

Package Leaflet: Information for the user

**Aceomel 12.5mg Tablets
Aceomel 25mg Tablets
Aceomel 50mg Tablets**

Captopril

Read all of this leaflet carefully before you start using 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 Aceomel Tablets are and what they are used for
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1. WHAT ACEOMEL TABLETS ARE AND WHAT THEY ARE USED FOR

The name of this medicine is Aceomel Tablets. Each tablet contains captopril (12.5mg, 25mg or 50mg) as the active ingredient.

Aceomel Tablets belong to the group of medicines called Angiotensin Converting Enzyme (ACE) Inhibitors. ACE inhibitors work by helping to widen your blood vessels, which then make it easier for your heart to pump blood through them.

Aceomel Tablets are used to treat high blood pressure and certain heart conditions. High blood pressure can lead to an increased risk of heart disease or stroke. Aceomel Tablets work by lowering your blood pressure which reduces this risk.

Aceomel Tablets can also help people whose heart no longer pumps blood as well as it once did. This condition is known as heart failure.

Aceomel Tablets may also be used to treat patients who recently suffered a heart attack. A heart attack happens once one of the major blood vessels supplying blood to the heart muscle becomes blocked. This means that the heart does not receive the oxygen it needs and the heart muscle becomes damaged.

In addition, Aceomel Tablets can be used for the treatment of kidney disease in patients with diabetes.

2. WHAT YOU NEED TO KNOW BEFORE YOU TAKE ACEOMEL TABLETS

Do Not take Aceomel Tablets

- If you are allergic to captopril, any other medicines, including other ACE inhibitors, or any of the other ingredients of this medicine (listed in section 6).
- If you are more than 3 months pregnant. (It is better to avoid Aceomel in early pregnancy – see pregnancy section).

- If you have ever had a reaction which included swelling of the hands, lips, face or tongue where the cause was unknown.
- If you suffer from any auto-immune disease (e.g. rheumatoid arthritis, systemic lupus erythematosus or scleroderma).
- If you have a narrowing of the aortic valve in your heart (aortic stenosis) which is obstructing the pumping of blood from your heart.
- If you have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.

If any of the above affects you, or you are unsure if they do, tell your doctor who will be able to advise you.

Warnings and precautions

Talk to your doctor or pharmacist before taking Aceomel

- If you are suffering or have ever suffered from any of the following conditions or illnesses:
 - Kidney disease,
 - Liver disease,
 - Are undergoing dialysis,
 - Diabetes,
 - Suffer from heart disease, in particular problems with the valves of the heart,
 - Have recently suffered from excessive vomiting or diarrhoea,
 - Are receiving immuno-suppressant therapy.
- If you are taking any of the following medicines used to treat high blood pressure:
 - an angiotensin II receptor blocker (ARBs) (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.

See also information under the heading “Do not take Aceomel Tablets”.

- Changes in the number of blood cells have been reported during treatment with ACE inhibitors. These changes may make you more prone to infections, bleeding or bruising. Please tell your doctor if you notice any of these signs. He/she will check your blood counts and might tell you to stop the treatment, if necessary.
- Aceomel Tablets may rarely cause low blood pressure (symptomatic hypotension), especially at the beginning of the treatment.

This is more likely to occur in patients who

- are dehydrated or salt depleted, e.g. by the use of water tablets (diuretic therapy), dietary salt restriction (such as low-sodium diet), dialysis, diarrhoea or vomiting (see also section 2. Other medicines and Aceomel Tablets” and 4. “Possible side effects”)
- have severe heart failure (due to the use of high doses of water tablets, with or without impairment of the kidney function)
- have ischaemic heart disease (in which the blood supply to your heart is insufficient) or cerebrovascular disease (a disease of the blood vessels supplying the brain). Aceomel Tablets could cause a heart attack (myocardial infarction) or stroke (cerebrovascular accident). Hence, these patients require careful medical supervision.

If you are at increased risk of suffering from a fall in blood pressure, your doctor will monitor you closely, especially when starting the treatment or changing the dose.

- You must tell your doctor if you think you are pregnant or might become pregnant. Aceomel 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).

