Package Leaflet: Information for the User

Triampur compositum 25 mg/12.5 mg, tablet
triamterene and hydrochlorothiazide

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 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.

1. What Triampur compositum is and what it is used for
2. Before you take Triampur compositum
3. How to take Triampur compositum
4. Possible side effects
5. How to store Triampur compositum
6. Further information

1. WHAT TRIAMPUR COMPOSITUM IS AND WHAT IT IS USED FOR
Triampur compositum is a heart medication with properties that lower the blood pressure and increase urine output. It belongs to the so-called diuretic group.

Triampur compositum is used in:
- for high blood pressure (arterial hypertension)
- for oedema (abnormal fluid accumulation in tissue), caused by heart, liver or kidney disease, especially when potassium loss must be avoided
- to support glycoside treatment in heart failure (cardiac insufficiency), when extra fluid clearance and reduced potassium excretion are indicated.

2. BEFORE YOU TAKE TRIAMPUR COMPOSITUM
Do not take Triampur compositum
- if you are allergic (hypersensitive) to triamterene and/or hydrochlorothiazide or any of the other ingredients of Triampur compositum
- if you suffer from severe kidney dysfunction
- if you have anuria (marked reduction in urine output)
- if you are suffering from acute inflammation of the kidneys (acute glomerulonephritis)
- if you have severe liver dysfunction (precoma and hepatic coma)
- if you have been diagnosed with electrolyte imbalances, such as high potassium or calcium levels, severely low potassium or sodium levels
- if you have hypovolaemia (low circulating fluid volumes in the blood vessels)

Take special care with Triampur compositum
- if you have excessively low blood pressure, low circulating blood volumes (hypovolaemia) or severe hardening of the arteries in the brain (cerebral sclerosis) or coronary arteries (coronary sclerosis).

Careful consideration of the benefits and risks and particularly careful monitoring of treatment by your doctor is required if you have poor kidney function, kidney stones, liver dysfunction, gout, diabetes mellitus or suspected folic acid deficiency (e.g. in liver cirrhosis due to chronic alcohol abuse).
During prolonged treatment with Triampur compositum, certain laboratory parameters (residual nitrogen and serum electrolyte concentrations, particularly levels of potassium, serum creatinine, blood fats, blood sugar and uric acid) must be checked at regular intervals. Particularly in the elderly, blood potassium, creatinine and glucose concentrations must be more frequently monitored. This also applies to patients on existing treatment with cardiac glycosides, adrenal cortex hormones (glucocorticoids, e.g. betamethasone, prednisone, triamcinolone) or laxatives. If folic acid deficiency is suspected (lack of a certain B vitamin, e.g. in liver cirrhosis due to alcohol abuse), the blood count must be regularly monitored.

Therapy with Triampur compositum must be suspended before any parathyroid function test and at least three days before carrying out any glucose tolerance test, as this can otherwise lead to false test results.

Contact lens wearers should bear in mind that tear flow may be reduced during treatment with Triampur compositum (see section “Side effects”).

**Effects if misused for doping purposes**
Use of Triampur compositum can lead to positive results in doping tests.

**Taking other medicines**

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

The blood-pressure-lowering effect of Triampur compositum is enhanced when prescribed at the same time as certain other medicines, i.e. high blood pressure medications, diuretics (water tablets), vasodilators (used to widen the blood vessels), sedatives (e.g. barbiturates), CNS depressants (phenothiazines) or tricyclic antidepressants. If combined with ACE inhibitors (substances that likewise reduce blood pressure), there may be an excessive drop in blood pressure at the start of treatment. Non-steroidal anti-inflammatory/anti-rheumatic drugs (painkillers that reduce inflammation, e.g. salicylates, indomethacin) can make Triampur compositum less effective in lowering the blood pressure and increasing urine output. When Triampur compositum is given at the same time, indomethacin can have an adverse effect on kidney function (decrease in the glomerular filtration rate). Absorption of the active substance hydrochlorothiazide is reduced by cholestyramine and colestipol (used to treat high blood fat levels), thereby possibly weakening its effect and causing a rise in blood potassium. Very rarely, damage to the blood (haemolysis due to the formation of antibodies against hydrochlorothiazide) has been observed during combined treatment with methyldopa (a high blood pressure medication).

High blood potassium levels can be caused by administration of potassium salts, treatment with potassium-sparing medications or by certain high blood pressure medications (ACE inhibitors). Low blood potassium levels can occur in patients on existing treatment with adrenal cortex hormones (glucocorticoids) or laxatives (abuse).

