Package leaflet: Information for the user

Edarclor 40 mg/12,5 mg filmomhulde tabletten
Edarclor 40 mg/25 mg filmomhulde tabletten
azilsartan medoxomil/chlortalidone

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

1. What Edarclor is and what it is used for

Edarclor contains two active substances, azilsartan medoxomil and chlortalidone, that are used for treating high blood pressure (hypertension) in adult patients (over 18 years of age):

- Azilsartan medoxomil belongs to a class of medicines called angiotensin II receptor blockers. It lowers the blood pressure by relaxing the blood vessels.
- Chlortalidone belongs to a class of medicines called diuretics. It lowers the blood pressure by helping the body to get rid of extra fluid by making your kidneys produce more urine.

You will only be given Edarclor if treatment with azilsartan medoxomil alone has not adequately controlled your blood pressure. When given together, the two active substances in Edarclor help to lower the blood pressure more than if either of them were given alone.

2. What you need to know before you take Edarclor

Do NOT take Edarclor if you:
- are **allergic** to azilsartan medoxomil or to chlortalidone, or any of the other ingredients of this medicine (listed in section 6).
- are **pregnant.** (Edarclor should not be used in pregnancy - see pregnancy section).
- have **severe liver disease**.
- have **severe kidney disease**.
- do not produce any **urine.**
- have **low blood sodium** levels that cannot be corrected despite treatment.
- have **abnormally high levels of calcium** in your blood.
- have **abnormally high levels of uric acid** in your blood that cause symptoms **(gout)**.
- have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing **aliskiren**.

Warnings and precautions
Talk to your doctor before taking Edarclor, especially if you
- have kidney problems

- are on dialysis or had a recent kidney transplant
- suffer from liver problems
- have heart problems (including heart failure, recent heart attack)
- have ever had a stroke
- have low blood pressure or feel dizzy, weak, restless or lightheaded
- have muscle pains or cramps, or muscular fatigue
- have nausea and vomiting, diarrhoea, dry mouth, thirst, or tiredness
- are taking diuretics (a water tablet), or
- develop a decreased amount of urine
  These may be signs of severe dehydration or salt-depletion. Your doctor should correct these problems before you take Edarclor
- have a disease of the adrenal gland called primary hyperaldosteronism
- have been told that you have a narrowing of the valves in your heart (called "aortic or mitral valve stenosis") or that the thickness of your heart muscle is abnormally increased (called "hypertrophic obstructive cardiomyopathy")
- are being treated with lithium (used for treating mental health problems).
- are taking any of the following medicines used to treat high blood pressure:
  - an "ACE-inhibitor" (for example enalapril, lisinopril, ramipril, etc.), in particular if you have diabetes-related kidney problems.
  - Aliskiren
- 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 Edarclor. 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.

Talk to your doctor if you experience abdominal pain, nausea, vomiting or diarrhoea after taking Edarclor. Your doctor will decide on further treatment. Do not stop taking Edarclor on your own.

Your doctor may check your kidney function, blood pressure, and the amount of electrolytes (e.g. potassium, calcium, sodium, magnesium or chloride) in your blood at regular intervals. Your doctor may also check your glucose, uric acid, cholesterol and triglyceride (blood lipid) levels.

See also information under the heading "Do not take Edarclor".

You must tell your doctor if you think you are (or might become) pregnant. Edarclor should not be used during pregnancy, and must be stopped if you become pregnant, as it may cause serious harm to your baby if used (see pregnancy section).

Children and adolescents
There is no experience with the use of Edarclor in children or adolescents under 18 years of age. Therefore, Edarclor should not be given to children or adolescents under 18 years of age.

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

Edarclor can affect the way some other medicines work and some medicines can have an effect on Edarclor.

