



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

Read this leaflet carefully before you start taking this medicine.

- If you have any further questions, ask your health care provider.
- This medicine has been prescribed for you only. 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 become serious, or if you notice any side effects not listed in this leaflet, please inform your health care provider.

In this leaflet:

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

1. WHAT TRICARDIN TABLET IS AND WHAT IT IS USED FOR

Olmesartan belongs to a group of medicines called “Angiotensin-II receptor antagonists” which lower blood pressure by relaxing the blood vessels.

Hydrochlorothiazide is one of a group of medicines called thiazide diuretics (“water tablets”). It lowers blood pressure by helping the body to get rid of extra fluid by making your kidneys excrete more urine.

Amlodipine belongs to a group of substances called “Calcium channel blockers”. Amlodipine stops calcium from moving into the blood vessel wall which stops the blood vessels from tightening thereby also reducing blood pressure.

Olmesartan, Amlodipine and Hydrochlorothiazide tablets are indicated for the treatment of hypertension, alone or with other antihypertensive agents, to lower blood pressure. Lowering blood pressure reduces the risk of fatal and nonfatal cardiovascular (CV) events, primarily strokes and myocardial infarctions. These benefits have been seen in controlled trials of antihypertensive drugs from a wide variety of pharmacologic classes including the class to which this drug principally belongs. There are no controlled trials demonstrating risk reduction with Olmesartan, Amlodipine and Hydrochlorothiazide fixed dose combination.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE TRICARDIN TABLET

Do not take Tricardin:

- If you are allergic to any sulfa drug
- If you are unable to urinate.
- If you have diabetes, do not use Amlodipine, Hydrochlorothiazide, and Olmesartan together with any medication that contains Aliskiren (a blood pressure medicine).



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

Warnings and precautions

Tell your doctor if you have any of the following health problems:

- Kidney transplant
- Liver diseases
- Heart failure or problems with your heart valves or heart muscles
- Vomiting (being sick) or diarrhoea which is severe or it goes on for several days
- Treatment with high doses of water tablets (diuretics) or if you are on a low salt diet.
- Problems with your adrenal glands (e.g. primary aldosteronism)
- Diabetes
- A penicillin allergy.
- Lupus erythematosus (an autoimmune disease)
- Allergies or asthma.

If you are taking any of the following medicines used to treat high blood pressure:

- An ACE-inhibitor (for example Enalapril, Lisinopril, Ramipril), 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.

See also information under the heading “Do not take Tricardin”

Your doctor may want to see you more often and do some tests if you have any of these conditions.

Tricardin may cause a rise in blood fat levels and uric acid levels (the cause of gout – painful swelling of the joints), this is because of the Hydrochlorothiazide. Your doctor will probably want to do a blood test from time to time to check these.

It may change the levels of certain chemicals in your blood called electrolytes. Your doctor will probably want to do a blood test from time to time to check these. Signs of electrolyte changes are thirst, dryness of the mouth, muscle pain or cramps, tired muscles, low blood pressure (hypotension), feeling weak, sluggish, tired, sleepy or restless, nausea, vomiting, less need to pass urine, a rapid heart rate. **Tell your doctor if you notice these symptoms.**

As with any medicine which reduces blood pressure, an excessive drop in blood pressure in patients with blood flow disturbances of the heart or brain could lead to a heart attack or stroke. Your doctor will therefore check your blood pressure carefully.



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

If you are due to have tests for parathyroid function, you should stop taking Tricardin before these tests are carried out because Olmesartan and Hydrochlorothiazide combination may cause a false test result.

If you are a sports person, this medicine could change the results of an anti-dope test to make it positive. You must tell your doctor if you think that you are (or might become) pregnant. Tricardin is not recommended in early pregnancy and must not be taken if you are more than 3 months pregnant, as it may cause serious harm to your baby if used at that stage (see pregnancy section).