**Other possible interactions between Triampur compositum and other medications:**

- Reduced effect of diabetic medications, gout medications and medicines containing noradrenaline or adrenaline
- In patients on existing, high-dose lithium therapy: an increase in the unwanted side effects of lithium
- Increased side effects of certain medicines used to treat pain and rheumatism (salicylates), affecting the central nervous system of patients on high-dose salicylate therapy
- Enhanced effect of muscle relaxants (curare-type)
- Increased effects and side effects of cardiac glycosides in patients with potassium and/or magnesium deficiency
Reduced quinidine excretion in patients on existing quinidine treatment
- Increased toxic effect of co-administered cytostatics (used in anti-tumour treatment), affecting the bone marrow
- Erectile dysfunction if taken at the same as beta-receptor blockers (cardiovascular medications)
- Increased uric acid levels can result from using Triampur compositum at the same time as certain broad-spectrum antibiotics (tetracyclines).

**Taking Triampur compositum with food and drink**
The blood pressure-lowering effect of Triampur compositum can be enhanced by alcohol. Avoid excessive alcohol consumption.

**Pregnancy and breast-feeding**
Ask your doctor or pharmacist for advice before taking any medicine.
Triampur compositum may not be taken during pregnancy.
Triampur compositum may not be taken while you are breast-feeding; if required, you must stop breast-feeding.

**Driving and using machines**
Treatment with this medicine requires regular monitoring by your doctor. Due to various reactions that occur in some individuals, responsiveness may be altered to such an extent that the ability to drive, use machines or perform hazardous tasks is impaired. This particularly applies at the start of treatment, when increasing the dose or switching from another medication and in interaction with alcohol.

**Important information about some of the ingredients of Triampur compositum**
This medicine contains lactose. For this reason, if you have been told that you have an intolerance to some sugars, please consult your doctor before taking this medicinal product.

3. **HOW TO TAKE/USE TRIAMPUR COMPOSITUM**
Always take Triampur compositum exactly as your doctor has told you. You should check with your doctor or pharmacist if you are not sure.
The usual dose is:

Dosage is determined by the doctor for each individual patient.
In general, the following dosing guidelines apply to adults and adolescents weighing more than 50 kg:

**Oedema:**
At the start of treatment, 2 tablets in the morning and at midday (4 in total) until fluid starts to clear. Further dosing depends on the extent of fluid clearance. In general, the maintenance dose is 1 tablet daily in the morning or 2 tablets every other day (one tablet morning and midday). If required, this maintenance dose can be increased to 4 tablets daily (2 tablets morning and midday).

**High blood pressure:**
The starting dose is 2 tablets in the morning and 2 tablets at midday. Initially, 2 tablets daily (one tablet in the morning and one at midday) may be used and thereafter the dose is adjusted to the patient's needs. If other high blood pressure medications are being taken, or for long-term treatment, a dose of 2 tablets daily (1 tablet morning and midday) is sufficient in most cases.

**As treatment to accompany glycoside therapy in heart failure:**
The dosage is dependent on examination findings. 2 tablets daily are generally taken, up to a maximum of 4 tablets daily if required (1 up to a maximum of 2 tablets, morning and midday). In patients with failing kidney function (serum creatinine 1.5-1.8 mg/dl or creatinine clearance 50-30 ml/min), a dose of 1 tablet daily must not be exceeded. The tablets are taken whole (without chewing) with some liquid after a meal.
They should be taken in the morning if taken once daily, or in the morning and at midday if taken twice daily. Please ensure that you drink sufficient amounts of liquid during treatment with Triampur compositum. Your doctor will decide on the duration of treatment.

*Please talk to your doctor if you have the impression that the effect of Triampur compositum is too strong or too weak.*

**If you take more Triampur compositum than you should**
In the event of an overdose with Triampur compositum, the following may occur: a constant urge to pass water, weakness, tiredness, states of confusion, tingling in the arms and legs, a drop in blood pressure, heart rhythm disorders and possibly seizures. Tell a doctor immediately. In treating the overdose, he/she will be guided by the symptoms (possibly forced vomiting or stomach pumping if required).

**If you forget to take Triampur compositum**
Do not take a double dose to make up for a forgotten dose. Make up for the forgotten dose immediately afterwards, except if it is already late afternoon; otherwise, you will feel the urge to urinate during the night. Then continue your treatment as usual.

