkalaemia). The symptoms of this are pins and needles, fatigue, muscle weakness (or paralysis), and abnormally slow heart and shock.

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 at: 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 TRIAMTERENE/CHLORTALIDONE TABLETS

Keep this medicine out of the reach and sight of children.

Do not store your tablets above 25°C.

Do not use Triamterene/Chlortalidone tablets after the expiry date printed on the pack.

6. FURTHER INFORMATION

What Triamterene/Chlortalidone tablets contain

The active ingredients are 50mg triamterene BP and 50mg chlortalidone BP

The inactive ingredients are lactose, starch, STA RX 1500 starch, microcrystalline cellulose, sodium starch glycollate, magnesium stearate, hypromellose, polyethylene glycol 4000, polyethylene glycol 400, antifoam, sodium propyl hydroxybenzoate, carnauba wax, titanium dioxide E171, sunset yellow E110.

Product licence holder:

DHP Healthcare Ltd,
Maidstone,
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Manufacturer:

Farmalabor - Produtos Farmacêuticos, S.A.
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