

1.3.2 PATIENT INFORMATION LEAFLET

SCHEDULING STATUS

S3

TENCHLOR 100 mg/ 25 mg film-coated tablets

TENCHLOR HS 50 mg/ 12,5 mg film-coated tablets

Atenolol and chlorthalidone

TENCHLOR contains sugar: Lactose monohydrate 228 mg

TENCHLOR HS contains sugar: Lactose monohydrate 114 mg

Read all of this leaflet carefully before you start taking TENCHLOR

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other healthcare provider.
- TENCHLOR has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.

What is in this leaflet

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

1. What TENCHLOR is and what it is used for

TENCHLOR is used for the management of mild to moderately high blood pressure (hypertension).

2. What you need to know before you take TENCHLOR

Do not take TENCHLOR:

- if you are hypersensitive (allergic) to atenolol, chlorthalidone, or to any of the other ingredients of TENCHLOR (listed in section 6).
- if you have heart problems such as abnormal heart rhythm where the heart beats too slowly; your heart muscle doesn't pump blood as well as it should; abnormally slow heart action.
- if you suffer from phaeochromocytoma that is not being treated. Phaeochromocytoma is a rare abnormal growth of tissue (tumour) that can form in cells in the middle of the adrenal glands.
- if you have been told that you have higher than normal levels of acid in your blood (metabolic acidosis).
- if you have undergone prolonged fasting.
- if you are also taking verapamil as neither verapamil nor TENCHLOR should be administered within several days of stopping the other (see Other medicines and TENCHLOR).
- if you have asthma, bronchitis, bronchospasm or chronic lung diseases.
- if you have low blood sugar.
- if you have circulation problems and Raynaud's phenomenon (fingers and toes feel numb and cold).
- if you have severe liver problems.
- if you are elderly.

- if you have severe kidney function problems.
- if you have a rare disorder of the adrenal glands (Addison's disease).
- if you are having surgery, your usual dose should not be reduced as it may increase risk of heart problems and increased blood pressure.
- if you have been told that you have higher than normal levels of calcium in the blood.
- if you have abnormally low blood pressure (hypotension).
- if you have heart rhythm problems due to the inability of your heart's natural pacemaker (sinus node) to create a heart rate that is appropriate for your body needs (sick sinus syndrome).
- if you are pregnant or breastfeeding your baby (see Pregnancy and breastfeeding).

Warnings and precautions

Take special care with TENCHLOR:

- **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 first checking with your healthcare provider.**
- if you have congestive heart failure (a heart condition that causes symptoms of shortness of breath, weakness, fatigue, and swelling of the legs, ankles, and feet).
- if you have a type of chest pain (angina) called Prinzmetal's angina.
- If you have first-degree heart block.
- If you have diabetes or if you have gout (hyperuricemia). These conditions may be made worse by TENCHLOR. You should monitor your blood sugar levels regularly. 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 are scheduled to undergo general anaesthesia.
- 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 weeks of taking TENCHLOR. This can lead to permanent vision loss, if not treated. If you have had a penicillin or sulfonamide allergy before, you can be at higher risk of developing this.
- if you have fluid or electrolyte imbalances, or if you are on a diet restricting the amount of salt that you take in daily, or if you are vomiting or have diarrhoea, etc. The electrolyte imbalance must be corrected before you start treatment with TENCHLOR. Warning signs of fluid or electrolyte imbalance are dry mouth, thirst, weakness, tiredness, sleepiness, restlessness, muscle pain or cramps, muscle tiredness, low blood pressure, reduced frequency of urination, fast heartbeat, nausea and vomiting. Your doctor may want to monitor the different levels of salt or electrolytes in your blood, especially if you have kidney problems.
- if your gallbladder is inflamed (cholecystitis). Your gallbladder is a small, pear-shaped organ on the right side of your stomach, beneath your liver.
- if you have a rare long-term condition that causes muscle weakness (myasthenia gravis), as this may be unmasked.
- if you have psoriasis as this may be made more serious.

Children and adolescents

TENCHLOR is not recommended for children.

Other medicines and TENCHLOR

Always tell your healthcare provider if you are taking any other medicines (this includes complementary or traditional medicines).

Tell your doctor if you are taking any of the following:

- Alcohol, especially large amounts.
- Allopurinol: medicine used to treat gout.
- Amiodarone: medicine used for uneven heartbeat.
- Amphotericin: medicine used to treat serious fungal infections.
- Ampicillin: medicine used to treat bacterial infections.
- Anaesthetics such as ether, cyclopropane, and trichloroethylene: medicines used during anaesthesia.
- Astemizole, terfenadine: medicines to treat allergies and allergic inflammatory conditions.
- Barbiturates: medicines used to help you sleep or to reduce anxiety.
- Carbenoxolone: medicine used to treat ulcers.
- Colestyramine and cholestipol: medicines used to lower the cholesterol levels.
- Cimetidine: medicine used to treat stomach ulcers.
- Clonidine: medicine for high blood pressure or migraine.
- Corticosteroids: medicines used to treat conditions such as arthritis, allergic conditions, or asthma.
- Corticotrophin: used to treat many different conditions such as multiple sclerosis, rheumatoid arthritis, lupus, severe allergic reactions, breathing disorders, and inflammatory conditions of the eyes.
- Digoxin: medicine used for heart conditions.
- Diltiazem, nifedipine and verapamil: medicines for high blood pressure or chest pain.
- Procainamide, lignocaine: These prevent abnormal heart rhythms.
- Erythromycin: medicine used to treat bacterial infections.
- Fluvoxamine: medicine used for depression and anxiety.
- Guanethidine, bethanidine, reserpine, or diuretics: medicines used to lower the blood pressure.