**If you stop taking Triampur compositum**
Do not stop taking your medicine without firstly consulting your doctor. Otherwise, your symptoms may reappear. In long-term use, Triampur compositum should not be suddenly stopped. If scheduled, treatment should be stopped with a slow reduction in the 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, Triampur compositum can cause side effects, although not everybody gets them. The following categories are used for stating the frequency of side effects:

Very common: more than 1 in 10 patients treated  
Common: 1 to 10 out of 100 patients treated  
Uncommon: 1 to 10 out of 1,000 patients treated  
Rare: 1 to 10 out of 10,000 patients treated  
Very rare: fewer than 1 in 10,000 patients treated  
Not known: cannot be estimated from the available data

**Possible side effects**

*Very common side effects:*
Blood fats may rise in predisposed patients, depending on the overall dose taken. Due to an increase in blood sugar levels, latent (hidden) diabetes may become manifest or known diabetes may get worse.
Changes in blood electrolytes may occur if this medicine is continuously taken over the long term, particularly decreased sodium, magnesium and chloride levels, decreased or increased potassium levels, increased calcium levels and fluid imbalances.
This medicine may promote the onset of metabolic acidosis (too much acid in the blood).

*Common side effects:*
If taken before a meal, nausea, vomiting and possibly diarrhoea may occur. These side effects can generally be avoided if the medicine is taken after a meal.
Central nervous symptoms (uncoordinated movements, drowsiness) have been commonly observed, as well as dry mouth, thirst, upper abdominal complaints, cramp-like abdominal pain, constipation (and even bowel obstruction in isolated cases), muscle tension, poor muscle tone, calf cramps, tiredness, headache, nervousness, palpitations, irregular heartbeat and problems in blood pressure regulation with dizziness, light-headedness and susceptibility to fainting.

Common: Particularly at the start of treatment, nitrogenous waste products normally excreted with the urine (urea, creatinine) may temporarily accumulate in blood.

Uncommon side effects:
Erectile dysfunction may uncommonly occur, as well as minor eyesight problems, e.g. blurred vision, abnormal colour vision (yellow vision), worsening short-sightedness or reduced tear production (to be considered by contact lens wearers).
Although uncommon, it cannot be ruled out that pancreatitis may be triggered, as well as gallbladder inflammation in patients with kidney stones. Although uncommon, yellow discolouration of the skin, mucous membranes and eyeballs (jaundice) is also possible.
Allergic skin reactions may uncommonly occur, such as redness, itching, nettle rash, cutaneous lupus erythematosus and sun allergy (photoallergic rash), as well as drug fever.
At high doses and/or if urine output is excessive, thrombosis and embolisms may occur due to the heavy fluid loss and reduction in circulating fluid volume within the blood vessels, as well as seizures (uncommon), states of confusion, circulatory collapse and acute kidney failure.
Uric acid levels may rise, which may uncommonly trigger gout attacks in particularly predisposed patients.

Rare side effects:
Changes in the blood picture, e.g. a reduction in red or white blood cells or platelets (aplastic anaemia, leukopenia, thrombopenia, agranulocytosis, megaloblastic anaemia in patients with pre-existing folic acid deficiency), have been rarely observed, as well as blood damage (haemolysis) caused by the formation of antibodies against the active substance hydrochlorothiazide in patients taking concomitant methyldopa, hypersensitive reactions (anaphylactoid reactions), severely inflamed blood vessels and non-bacterial kidney inflammation (abacterial interstitial nephritis), resulting in acute kidney failure.
Sudden onset of lung oedema with symptoms of shock has been described in rare cases. This is assumed to be caused by an allergic reaction to the active substance hydrochlorothiazide. Rarely, acute lung inflammation (interstitial pneumonia) has been reported to occur.
In rare cases, stones may form in the urinary tract.

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.

5. HOW TO STORE TRIAMPUR COMPOSITUM
Keep out of the reach and sight of children.
Do not use Triampur compositum after the expiry date which is stated on the outer carton/container. The expiry date refers to the last day of that month.
This medicinal product does not require any special storage conditions.

6. FURTHER INFORMATION
What Triampur compositum contains
The active substances are: triamterene and hydrochlorothiazide
1 tablet contains 25 mg triamterene and 12.5 mg hydrochlorothiazide.
The other ingredients are: lactose monohydrate, potato starch, polyvidone K25, highly dispersed silica, sodium carboxymethyl starch (type A) (Ph.Eur.), magnesium stearate (Ph.Eur.) [plant-based].

**What Triampur compositum looks like and contents of the pack**

Triampur compositum are yellow, round, flat tablets with a score line on one side. Triampur compositum is available in packs of 50 (N2) and 100 (N3) tablets.

**Marketing Authorisation Holder**

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