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PIL-618361202-v1

NORTHUMBRIA PHARMA

Package leaflet:
Information for the patient

Tanatril 5 mg Tablets
Tanatril 10 mg Tablets
Tanatril 20 mg Tablets

imidapril hydrochloride

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

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1 What Tanatril is and what it is used for

Tanatril is used to treat **high blood pressure** (hypertension). Tanatril is one of a group of medicines called ACE (angiotensin-converting enzyme) inhibitors.

If you have high blood pressure, Tanatril works by widening blood vessels, so that blood passes through them more easily. Since blood pressure depends on the diameter of blood vessels, your blood pressure will be lowered by Tanatril. Also, it will be easier for your heart to pump blood through the vessels around the body.

2 What you need to know before you take Tanatril

Do not take Tanatril

- if you are **allergic** to imidapril, other ACE inhibitors or any of the other ingredients of this medicine (listed in section 6)
- if you have suffered from angioedema (a serious **allergic reaction** that causes **swelling of the hands, feet or ankles, face, lips, tongue and throat** and may lead to **difficulty with swallowing or breathing**) after taking a similar medicine to imidapril (ACE inhibitor)
- if you or a close family member has suffered from **angioedema** before
- if you have **any problem with your kidneys** or if you need to be **dialysed**
- if you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren
- if you are taking sacubitril/valsartan
- if you are more than 3 months **pregnant**. (It is also better to avoid Tanatril in early pregnancy - see pregnancy section).

If any of these situations applies to you, do not take Tanatril.

Warnings and precautions

Talk to your doctor, pharmacist or nurse before taking Tanatril

- if you are dehydrated due to treatment with **diuretics ('water tablets'), dialysis, a low salt diet** or because you have had strong and **prolonged vomiting or diarrhoea**. You are more likely to suffer from a very large drop in your blood pressure (hypotension) when you **start to take tablets** and may feel faint or light-headed
- if you have been told that you have a **problem with your heart**. Ask your doctor, if you are not sure if this applies to you
- if you have **any liver problems**
- if you suffer from **diabetes**
- if you are taking **potassium supplements** or **potassium-containing salt substitutes**
- if you are being treated with **allopurinol** to prevent gout, kidney stones, or high levels of uric acid
- if you are being treated with **procainamide** to correct irregular heartbeats and to slow a rapid heart rate
- if you are taking a **lithium medicine** used for the treatment of mania or depression
- if you are allergic to insect bites and undergo a **desensitisation treatment**
- if you receive **a treatment for your immune system**, for example after a transplant
- if you have had a recent **kidney transplant**
- if you are having a certain treatment called **'LDL apheresis'** to reduce cholesterol-levels in your blood
- if you are suffering from a condition called **'cerebrovascular disease'** (narrowing of the blood vessels in the brain)
- if you have a disease known as **'collagen vascular disease'**, such as rheumatoid arthritis
- if you are undergoing any **surgery** or receive **anaesthetics**, tell your doctor or dentist
- if your blood pressure is not sufficiently lowered. Medicines of this type seem to be less effective in persons with black skin
- if you suffer from **sudden swelling of the lips and face, tongue and throat, neck, possibly also hands and feet, difficulty to swallow or to breathe, hives or hoarseness ('angioedema')**. This may occur at any time during the treatment. Persons with black skin may have a higher risk of suffering from this condition. If you develop such symptoms you should let your doctor know **immediately.**
- if you are taking any of the following medicines used to treat high blood pressure:
  - an angiotensin II receptor blocker (ARB) (also known as sartans - for example valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
  - aliskiren.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium) in your blood at regular intervals.

Children and adolescents

Tanatril is not suitable for the use in children.

While taking Tanatril

If you develop any of the following symptoms you should let your doctor know immediately:

- You feel dizzy after your first dose. A few people react to their first dose or when their dose is increased by feeling dizzy, weak, faint or sick.
- High temperature, sore throat or mouth ulcers (these may be symptoms of infection caused by lowering of the number of white blood cells).
- Yellowing of the skin and whites of eyes (jaundice) that may be sign of liver disease.

You will need medical check-ups whilst you are taking Tanatril, which may involve regular blood tests. You will be closely monitored when you start your treatment or if your dose is changed. Your doctor will advise you how often you will need to see him/her.

Other medicines and Tanatril

Tell your doctor if you are taking, have recently taken or might take any other medicines.