- Halofantrine: medicine used to treat malaria.
- Hydralazine: medicine used to treat high blood pressure.
- Insulin and oral hypoglycaemics: medicines used to treat diabetes.
- Isoprenaline; medicine used for the treatment of slow heart rate.
- Labetalol, propranolol, nadolol: medicines used to treat high blood pressure.
- Lithium: medicine used for depression or mental illness.
- Nonsteroidal anti-inflammatories (such as ibuprofen and indomethacin): medicines used for pain and inflammation.
- Noradrenaline or adrenaline: medicines that stimulate the heart.
- Opioids (such as codeine, morphine, pethidine): medicines used for moderate to severe pain.
- Phenytoin: medicine used to treat epilepsy.
- Prazosin: medicine used to treat high blood pressure.
- Pimozide: medicine used to reduce uncontrolled movements.
- Quinidine: medicine used to treat irregular heart rate and malaria.
- Rifampicin: antibiotic medicine used to prevent and treat tuberculosis and other infections.
- Salbutamol: medicine used to treat asthma.
- Sotalol: medicine used to treat certain fast/irregular heartbeats.
- Tetracyclines: medicines used to treat a wide variety of infections, including acne.
- Timolol: medicine used to treat increased pressure inside the eye.
- Tubocurarine and baclofen: medicine used as a muscle relaxant.
- Vitamin D: used to treat weak bones or bone pain.
- Aldesleukin: used to fight against diseases and general anaesthetics.
- Diagnostic tests: Tests done to identify a condition or its cause.

TENCHLOR with food, drink and alcohol

No alcohol should be consumed during treatment with TENCHLOR, as it may worsen side effects.

Pregnancy, breastfeeding and fertility

You should not take TENCHLOR if you are pregnant or breastfeeding your baby.

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other healthcare provider for advice before taking this medicine.

Driving and using machines

TENCHLOR has minor influence on the ability to drive and use machines.

It is not always possible to predict to what extent TENCHLOR may interfere with the daily activities of a patient. Patients should ensure that they do not engage in the above activities until they are aware of the measure to which TENCHLOR affects them (see section 4).

TENCHLOR contains lactose monohydrate

Patients with rare hereditary problems of galactose intolerance, total lactase deficiency or glucose galactose malabsorption should not take this medicine.

3. How to take TENCHLOR

Do not share medicines prescribed for you with any other person.

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

TENCHLOR:

The usual dose is half to one tablet of TENCHLOR daily in the morning.

TENCHLOR HS:

The usual dose is one to two tablets of TENCHLOR HS daily in the morning.

Your doctor will tell you how long your treatment with TENCHLOR will last. Do not stop treatment early. If you have the impression that the effect of TENCHLOR is too strong or too weak, tell your doctor or pharmacist.

If you take more TENCHLOR than you should

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.

If you forget to take a dose of TENCHLOR

Do not take a double dose to make up for forgotten individual doses.

If you stop taking TENCHLOR

Do not stop taking TENCHLOR without speaking to your doctor. In some cases, you may need to stop taking it gradually. You should limit the extent of physical activity during this period. If you stop taking TENCHLOR and your high blood pressure is not treated, it can cause serious problems such as heart failure, blood vessel disease, stroke or kidney disease.

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

4. Possible side effects

TENCHLOR can have side effects.

Not all side effects reported for TENCHLOR are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking TENCHLOR, please consult your healthcare provider for advice.

If any of the following happens, stop using TENCHLOR and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips, mouth or throat, which may cause difficulty in swallowing or breathing,
- rash or itching.

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to TENCHLOR. You may need urgent medical attention or hospitalisation.

Tell your doctor immediately or go to the casualty department at your nearest hospital if you notice any of the following:

- Changes in the way your heart beats, for example, an abnormally slow heartbeat (bradycardia), heart block, heart failure,
- blood disorders (purpura, thrombocytopenia, granulocytopenia, leucopenia, aplastic and haemolytic anaemia, agranulocytosis),
- difficulty breathing, rare, severe lung disease (acute interstitial pneumonitis), sudden onset of fluid build-up in the lungs (acute pulmonary oedema),
- yellowing of the skin or whites of the eyes (jaundice), inflammation of the pancreas (pancreatitis) symptoms include pain on the upper stomach that feels worse after eating,
- a disease where the immune system produces antibodies that attacks mainly skin and joints (lupus-like syndrome),
- pulmonary fibrosis (a lung disease that occurs when lung tissue becomes damaged and scarred).