During treatment

Contact your doctor if you experience severe, persistent diarrhoea and substantial weight loss. Your doctor may evaluate your symptoms and decide on how to continue your blood pressure medication.

Children and adolescents (under 18)

Tricardin is not recommended for children and adolescents under the age of 18.

Other medicines and Tricardin

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

In particular, tell your doctor or pharmacist about any of the following:

- Medicines which may raise the levels of Potassium in your blood if used at the same time as Tricardin. These include:
 - Potassium supplements (as well as salt substitutes containing Potassium)
 - Water tablets (diuretics)
 - Heparin (for thinning the blood)
 - Laxatives
 - Steroids
 - Adrenocorticotrophic hormone (ACTH)
 - Amphotericin, a medicine used to treat fungal infections
 - Carbenoxolone (a medicine used to treat mouth and stomach ulcers)
 - Penicillin G sodium (also called Benzylpenicillin sodium, an antibiotic)
 - Certain pain killers such as Aspirin or Salicylates

- Lithium (a medicine used to treat mood swings and some types of depression) used at the same time as Tricardin may increase the toxicity of Lithium. If you have to take Lithium, your doctor will measure your Lithium blood levels

- Non-steroidal anti-inflammatory drugs (NSAIDs, medicines such as Ibuprofen, Aspirin and Diclofenac used to relieve pain, swelling and other symptoms of inflammation, including arthritis) used at the same time as Tricardin may increase the risk of kidney failure and the effect of Tricardin can be decreased by NSAIDs



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

- Other blood pressure lowering medicines (anti-hypertensives such as Methyldopa), as the effect of Tricardin can be increased
- Sleeping tablets, sedatives and anti-depressant medicines, as using these medicines together with Tricardin may cause a sudden drop in blood pressure when standing up
- Certain medicines such as baclofen and tubocurarine, used to relax muscles
- Amifostine and some other medicines used to treat cancers, such as Cyclophosphamide or Methotrexate
- Colestyramine and Colestipol, medicines for lowering blood fat levels
- Colesevelam hydrochloride, a medicine that lowers the level of cholesterol in your blood, as the effect of Tricardin may be decreased. Your doctor may advise you to take Tricardin at least 4 hours before Colesevelam hydrochloride.
- Anticholinergic agents, such as Atropine and Biperiden, used to treat irritable bowel syndrome, asthma, Parkinson's disease or other muscular problems
- Medicines such as Thioridazine, Chlorpromazine, Levomepromazine, Trifluoperazine, Cyamemazine, Sulpiride, Amisulpride, Pimozide, Sultopride, Tiapride, Droperidol or Haloperidol, used to treat certain psychiatric disorders
- Certain medicines such as Quinidine, Hydroquinidine, Disopyramide, Amiodarone, Sotalol or Digitalis, used to treat heart problems
- Medicines such as Bepridil, Mizolastine, Pentamidine, Terfenadine, Dofetilide, Ibutilide and Erythromycin or Vincamine injections, which may change the heart rhythm
- Oral anti-diabetic medicines, such as Metformin, or Insulin, used to lower blood sugar
- Beta-blockers and diazoxide, medicines used to treat high blood pressure or low blood sugar, respectively, as Tricardin can enhance their blood-sugar increasing effect
- Medicines such as Noradrenaline, used to increase blood pressure and slow heart rate
- Diphemanil, used to treat a slow heartbeat or reduce sweating
- Medicines such as Probenecid, Sulfapyrazone and Allopurinol, used to treat gout
- Calcium supplements
- Amantadine used to treat Parkinson's disease & Dyskinesia
- Ciclosporin, a medicine used to stop rejection of organ transplants
- Certain antibiotics called Tetracyclines or Sparfloxacin
- Certain antacids, used to treat too much stomach acid, such as Aluminium Magnesium hydroxide, as the effect of Tricardin can be slightly decreased.
- Cisapride, used to increase food movement in the stomach and gut.
- Halofantrine, used for malaria.

