



Patient package insert according to Pharmacists' Regulations (Preparations) – 1986

This medicine can be sold with a physician's prescription only

Aceril® 12.5, 25, 50 mg, Tablets

Each tablet contains Captopril 12.5, 25 or 50 mg respectively.

Inactive ingredients and allergens in the medicine – see section 6 "Additional information" and in section 2 "Important information about some of the ingredients of the medicine".

Read this entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have any further questions, ask the doctor or pharmacist. This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if you think that their medical condition is the same as yours.

1. What is the medicine intended for?

The medicine is intended for the treatment of high blood pressure, congestive heart failure, diabetic nephropathy (kidney damage caused by diabetes), for treatment after a heart attack.

Therapeutic group: Angiotensin Converting Enzyme (ACE) inhibitors.

Angiotensin converting enzyme inhibitors work by dilating your blood vessels, so that it will be easier for your heart to pump blood through them.

2. Before using the medicine:

Do not use the medicine if:

- You are hypersensitive (allergic) to the active ingredient (captopril), to any of the other ingredients this medicine contains (see section 6) or to other medicines of the ACE inhibitors group.
- You have ever had a reaction which included swelling of the hands, lips, face or tongue where the cause was unknown.
- You have diabetes or impaired kidney function and you are treated with a blood pressure lowering medicine containing aliskiren.
- You are more than three months pregnant (it is also better to avoid taking **Aceril** in early pregnancy – see section "Pregnancy and breastfeeding").
- If you have taken or are currently taking sacubitril/valsartan, a medicine used to treat a type of long-term (chronic) heart failure in adults, as the risk of angioedema (rapid swelling under the skin in an area such as the throat) is increased.

Do not take **Aceril** if any of the above conditions apply to you. If you are not sure, consult the doctor before taking **Aceril**.

Special warnings regarding the use of the medicine

Before the treatment with Aceril, tell the doctor:

- If you suffer from kidney disease.
- If you suffer from liver disease.
- If you are undergoing dialysis.
- If you have suffered from heart disease, in particular problems with the valves of the heart.
- If you are treated with medicines that suppress the immune system (see also section "Drug interactions").
- If you have recently suffered from excessive diarrhea or vomiting.
- If you have diabetes.
- If you suffer from a collagen vascular disease such as rheumatoid arthritis, systemic lupus erythematosus (lupus) or connective tissue sclerosis (scleroderma).
- If you experience more infections such as sore throat or fever, which can be due to changes in your blood cells and can be monitored by the doctor through a blood test.
- If you are going to have dental surgery or major surgery involving anesthesia.

- If you are about to receive desensitization treatment for example to reduce the allergic reaction to wasp or bee stings.
- If you are about to have treatment for the removal of excess cholesterol from your blood by a machine (called LDL apheresis).
- You must tell your doctor if you think you are pregnant or might become pregnant. **Aceril** is not recommended in early pregnancy. Do not take **Aceril** after the third month of pregnancy, because the use of **Aceril** at this stage may cause serious harm to your baby (see section "Pregnancy and breastfeeding").
- Some Afro-Caribbean patients may require a higher dosage of **Aceril** to obtain an adequate reduction in blood pressure.
- If you are taking any of the following medicines, the risk of angioedema may be increased:
 - Racecadotril, a medicine used to treat diarrhea.
 - Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
 - Vildagliptin, a medicine used to treat diabetes.
- If you are taking potassium supplements (including salt substitutes), potassium-sparing diuretics and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
- If you are taking any of the following medicines to treat high blood pressure:
 - an angiotensin II receptor blockers (ARBs) (such as valsartan, telmisartan, irbesartan), in particular if you have diabetes-related kidney problems.
 - aliskiren.

Your doctor may refer you to check kidney function, blood pressure and electrolyte levels (such as potassium) in your blood at regular intervals. See also information in section 2 "Do not use the medicine if".

Drug interactions

If you are taking, have recently taken or might take other medicines, including non-prescription medicines and nutritional supplements, tell the doctor or pharmacist.