These are all serious side effects. You may need urgent medical attention.

Tell your doctor if you notice any of the following:

Frequent side effects:

- Cold hands and feet,
- nausea,

- extreme tiredness,

Less frequent side effects:

- seeing or hearing something that is not really there (hallucinations),
- mood changes, confusion, mental episodes,
- dry eyes and disturbance in vision,
- disturbances of sleep, including nightmares,
- reversible hair loss (alopecia),
- swelling due to retaining fluid,
- weight gain,
- being unable to get an erection (male impotence),
- headache, “pins and needles” sensation (paraesthesia),
- dizziness,
- blood pressure drop when you go from lying down to sitting up, or from sitting to standing (postural hypotension),
- dry mouth,
- skin condition that causes flaky patches of skin which form scales (psoriasiform skin reaction),
- increase in liver enzymes and antinuclear antibodies.

Side effects with an unknown frequency:

- depression,
- eating disorder (anorexia),
- vomiting, diarrhoea, constipation, stomach cramping, stomach irritation,
- loss of hearing,
- blood problems such as a low number of platelets or white blood cells in the blood,

- decreased tear production, blurred vision, eye soreness,
- skin reactions due to exposure to sunlight,
- 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),
- inflammation and scarring of the lungs or excess fluid in the lungs (pneumonitis, pleurisy),
- fever,
- weakness,
- high levels of sugar in the blood (hyperglycemia) or urine (glycosuria),
- electrolyte imbalances including low levels of chloride, sodium, magnesium, or potassium in the blood,
- high level of uric acid in the blood causing gout attacks,
- peripheral neuropathy, a result of damage to the nerves located outside of the brain and spinal cord (peripheral nerves), often causes weakness, numbness and pain, usually in the hands and feet. It can also affect other areas and body functions including digestion, urination and circulation,
- increased levels of calcium (hypercalcaemia), LDL (low-density lipoprotein) cholesterol and triglycerides (a type of fat in your blood that your body uses for energy),
- muscle cramps, muscle disorder where muscle weakness is the main symptom (myopathies),
- inflammation of the mucous membrane of the mouth (stomatitis),
- inflammation and fibrous thickening of the surfaces of the abdominal cavity.

If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

If you get side effects, talk to your doctor, pharmacist or nurse. You can also report side effects to:

SAHPRA: via the “6.04 Adverse Drug Reactions Reporting Form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8>

Aspen Pharmacare:

E-mail: Drugsafety@aspenpharma.com

Tel: 0800 118 088

By reporting side effects, you can help provide more information on the safety of TENCHLOR.

5. How to store TENCHLOR

Store all medicines out of reach of children.

Store at or below 25 °C.

Keep the container tightly closed.

Keep in original container until required for use.

Do not store in a bathroom.

Do not use after the expiry date stated on the label.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems (e.g. toilets).

6. Contents of the pack and other information

What TENCHLOR contains:

TENCHLOR

The active substances are 100 mg of atenolol and 25 mg of chlorthalidone.

The other ingredients are croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, povidone, purified talc.

Contains sugar: Lactose monohydrate 228 mg

TENCHLOR HS

The active substances are 50 mg of atenolol and 12,5 mg of chlorthalidone.

The other ingredients are croscarmellose sodium, hypromellose, lactose monohydrate, magnesium stearate, povidone, purified talc.

Contains sugar: Lactose monohydrate 114 mg

What TENCHLOR looks like and contents of pack

TENCHLOR: A white to cream biconvex film-coated tablet, bisected on one side and engraved with the word "TENCHLOR" on the other side.

TENCHLOR HS: A white, to cream, biconvex, film-coated tablet, bisected on one side.

TENCHLOR and TENCHLOR HS:

28 or 30 film-coated tablets are packed in a round, white, high density polyethylene bottle sealed with a round, white opaque polypropylene cap with induction sealing wad, together with rayon or a foam insert, two silica gel bags or desiccant disc, and a leaflet.

28 or 30 film-coated tablets are packed in a cylindrical, white, polypropylene container sealed with a round, white, low density polyethylene tamper evident cap, together with rayon or a foam insert, two silica gel bags or desiccant disc, and a leaflet.

Not all packs and pack sizes are necessarily marketed.

Holder of Certificate of Registration

PHARMACARE LIMITED

Healthcare Park

Woodlands Drive

Woodmead 2191

Hotline: 0800 122 912

This leaflet was last revised in

21 May 2023

Registration numbers

TENCHLOR: W/7.1.3/53

TENCHLOR HS: Z/7.1.3/96

Access to the corresponding Professional Information

SAHPRA Repository of Professional Information and Patient Information Leaflets:

<https://www.sahpra.org.za/pi-pil-repository/>

Aspen Pharmacare:

E-mail: Medinfo@aspenpharma.com

Tel: 0800 118 088

ZA_TENCHTAB_2305_00