In particular, tell your doctor if you are taking any of the following medicines:
- Lithium (a medicine for mental health problems)
- Non-steroidal anti-inflammatory drugs (NSAIDs), such as ibuprofen, diclofenac or celecoxib (medicines to relieve pain and inflammation)
- Aspirin (acetylsalicyclic acid) if taking more than 3 g per day (medicine to relieve pain and inflammation)

- Medicines that increase the amount of potassium in your blood; these include potassium supplements, potassium-sparing medicines (certain 'water tablets') or salt substitutes containing potassium
- Medicines associated with low blood potassium (hypokalaemia) such as corticosteroids (e.g. prednisone), ACTH (a hormone), amphotericin (an antifungal medicine) and carbenoxolone (used to treat mouth ulcers)
- Heparin (a medicine for thinning the blood)
- Aliskiren or other medicines to lower your blood pressure, such as enalapril, lisinopril, ramipril or valsartan, telmisartan, irbesartan
- Other medicines used to treat high blood pressure, diabetes, gout, or asthma
- Digitalis (a medicine for heart problems)
- Anticholinergics such as atropine used for abdominal or stomach spasms or cramps
- Amantadine (a medicine for Parkinson´s disease)
- Colestyramine (used to reduce cholesterol levels in the blood)
- Ciclosporin (used to treat rheumatic disease or after a transplant)
- Medicines to treat cancer such as cyclophosphamide or methotrexate
- Vitamin D and calcium supplements

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 Edarclor" and "Warnings and precautions").

Pregnancy and breast-feeding

Pregnancy
You must tell your doctor if you think you are (or might become) pregnant. Your doctor will normally advise you to stop taking Edarclor before you become pregnant or as soon as you know you are pregnant and will advise you to take another medicine instead of Edarclor.

Edarclor should not be used in pregnancy, and must be stopped if you become months pregnant, as it may cause serious harm to your baby if used.

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

Driving and using machines
Edarclor is unlikely to have an effect on driving or using machines. However, some people may feel tired or dizzy when taking Edarclor and if this happens to you, do not drive or use any tools or machines.

Edarclor contains sodium
This medicine contains less than 1 mmol sodium (23 mg) per tablet, that is to say essentially 'sodium-free'.

3. How to take Edarclor

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

It is important to keep taking Edarclor every day.

Edarclor is for oral use. Take the tablet with plenty of water. You can take Edarclor with or without food.

- The usual starting dose is one 40 mg/12.5 mg tablet once a day. Your doctor may increase this dose to a maximum of one 40 mg/25 mg tablet once a day depending on blood pressure response.
- If you have recently lost body fluids e.g. through vomiting or diarrhoea, or by taking water tablets, you should tell your doctor before you start taking Edarclor.
- If you suffer from other coexisting illnesses such as heart failure your doctor will decide on the most appropriate starting dose.

A reduction in your blood pressure will be measurable within 1-2 weeks of starting treatment and the full effect of your dose will be observed by 4 weeks.

If you take more Edarclor than you should
If you take too many tablets, or if someone else takes your medicine, contact your doctor immediately. You may feel faint or dizzy if you have taken more than you should.

If you forget to take Edarclor
Do not take a double dose to make up for a forgotten dose. Just take the next dose at the usual time.

If you stop taking Edarclor
If you stop taking Edarclor, your blood pressure may increase again. Therefore, do not stop taking Edarclor without first talking to your doctor about alternative treatment options.

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.

Edarclor
STOP taking Edarclor and seek medical help immediately if you have any of the following serious allergic reactions, which occur rarely (may affect up to 1 in 1 000 people):
- Difficulties in breathing, or swallowing, or swelling of the face, lips, tongue and/or throat (angioedema)

Other possible side effects include:
Very common (may affect more than 1 in 10 people):
- Increased serum creatinine in the blood (an indicator of kidney function)

Common (may affect up to 1 in 10 people):
- Dizziness and feeling faint when getting up
- Diarrhoea
- Nausea
- Low blood pressure (hypotension), which may make you feel faint or dizzy
- Feeling tired (fatigue)
- Muscle spasms
- Increased uric acid in the blood

Uncommon (may affect up to 1 in 100 people):
- Skin rash and itching
- Fainting (syncope)
- Sensation of tingling, pins and needles (paraesthesia)
- Vomiting
- Gout which causes pain and swelling in the joints
- Deficiency in red blood cells (anaemia)
- Increase or decrease in blood potassium
- Decrease in blood sodium levels

- Increased blood glucose levels

Adverse reactions reported with one of the individual components may be potential adverse reactions with Edarclor, even if not observed in clinical studies with this product.