The doctor may need to change the dose and/or take other precautions:

If you are taking an angiotensin II receptor blockers (ARBs) or aliskiren (see also information in section 2 "Do not use the medicine if" and in section "Special warnings regarding the use of the medicine").

Especially tell the doctor or pharmacist if you are taking:

- Diuretics.
- Potassium supplements (including salt substitutes), potassium-sparing diuretics (such as triamterene, amiloride, spironolactone) and other medicines that can increase the amount of potassium in your blood (e.g. trimethoprim and co-trimoxazole for infections caused by bacteria; ciclosporin, an immunosuppressant medicine used to prevent organ transplant rejection; and heparin, a medicine used to thin blood to prevent clots).
- Medicines that cause dilation of the blood vessels (such as minoxidil, clonidine).
- Medicines for the treatment of mental problems including manic depression or depression (such as lithium, amitriptyline).
- Medicines that suppress the immune system (such as azathioprine, cyclophosphamide).
- Medicines for the treatment of gout (such as allopurinol, probenecid).
- Medicines for the treatment of irregular heartbeats (such as procainamide).
- Non-steroidal anti-inflammatory pain killers (NSAIDs) (such as indometacin, ibuprofen).
- Medicines for the treatment of diabetes (such as oral antidiabetics, insulin).
- Medicines for the treatment of high blood pressure (e.g. beta blockers [such as propranolol, atenolol] or calcium channel blockers [such as amlodipine, nifedipine]).
- Any medicine that may be given during and after a heart attack.
- Medicines that contain sympathomimetics (such as cough and cold medicines).
- Any of the following medicines, as the risk of angioedema may be increased:
 - Racecadotril, a medicine used to treat diarrhea.

- Medicines used to prevent organ transplant rejection and for cancer (e.g., temsirolimus, sirolimus, everolimus).
- Vildagliptin, a medicine used to treat diabetes.

Use of the medicine and food

The medicine can be taken with or without food.

Use of the medicine and alcohol consumption

Moderate amounts of alcohol will not affect **Aceril**, however consult the doctor before consuming alcoholic beverages.

Pregnancy and breastfeeding

Tell the doctor if you think you are pregnant or might become pregnant. Usually, your doctor will advise you to stop taking **Aceril** before you become pregnant or as soon as you know you are pregnant and will advise you to take a different medicine instead of **Aceril**. **Aceril** is not recommended in early pregnancy and is forbidden for use after the third month of pregnancy as it may cause serious harm to your baby if it is taken after the third month of pregnancy.

Tell the doctor if you are breastfeeding or plan to start breastfeeding. Breastfeeding newborn babies (during the first weeks after birth) and especially premature babies, is not recommended while taking **Aceril**. In the case of an older baby, the doctor will advise you on the benefits and risks of taking **Aceril** whilst breastfeeding, compared with other treatments.

Consult the doctor or pharmacist before taking any medicine.

If you are about to undergo surgery

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

Driving and using machines

Aceril can affect your ability to drive, usually in the beginning of treatment or if your doctor changes the dosage you are taking. If you have dizziness when taking **Aceril**, do not drive or use machines.

Important information about some of the ingredients of the medicine

Aceril contains lactose. If you have been told by a doctor that you have an intolerance to some sugars, consult the doctor before taking this medicine.

3. How to use the medicine?

Always use the medicine according to the doctor's instructions. Check with the doctor or pharmacist if you are not sure about the dosage and the manner of treatment with the medicine.

The dosage and manner of treatment will be determined by the doctor only.

Do not exceed the recommended dose.

This medicine is usually not intended for children and infants.

Sometimes, patients may suffer from dizziness after taking the first dose or first two doses of **Aceril**. If this happens to you, lie down until it passes.

Method of administration:

- Take the tablet with a glass of water. Try to take **Aceril** at about the same hour every morning. The medicine can be taken before, during or after the meal.
- The tablet cannot be halved. The score line on the tablet is not meant for halving. There is no information regarding chewing/crushing the tablet.

If you have accidentally taken a higher dosage

If you have taken an overdose or if a child has accidentally swallowed the medicine, proceed immediately to a doctor or a hospital emergency room and bring the package of the medicine with you.