Your doctor may need to change your dose and/or to take other precautions:

If you are taking an ACE-inhibitor or Aliskiren (see also information under the headings "Do not take Tricardin" and "Warnings and precautions")

Tricardin with food and drink

Tricardin can be taken with or without food. Swallow the tablet with some fluid (such as one



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

glass of water). If possible, take your daily dose at the same time each day, for example at breakfast time.

Tricardin with alcohol

Take care when drinking alcohol while you are taking Tricardin, as some people feel faint or dizzy. If this happens to you, do not drink any alcohol, including wine or beer.

Pregnancy and breast-feeding

Pregnancy

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

Breast-feeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Tricardin is not recommended for mothers who are breast-feeding, and your doctor may choose another treatment for you if you wish to breast-feed. Ask your doctor or pharmacist for advice before taking any medicine.

Driving and using machines

You may feel sleepy or dizzy while being treated for your high blood pressure. If this happens, do not drive or use machines unless these effects wear off. Ask your doctor for advice.

3. HOW TO TAKE TRICARDIN TABLET

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

The recommended dose is one Tricardin 20/12.5/5 mg tablet a day. However, if your blood pressure is not controlled, your doctor may decide to change your dose to one Tricardin 40/25/10 mg tablet a day.

Swallow the tablet with water. If possible, you should take your dose at the same time each day, for example at breakfast time.

If you take more Tricardin than you should

If you take more tablets than you should, or if a child accidentally swallows one or more, go to your doctor or nearest accident and emergency (A&E) department immediately and take your medicine pack with you. Signs of an overdose may include feeling sick or sleepy, low



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

blood pressure, causing you to feel faint or dizzy, changes to the speed or rhythm of your heartbeat or excessive thirst.

If you forget to take Tricardin

If you forget a dose, take your normal dose on the following day as usual. Do not take a double dose to make up for a forgotten dose.

If you stop taking Tricardin

It is important to continue to take Tricardin unless your doctor tells you to stop.

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.

If you notice any of the following, stop taking Tricardin and contact your doctor or nearest hospital emergency department immediately:

Uncommon (may affect up to 1 in 100 people):

- Allergic reactions that may affect the whole body. Signs include sudden rash or itching, swelling of the face, lips, mouth, tongue and/or voice box (larynx) and difficulty breathing
- Sudden pain or a feeling of tightness, heaviness or pressure in the chest. These may be signs of a problem with your heart known as angina pectoris
- Severe difficulty breathing, possibly also coughing up blood, increased sweating, anxiety or pale skin. These may be signs of a problem with your lungs such as fluid or inflammation.

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

- Passing little or no urine or pain when urinating, with back pain, fever, feeling or being sick, feeling drowsy, breathless or generally unwell. These may be signs of problems with your kidneys
- Swollen and sore salivary glands
- Signs of reduced numbers of different blood cells, which may cause pale skin, feeling tired and breathless and having dark urine (reduced number of red blood cells), frequent infections with fever, chills, sore throat or mouth ulcers (reduced number of white blood cells), bleeding or bruising for longer than normal or unexpectedly, when you have not hurt yourself (reduced number of platelets)
- Fits (convulsions)
- Falling in and out of consciousness, or blacking out
- Difficulty breathing, chest pain, fainting, rapid heart rate, bluish skin discoloration, or sudden arm or leg or foot pain (signs that a blood clot may have formed)
- Severe pain in the upper stomach, spreading to the back, possibly with feeling or being sick. These may be signs of inflammation of the pancreas



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

- Yellowing of the skin or of the whites of the eyes (jaundice)
- Signs of lupus erythematosus such as rash, joint pains and cold hands and fingers. This may be something you have had in the past or may be new to you
- Severe skin reactions, causing painful red patches with peeling and blistering of the skin.