Azilsartan medoxomil

In patients taking azilsartan medoxomil alone, the following additional side effects have been reported:

Common (may affect up to 1 in 10 people):
- Swelling of the hands, ankles or feet is more common when azilsartan medoxomil is taken with amlodipine (a calcium channel blocker for treating hypertension) than when azilsartan medoxomil is taken alone (less than 1 in 100 users)

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

Rare (may affect up to 1 in 1 000 people):
- Changes in blood test results including decreased levels of a protein in the red blood cells (haemoglobin)

Not known (frequency cannot be estimated from the available data):
- Joint pain
- Intestinal angioedema: a swelling in the gut presenting with symptoms like abdominal pain, nausea, vomiting, and diarrhoea has been reported after the use of similar products

Chlortalidone

In patients taking chlortalidone alone the following additional side effects have been reported:

Very common (may affect more than 1 in 10 people):
- Increased levels of fat (blood lipids) in the blood

Common (may affect up to 1 in 10 people):
- Loss of appetite
- Upset stomach
- Itchy skin rash
- Impotence in men
- Low blood levels of magnesium

Rare (may affect up to 1 in 1 000 people):
- Sugar in the urine (glycosuria)
- Worsening of diabetes
- Irregular heart beat
- Yellowing of the skin or eyes caused by liver problems (jaundice)
- Increased sensitivity to sunlight
- Inflamed blood vessels in the skin
- Breathing problems due to water (oedema) in the lungs
- Inflammation of the kidneys
- Headache
- Stomach pain
- Constipation
- Increased calcium in the blood
- Changes in the number of cells in the blood, including increase in certain white blood cells (eosinophilia), low white blood cell count (leucopenia, agranulocytosis) and low platelet count (thrombocytopenia)

Very rare (may affect up to 1 in 10 000 people):
- Low blood levels of chloride in the blood
- Inflammation of the pancreas which causes severe stomach and back pain

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

Reporting of side effects
If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via the national reporting system listed in Appendix V. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Edarclor

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

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

Store Edarclor in the original package in order to protect it from moisture. This medicine does not require any special temperature storage conditions.

Do not throw away any medicines via wastewater 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 Edarclor contains
- The **active substances** are azilsartan medoxomil (as potassium) and chlortalidone either 40 mg/12.5 mg or 40 mg/25 mg.
- The **other ingredients** are mannitol, fumaric acid (for pH adjustment), sodium hydroxide (for pH adjustment), hydroxypropylcellulose, crospovidone (Type A), microcrystalline cellulose, magnesium stearate, titanium dioxide (E171), iron oxide, red and iron oxide, black (E172), hypromellose 2 910, talc, macrogol 8 000 and shellac.

What Edarclor looks like and contents of the pack
Edarclor 40 mg/12.5 mg are pale red, round, biconvex, film-coated tablets with “A/C 40/12.5” on one side.
Edarclor 40 mg/25 mg are light red, round, biconvex, film-coated tablets with “A/C 40/25” on one side.

Edarclor is provided in desiccated or non-desiccated aluminium/aluminium blister packs, with each blister strip having 14 tablets. The strips of 14 tablets are placed within cartons containing:
- 14, 28 or 56 tablets for 40 mg/12.5 mg tablets
- 14, 28 or 56 tablets for 40 mg/25 mg tablets

Not all pack sizes may be marketed.

Marketing Authorisation Holder
Takeda Pharma A/S
Delta Park 45

2665 Vallensbaek Strand
Denemarken

Manufacturer
Takeda Ireland Limited
Bray Business Park
Kilruddery, Co. Wicklow
Ierland

This medicine is authorised in the Member States of the European Economic Area under the following names:

Member state	**Name of the medicine**
Netherlands, Portugal	Edarclor
Ireland	Azilsartan medoxomil/Chlortalidone

In het register ingeschreven onder:
Edarclor 40 mg/12,5 mg, filmomhulde tabletten RVG 116373
Edarclor 40 mg/25 mg, filmomhulde tabletten RVG 116387

Deze bijsluiter is voor het laatst goedgekeurd in januari 2025.

Detailed information on this medicine is available on the website of College ter Beoordeling van Geneesmiddelen, http://www.cbg-meb.nl/