If you forgot to take the medicine

If you forgot to take this medicine at the designated time, take it as soon as you remember and carry on as usual. If it is almost time for the next dose, skip the forgotten dose and continue as usual. Do not take a double dose to make up for a forgotten dose.

Continue with the treatment as recommended by the doctor.

Even if there is an improvement in your health, do not stop taking this medicine without consulting the doctor.

Do not take medicines in the dark! Check the label and the dose each time you take a medicine. Wear glasses if you need them.

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

4. Side effects

Like any medicine, the use of **Aceril** may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not suffer from any of them.

Stop taking this medicine and refer to a doctor immediately with the occurrence of:

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

Common side effects (effects that occur in 1-10 out of 100 users):

- Dizziness
- Itching, rashes, hair loss
- Dry mouth
- Sleep disorders
- Diarrhea or constipation
- Dry, irritating cough
- Loss of taste (usually reversible on stopping treatment)
- Upper abdominal discomfort, nausea, vomiting, abdominal pain
- Shortness of breath
- Stomach ulcers

Uncommon side effects (effects that occur in 1-10 out of 1,000 users):

- Headache
- Fast, irregular, strong heartbeat
- Chest pain
- Low blood pressure, reduced blood flow to the hands and feet (e.g. Raynaud's phenomenon), flushing
- Pins and needles, numbness or tingling
- Tiredness, generally feeling unwell
- Paleness
- Swelling of the eyes and lips (angioedema)

Rare side effects (effects that occur in 1-10 out of 10,000 users):

- Ulcers in the mouth
- Drowsiness
- Changes in frequency of urination, kidney disorders or kidney failure
- Loss of appetite

Very rare side effects (effects that occur in less than 1 in 10,000 users):

- Impaired liver function and raised liver enzymes

- Confusion, depression, fainting
- Mini-stroke
- Blurred vision
- Heart problems including heart attack and chest infections
- Inflammation of the pancreas
- Runny nose
- Swollen tongue (inflammation of the tongue)
- Impotence
- Stevens-Johnson syndrome (a serious illness that is manifested as blisters on the skin, mouth, eyes and genitals)
- Liver damage, inflammation of the liver or jaundice
- Muscle pain, joint pain
- Wheezing or difficulty breathing
- Rashes or skin reactions
- Swelling of breast tissue in men
- Fever
- Sensitivity of the skin to light
- Changes in the levels of cells and/or in the chemistry tests of the blood or lymphatic system (e.g. red or white blood cells, sodium, potassium, sugars)

If a side effect occurs, if one of the side effects worsens or if you suffer from a side effect which is not mentioned in this leaflet, consult the doctor.

Side effects can be reported to the Ministry of Health by clicking the link "דיווח על תופעות לוואי עקב טיפול תרופתי" found on the homepage of the Ministry of Health website (www.health.gov.il) directing to the online form for reporting side effects or via the link: <https://sideeffects.health.gov.il>

5. How to store the medicine?

- Avoid poisoning! This medicine and any other medicine must be stored in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting unless explicitly instructed to do so by the doctor.
- Do not use the medicine after the expiry date (תאריך תפוגה) stated on the package. The expiry date refers to the last day of that month.
- **Storage conditions:** Do not store above 25°C.
- Do not throw away any medicines via wastewater or household waste. Ask the pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Additional information

In addition to the active ingredient, the medicine also contains:

Cellulose microcrystalline, lactose monohydrate, starch pregelatinized, stearic acid

What the medicine looks like and what the package contains:

White, round tablet, biconvex, with a score line.

Approved package sizes: 10, 20, 90, 100 tablets. Not all package sizes may be marketed.

Revised in June 2023 according to MOH guidelines.

Drug registration number at the national drug registry of the Ministry of Health:

Aceril 12.5: 106-49-29061-00

Aceril 25: 106-50-29062-00

Aceril 50: 106-51-29063-00

Manufacturer and registration holder: Dexcel Ltd., 1 Dexcel St., Or Akiva 3060000, Israel