- If you are to have desensitisation treatment for wasp or bee stings you should tell the doctor who is treating you that you are taking Aceomel Tablets.
- If you are about to have treatment for the removal of cholesterol from your blood by a machine, (called LDL apheresis) you should tell your doctor you are taking Aceomel Tablets.
- Tell your doctor you are taking Aceomel Tablets before you have any blood or urine tests as Aceomel Tablets may interfere with the results of some tests.
- Some Afro-Caribbean patients may require higher doses of Aceomel Tablets to obtain an adequate reduction in blood pressure.

Other medicines and Aceomel Tablets

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines. It is especially important to tell your doctor if you are taking any of the following:

- Non steroidal anti-inflammatory painkillers NSAIDs (e.g. indometacin, ibuprofen),
- Immunosuppressants (e.g. azathioprine and cyclophosphamide),
- Potassium supplements, salt substitutes containing potassium or any other medicines which can increase potassium in your body, e.g. (amiloride, spironolactone),
- Water tablets (diuretics),
- Medicines for gout (e.g. allopurinol),
- Medicines for diabetes (as the amount you need to use may have to be changed while taking Aceomel Tablets),
- Medicines that cause dilation of the blood vessels (e.g. minoxidil, clonidine),
- Medicines to treat mental health problems including depression (such as lithium or amitriptyline),
- Any other medicines to treat high blood pressure (e.g. beta-blockers such as propranolol, atenolol or calcium channel blockers such as amlodipine, nifedipine),
- Any medicine that may be used during and after a heart attack.

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 Aceomel Tablets” and “Warnings and precautions”)

Aceomel with food and drink

Aceomel Tablets can be taken with or without food.

Moderate amounts of alcohol will not affect Aceomel Tablets, however, you should check with your doctor first to see if drinking is advisable for you.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

Pregnancy

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

Breastfeeding

Tell your doctor if you are breast-feeding or about to start breast-feeding. Breast-feeding newborn babies (first few weeks after birth), and especially premature babies, is not recommended whilst taking Aceomel.

In the case of an older baby your doctor should advise you on the benefits and risks of taking Aceomel whilst breast-feeding, compared with other treatments.

If you are due to have surgery

Before surgery and anaesthesia (even at the dentist) you should tell your doctor or dentist that you are taking Aceomel Tablets as there may be a sudden fall in your blood pressure.

Driving and using machines

Aceomel tablets can affect your ability to drive, usually when you first start taking your medicine or if your doctor changes your dose. If you do feel light-headed or dizzy when taking Aceomel tablets, you should not drive or use machinery.

Aceomel Tablets contain lactose

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

3. HOW TO TAKE ACEOMEL TABLETS

Always take this medicine exactly as your doctor told you. Check with your doctor or pharmacist if you are not sure. Try to make Aceomel part of your daily routine so that you take the tablets at the same time each day, especially the morning dose.

Sometimes patients may feel dizzy after taking the first one or two doses of Aceomel Tablets. If this happens to you, lie down until these symptoms disappear.

The recommended doses are:

High blood pressure:

The usual starting dose is 12.5–25mg twice a day. Your doctor may gradually increase this dose to 100–150mg a day. You may also need to be given other medicines to lower your blood pressure. Older patients and those with kidney problems may be given a lower starting dose.

Heart failure:

The usual starting dose is 6.25–12.5mg two or three times a day. Your doctor may gradually increase this dose to a maximum of 150mg a day.

After a heart attack:

The usual starting dose is 6.25mg, which will then be increased by your doctor to a maximum of 150mg a day.

Diabetic patients with kidney disease:

The usual dose is 75–100mg a day.

Use in older people:

The usual starting dose is 6.25 mg twice a day. Your doctor may give you a lower starting dose if you have kidney problems.

Use in children:

The starting dose is 0.3mg/kg bodyweight, which may be increased gradually by the doctor.

For children with kidney problems, premature babies and newborn babies and infants.

The starting dose should be 0.15mg/kg bodyweight.

Doctors sometimes prescribe different doses to the above and if this applies to you, you should discuss it with your doctor.