Medicines:	**Used for instance in the treatment of:**
Potassium sparing diuretics (water tablets) (spironolactone, triamterene or amiloride)	heart failure, liver disease, certain kidney diseases
Potassium tablets or liquids or salt substitutes containing potassium	low blood levels of potassium
Non-potassium sparing diuretics (water tablets) (thiazide, furosemide)	high blood pressure, oedema (swelling of the fingers, legs, toes and face)
Lithium	mania or depression
Non-steroidal anti-inflammatory drugs (NSAIDs) (indomethacin, diflunisal or diclofenac, celecoxib or valdecoxib and aspirin)	muscle pain, stiffness and inflammation (arthritis)
Injectable gold	pain, stiffness and inflammation (arthritis)
Antihypertensives (such as methyldopa, clonidine, moxonidine)	high blood pressure
Nitroglycerin or other nitrates	heart disease, chest pain
Antidiabetics (insulin), oral antidiabetics (metformin, pioglitazone, vildagliptin)	diabetes
Thrombolytics (clopidogrel); beta blockers (bisoprolol, metoprolol)	heart attack, high blood pressure
Tricyclic antidepressants (such as amitriptyline); neuroleptics (such as phenothiazines or butyrophenones)	depression and mental disorders
Rifampicin	tuberculosis (known as TB), and other mycobacterial infections
Antacids (pantoprazole)	heartburn, sore stomach and acid indigestion
Sympathomimetics (medicines that stimulate the central nervous system) such as ephedrine, salbutamol (which may also be found in some cough/cold remedies) and noradrenaline or adrenaline	low blood pressure, shock, heart failure, asthma or allergies
Allopurinol	prevention of gout, treatment of kidney stones or high levels of uric acid
Procainamide	irregular heartbeats and to slow a rapid heart rate
Anaesthetics (agents suppressing nerve impulses)	used when you undergo surgery, even at the dentist
Immunosuppressants (medicines that suppress the body's immune response) e.g. sirolimus, everolimus, temsirolimus, tacrolimus, ciclosporin	used e.g. when you have had a recent organ transplant, or suffer from an autoimmune disease (condition in which your immune system is overactive)
Neprilysin inhibitors (e.g. sacubitril/valsartan, racecadotril),	heart failure
Heparin	used as a blood thinner to treat and prevent the formation of blood clots such as deep vein thrombosis, pulmonary embolism.

Your doctor may need to change your dose and/or to take other precautions:
If you are taking an angiotensin II receptor blocker (ARB) or aliskiren (see also information under the headings **Do not take Tanatril** and **Warnings and precautions**

Pregnancy

You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Tanatril before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Tanatril. Tanatril is not recommended in early pregnancy and must not be taken when more than 3 months pregnant, as it may cause serious harm to your baby if used after the third month of pregnancy.

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Tanatril is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed, especially if your baby is new-born, or was born prematurely.

Driving and using machines

Tanatril may make you feel dizzy or sleepy. Do not drive or operate machinery until you know if Tanatril affects you.

Tanatril contains lactose.

If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

3 How to take Tanatril

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

How to take Tanatril

- Take the tablets about 15 minutes before your meals
- Swallow the tablets with plenty of water
- Take your tablets at the same time each day
- The tablet can be divided into equal doses

How much to take (adults)

The usual starting dose is 5mg per day. After 3 weeks your blood pressure needs to be measured again to check the results. Your doctor might increase the daily dose to 10mg or even 20mg.

The doctor may want you to start on 2.5mg once a day,

- if you have mild kidney problems or liver problems,
- if you have heart problems, chest pain, problems related to blood vessels in the brain, low salt and/or fluid levels, or
- if there is a risk that your blood pressure could fall suddenly.

Patients over 65 years of age

Your doctor will start your treatment with 2.5mg once a day and increase this to 10mg depending on how you get on.

Tanatril is not suitable for the use in children.

If you take more Tanatril than you should

If you have accidentally taken more than your prescribed dose, contact your doctor immediately. Remember to take the pack and any remaining tablets with you. The most common signs and symptoms of overdose are fall in blood pressure, shock and stupor (a state of almost complete lack of consciousness), slower heartbeat, disturbances in the levels of potassium or other electrolytes and kidney failure. This can result in a feeling of general discomfort, feeling your heartbeat or in swelling of the fingers, legs and toes (oedema).

If you forget to take Tanatril

Simply leave out that dose completely and then take your next dose at the right time. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tanatril

Do not stop taking Tanatril, unless your doctor has advised you to do so. If you stop taking your medicine, your blood pressure may increase. If your blood pressure becomes too high, it may affect the function of your heart and kidneys.