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

- Persistent constipation with abdominal pain and vomiting (being sick), which may be signs of a blockage in the gut (paralytic ileus)

Tricardin can cause the blood pressure to fall too low in susceptible individuals or as the result of an allergic reaction. Light-headedness or fainting may occur uncommonly. **If this happens, stop taking Tricardin, contact your doctor immediately and lie down flat.**

Tricardin is a combination of three active substances and the following information firstly gives the other side effects reported so far with the combination Tricardin (besides those already mentioned above) and, secondly, those which are known about for the separate active substances.

These are the other side effects known about Tricardin:

If these side effects occur, they are often mild and **you do not need to stop your treatment.**

Common (may affect up to 1 in 10 people):

- Feeling dizzy, weak or tired
- Headache
- Chest pain
- Swelling of ankles, feet, legs, hands or arms.

Uncommon (may affect up to 1 in 100 people):

- Fluttering of the heartbeat
- Rash, eczema
- Spinning sensation (vertigo)
- Feeling drowsy or sleepy
- Cough
- Indigestion, abdominal pain, nausea (feeling sick), vomiting (being sick) or diarrhoea
- Muscle cramps or muscular pain
- Pain in joints, arms or legs, back pain
- Difficulties getting or maintaining an erection
- Blood in urine.



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

Some changes in blood test results have also been seen uncommonly and include: Rise in blood fat levels, rise in blood urea or uric acid, rise in creatinine, rise or decrease in blood Potassium levels, rise in blood calcium levels, rise in blood sugar, increase in levels of substances that measure liver function. Your doctor will know about these from a blood test and will tell you if you need to do anything.

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

- Feeling generally unwell
- Pale red, itchy or painful raised bumps on the skin (wheals, or hives)

Some changes in blood test results have also been seen in rare cases and include: Rise in blood urea nitrogen, decrease in haemoglobin and haematocrit values. Your doctor will know about these from a blood test and will tell you if you need to do anything.

Additional side effects reported with use of Olmesartan or hydrochlorothiazide alone, but not with Tricardin

Olmesartan:

Common (may affect up to 1 in 10 people):

- Bronchitis, which causes a persistent cough, wheezing and tightness of the chest
- Runny or stuffy nose, sore throat
- Gastroenteritis, causing loose, watery stools with stomach cramps and possibly fever
- Pain in the joints or bones
- Urinary tract infection, causing pain or difficulty when urinating
- Influenza-like symptoms
- Pain.

Some changes in blood test results have also been seen commonly and include: Increase in levels of substances that measure muscle function.

Uncommon (may affect up to 1 in 100 people):

- Swelling of the face
- Itching
- Sudden widespread rash with red or blistered skin, known as exanthema

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

- Impaired kidney function
- Lack of energy or enthusiasm.

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

- Severe persistent diarrhoea and substantial weight loss.



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

Hydrochlorothiazide:

Common (may affect up to 1 in 10 people):

- Feeling confused
- Stomach upset, bloated feeling, wind, constipation
- Excretion of glucose into the urine, which may cause your urine to smell sweet and will show in a urine test.

Some changes in blood results have also been seen and include:

Decrease in blood chloride magnesium or sodium levels, increase of serum amylase (hyperamylasaemia).

Uncommon (may affect up to 1 in 100 people):

- Decreased or loss of appetite
- Worsening of pre-existing short-sightedness
- Red patches on the skin (erythema) or skin reactions to light
- Purplish spots or patches under the skin due to small areas of bleeding (purpura).

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

- Feeling restless, 'down' or depressed, problems sleeping, feeling uninterested (apathy)
- Numbness or tingling ('pins and needles')
- Objects you look at appearing yellow, blurred vision, dry eyes
- Irregular heartbeat
- Inflammation of the blood vessels, which causes a rash and sometimes blistering of the skin
- Infection in the gall bladder, which causes severe pain and tenderness in the upper abdomen, with a fever
- Muscle weakness (sometimes causing difficulties with movement).