Aceomel Tablets can be taken before, during or after meals. Even if you feel well continue to take this medicine until your doctor tells you otherwise.

If you take more Aceomel Tablets than you should

If you or anyone else takes too many tablets you should go to your nearest hospital emergency department or tell your doctor immediately. Take the pack and any remaining tablets you have with you.

If you forget to take Aceomel Tablets

If you miss a dose do not worry. Just carry on taking your normal dose when the next one is due.

Do not take a double dose to make up for the one you missed.

If you stop taking Aceomel Tablets

Do not interrupt or stop treatment with Aceomel without consulting your doctor.

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 may cause some unwanted side effects although not everybody gets them. If you experience any of the following reactions **stop** taking Aceomel Tablets and contact your doctor **immediately**:

- Swelling of the hands, face, lips or tongue
- Difficulty in breathing
- A sudden, unexpected rash or burning, red or peeling skin
- Sore throat or fever
- Severe dizziness or fainting
- Severe stomach pain
- Unusually fast or irregular heartbeat
- Yellowing of the skin and/or eyes (jaundice).

Common (may affect up to 1 in 10 people)

- Dizziness
- Dry mouth
- Itching
- Sleep problems
- Rashes
- Diarrhoea or constipation
- Hair loss
- Dry, irritating cough
- Changes in the way things taste
- Upset stomach, sickness, abdominal pain
- Shortness of breath.

Uncommon (may affect up to 1 in 100 people)

- Fast, irregular, louder heartbeat
- Tiredness
- Chest pain
- Generally feeling unwell
- Low blood pressure (see Section 2)
- Looking pale
- Reduced blood flow to the hands and feet (e.g. Raynaud syndrome)
- Swelling of the eyes and lips (angiodema)
- Flushing.

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

- Loss of appetite

- Mouth ulcers
- Drowsiness
- Kidney disorders or failure
- Headache
- Changes in frequency of passing urine
- Pins and needles, numbness or tingling.

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

- Impaired liver function and raised liver enzymes
- Liver damage, inflammation of the liver or jaundice
- Confusion, depression, fainting
- Stomach ulcers
- Mini-stroke
- Muscle pain
- Blurred vision
- Joint pain
- Heart problems including heart attack
- Wheezing or difficulty breathing and chest infections
- Inflammation of the pancreas
- Rashes or skin reactions
- Runny nose
- Swelling of breast tissue in men
- Swollen tongue
- Fever
- Impotence
- Sensitivity of the skin to light
- Stevens-Johnson syndrome (a serious illness with blistering of the skin, mouth, eyes and genitals)
- Changes in levels of chemicals (e.g. potassium, sugars).
- Blood disorders including anaemia and thrombocytopenia (poorer than normal blood clotting and bruising very easily).

If any of the side effects become serious, or if you notice any side effects not listed in this leaflet, please tell your doctor or pharmacist immediately.

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 HPRA Pharmacovigilance, Earlsfort Terrace, IRL - Dublin 2; Tel: +353 1 6764971; Fax: +353 1 6762517. Website: www.hpra.ie; E-mail: medsafety@hpra.ie. By reporting side effects you can help provide more information on the safety of this medicine.

5. HOW TO STORE ACEOMEL TABLETS

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

Do not store above 25°C. Store the tablets in the original package in order to protect from moisture.

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

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 Aceomel contains:

The active substance is captopril. Each tablet contains 12.5 mg, 25 mg or 50 mg of captopril.

The other ingredients are lactose monohydrate, pregelatinised starch, stearic acid and microcrystalline cellulose.

What Aceomel looks like and contents of the pack:

- 12.5 mg tablet: White, round, flat tablets scored on both sides, diameter 6 mm.
- 25 mg tablet: White, round, flat tablets cross scored on both sides, diameter 8 mm.
- 50 mg tablet: White, round, flat tablets cross scored on both sides, diameter 10 mm.

Packaging:

Blister (PVC/Al), in 28, 30, 56, 60, 100 and 250 tablet pack sizes.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer:

Clonmel Healthcare Ltd, Waterford Road, Clonmel, Co. Tipperary, Ireland

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