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 them.

It is very important that you immediately contact your doctor and stop taking Tanatril if you develop any of the following symptoms:

- headache; dizziness; light headedness, perhaps along with impaired vision. This is especially important **at the start of treatment** or **when the dose is increased**
- difficulty in breathing
- rash or itching
- a serious allergic reaction which causes swelling of your face or throat (angioedema)
- blistering of the skin, mouth, eyes and genitals (toxic epidermal necrolysis, Stevens-Johnson syndrome)
- yellowing of the skin or whites of the eyes caused by liver or blood problems (jaundice).

Tell your doctor or pharmacist, if you develop any of the following side effects:

Common side effects

(may affect up to 1 in 10 people):

- cough

Uncommon side effects

(may affect up to 1 in 100 people):

- headache
- dizziness
- rash or itching
- low blood pressure (you may feel dizzy or faint)

Rare side effects

(may affect up to 1 in 1000 people):

- reduced number of white blood cells, which makes infections more likely
- reduced number of red blood cells, which can make the skin pale and cause weakness and breathlessness
- feeling your heartbeat (palpitations)
- ringing in your ears (tinnitus)
- feeling sick (nausea)
- vomiting
- diarrhoea
- pain in the abdomen
- swelling of the fingers, legs and toes (oedema)
- fatigue
- change in laboratory parameters: increased level of liver enzymes
- taste disturbances (dysgeusia)
- feeling lightheaded when standing up (dizziness postural)
- sleep disturbances (insomnia)
- kidney problems (renal impairment)
- protein in your urine (proteinuria)

Not known

(frequency cannot be estimated from the available data)

- oropharyngeal discomfort

Effects on the results of blood tests:

Tanatril may also cause changes in the composition of your blood with the frequency 'not known' (cannot be estimated from the available data). Your doctor will conduct regular blood tests and will explain the results to you.

The following side effects have also been reported with this class of medicine:

- changes in heart rhythm (faster, irregular), heart attack, stroke-like symptoms without lasting damage
- increased risk of bleeding or bruising
- shortness of breath, wheezing
- inflammations- for example of the nasal cavities (sinusitis), tongue (glossitis), liver (hepatitis), pancreas (pancreatitis) or of the stomach-lining (gastritis)
- diarrhoea, constipation, dry mouth
- intestinal blockage, swelling of the intestines causing cramping
- kidney problems
- fever
- muscle pain, joint pain.
- reduced number of blood platelets, which increases risk of bleeding or bruising
- depression
- impotence
- tingling or numbness in the hands or feet (paraesthesia)
- disorder of balance
- confusion
- blurred vision
- high or low potassium level in your blood
- weariness, somnolence, fatigue

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 Tanatril

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

Do not store your Aluminium/aluminium blister packed tablets above 30ºC.
Do not store your PVC/PVdC/aluminium blister packed tablets above 25ºC.

Keep them in the pack in which they were supplied to you.

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

Do not throw away medicines via waste water or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6 Contents of the pack and other information

What Tanatril contains

- The active substance is imidapril (as hydrochloride). Each tablet contains 5mg, 10mg or 20mg of imidapril hydrochloride.
- The other ingredients are calcium hydrogen phosphate (anhydrous), maize starch (pregelatinised), lactose monohydrate, croscarmellose sodium and glycerol distearate.

What Tanatril looks like and contents of the pack

Tanatril tablets are off-white in colour and are biconvex in shape with a plane edge and a break line on both sides.

Your medicine is available in aluminium/aluminium or PVC/PVdC/aluminium blister packs containing 7, 10, 14, 15, 20, 28, 30, 50, 56, 84, 90, 100, and 1000 tablets.
Not all packaging material or pack sizes may be marketed.

Marketing Authorisation Holder:

Northumbria Pharma Ltd
NETPark, Thomas Wright Way, Sedgefield
Stockton-on-Tees, TS21 3FD, United Kingdom.

Manufacturer:

Central Pharma (Contract Packing) Limited
Caxton Road, Bedford, MK41 0XZ, United Kingdom

This medicinal product is authorised in the Member States of the EEA under the following names:

Tanatril: Austria, United Kingdom
Cardipril: Portugal.
Hipertene: Spain.
Imidapril: United Kingdom

This leaflet was last revised in 08/2025

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For help contact:
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