Amlodipine

Very common (may affect more than 1 in 10 people):

Oedema (fluid retention)

Common (may affect less than 1 in 10 people):

Abdominal pain; nausea; ankle swelling; feeling sleepy; redness and warm feeling of the face, visual disturbance (including double vision and blurred vision), awareness of heartbeat, diarrhoea, constipation, indigestion, cramps, weakness, difficult breathing.

Uncommon (may affect less than 1 in 100 people):

- Trouble sleeping
- Sleep disturbances
- Mood changes including feeling anxious



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

- Depression
- Irritability
- Shiver
- Taste changes
- Fainting
- Ringing in the ears (tinnitus)
- Worsening of angina pectoris (pain or uncomfortable feeling in the chest)
- Irregular heartbeat
- Runny or stuffy nose
- Loss of hair
- Purplish spots or patches on the skin due to small haemorrhages (purpura)
- Discoloration of the skin
- Excessive sweating
- Eruption of the skin
- Itching
- Red itchy bumps (hives)
- Pain of joints or muscles
- Problems to pass urine
- Urge to pass urine at night
- Increased need to urinate (pass urine)
- Breast enlargement in men
- Chest pain
- Pain, feeling unwell
- Increase or decrease in weight.

Rare (may affect less than 1 in 1,000 people):

Confusion

Very rare (may affect less than 1 in 10,000 people):

- Reduction in the number of white cells in the blood, which could increase the risk of infections
- A reduction in the number of a type of blood cells known as platelets, which can result in easily bruising or prolonged bleeding time
- Increase in blood glucose
- Increased tightness of muscles or increased resistance to passive movement (hypertonia)
- Tingling or numbness of hands or feet
- Heart attack
- Inflammation of blood vessels
- Inflammation of the liver or the pancreas
- Inflammation of stomach lining



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

- Thickening of gums
- Elevated liver enzymes
- Yellowing of the skin and eyes
- Increased sensitivity of the skin to light

Allergic reactions: itching, rash, swelling of the face, mouth and/or larynx (voice box) together with itching and rash, severe skin reactions including intense skin rash, hives, reddening of the skin over your whole body, severe itching, blistering, peeling and swelling of the skin, inflammation of mucous membranes (Stevens Johnson Syndrome, toxic epidermal necrolysis), sometimes life-threatening.

Not known (frequency cannot be estimated from the available data):

Trembling, rigid posture, mask-like face, slow movements and a shuffling, unbalanced walk.

5. HOW TO STORE TRICARDIN TABLET

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Do not use Tricardin Tablet after the expiry date which is stated on the carton and label after 'EXP'. The expiry date refers to the last day of that month.

6. FURTHER INFORMATION.

Each tablet of Olmesartan 20 + Hydrochlorothiazide 12.5 + Amlodipine 5 contains 20mg of Olmesartan, 12.5mg of Hydrochlorothiazide and 5mg of Amlodipine

Each tablet of Olmesartan 40 + Hydrochlorothiazide 25 + Amlodipine 10 contains 40mg of Olmesartan, 12.5mg of Hydrochlorothiazide and 5mg of Amlodipine

What TRICARDIN TABLET looks like and contents of the pack

3 x 10 tablet placed in blisters




SUPPLIER AND MANUFACTURER

Fidson Healthcare Plc,
17-21, Fidson Avenue
Sango-Ota, Ogun State,
Nigeria.
Customercare@fidson.com



PATIENT INFORMATION LEAFLET: INFORMATION FOR THE USER
TRICARDIN TABLET

Olmesartan 20mg, Hydrochlorothiazide 12.5mg and Amlodipine 5mg
Olmesartan 40mg, Hydrochlorothiazide 25mg and Amlodipine 10mg

Approval of PIL text	Prepared by	Approved by:	Approved by:
Signature			
Date	25.06.2024	04-07-2024	06-07-2024
Designation	AMRA	HoM	HQRA