SCHEDULING STATUS

S3

MYLAN CAPTORPIL 12,5 (tablets)

Captopril, 12,5 mg

Contains sugar: Lactose

MYLAN CAPTOPRIL 25 (tablets)

Captopril, 25 mg

Contains sugar: Lactose

MYLAN CAPTOPRIL 50 (tablets)

Captopril, 50 mg

Contains sugar: Lactose

Read all of this leaflet carefully before you start taking MYLAN CAPTOPRIL

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor or your pharmacist.
- MYLAN CAPTOPRIL 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 MYLAN CAPTOPRIL is and what it is used for.

2. What you need to know before you take MYLAN CAPTOPRIL.

3. How to take MYLAN CAPTOPRIL.

4. Possible side effects.

5. How to store MYLAN CAPTOPRIL.

6. Contents of the pack and other information.

1. What MYLAN CAPTOPRIL is and what it is used for

What MYLAN CAPTOPRIL is:

- Captopril belongs to a group of medicines called ACE inhibitors which reduce blood pressure and make the blood vessels become wider.
- This makes blood flow more easily and reduces the effort needed for the heart to pump blood around the body.

What it is used for:

- MYLAN CAPTOPRIL tablets can be used to treat mild to moderately high blood pressure (hypertension) or to help treat congestive heart failure patients who have not responded adequately to or cannot be controlled by conventional therapy with diuretics and/or digitalis and in whom vasodilation is indicated.
- MYLAN CAPTOPRIL can be used alone or in combination with other antihypertensive medicines, especially thiazide-type diuretics. The blood pressure lowering effects of MYLAN CAPTOPRIL and thiazides are additive.
- MYLAN CAPTORPIL has been used with diuretics and digitalis.

2. What you need to know before you take MYLAN CAPTOPRIL:

Do not take MYLAN CAPTOPRIL:

- if you are hypersensitive (allergic) to captopril or any of the other ingredients of MYLAN CAPTOPRI;
- if you ever had a serious allergic reaction called “angioedema” when you have previously been treated with medicines called angiotensin converting enzyme (ACE)

inhibitors or angiotensin receptor blockers (ARBs). The signs including itching, hives (urticaria), red marks on the hands, feet and throat, swelling of the throat and tongue, swelling around the eyes and lips, difficulty breathing and swallowing. You must never again take these medicines such as MYLAN CAPTOPRI;

- if you are pregnant or plan to become pregnant;
- if you are breastfeeding;
- if you have kidney problems, including disorders where the blood supply to your kidneys is reduced (renal artery stenosis);
- if you have any heart problems;
- if you have been told you have cardiomyopathy (heart muscle disease), or aortic stenosis (narrowing of the main blood vessel from your heart), or any other heart problems;
- if you are receiving treatment with certain diuretics (water tablets) such as spironolactone, triamterene, amiloride (see '*Other medicines and MYLAN CAPTOPRIL'*);
- if you receive treatment with lithium (for mental health problems). MYLAN CAPTOPRIL may increase the amount of lithium in your blood;
- If you are receiving dialysis treatment;
- If you have any other health problems;
- if you suffer from porphyria;
- if you are using a medicine for high blood pressure containing aliskiren, as you cannot use these medicines together (see '*Other medicines and MYLAN CAPTOPRIL');*
- 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.

Concomitant use of fluoroquinolones with ACE inhibitors/Renin-Angiotensin blockers is

contraindicated in patients with moderate to severe renal impairment (see '*Other medicines and MYLAN CAPTOPRIL').*

Warnings and precautions

Take special care with MYLAN CAPTOPRIL if:

- Concomitant use of fluoroquinolones and ACE inhibitors/rening-angiotensin receptor blockers may precipitate acute kidney injury in patients, especially those with moderate to severe renal impairment and elderly patients *(see 'Do not take MYLAN CAPTOPRIL'*). Renal function should be assessed before initiating treatment and monitored during treatment, with fluoroquinolones or ACE inhibitors/renin-angiotensin receptor blockers;
- you have liver problems;
- you suffer from a heart problem (other than the one being treated);
- you have heart failure. Periodic evaluation will be done and should also include periodic monitoring of your kidney function.
- you need dialysis treatment;
- you have kidney problems or narrowing of the blood vessels to the kidney. Regular monitoring must be done of certain laboratory tests (serum potassium and creatinine levels). You may also experience changes in your kidney function.
- you have diabetes;
- you suffer from a collagen vascular disease (autoimmune diseases that occur when the body's immune system attacks its own skin, tissues and organs**)** e.g. scleroderma, SLE (systemic lupus erythematosus);
- you are dehydrated (dry) due to treatment with diuretics (or 'water' tablets), dialysis or dietary restriction of salt. You may be more likely to suffer from a very large drop in your blood pressure (hypotension) when you start taking the tablets and you may feel faint or lightheaded.

- you have had a kidney transplant. Your doctor will decide whether you may take MYLAN CAPTOPRIL;
- you have heart failure and you are taking MYLAN CAPTOPRIL. You may have an abnormally high concentration of potassium in your blood. Certain medicines can increase the amount of potassium in your blood such as water tablets called spironolactone, triamterene and amiloride. If you have certain serious heart diseases your doctor will decide whether you may take MYLAN CAPTOPRIL and he/she will monitor you on a regular basis;
- you are going to have an operation, tell your doctor or dentist if you are taking MYLAN CAPTOPRIL. This is because MYLAN CAPTOPRIL, when combined with some anaesthetics, may cause a drop in blood pressure. It may be so severe that you may have to receive specialised treatment;
- your blood pressure decreases too much and you have certain heart or kidney conditions, this could result in a heart attack or stroke;
- 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 a blood test carried out by your doctor;
- you are going to have desensitisation treatment, e.g. for an allergic reaction to wasp or bee stings;
- you have recently suffered from excessive vomiting or diarrhoea;
- 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 (see '*Do not take'*).
    - aliskiren.

- **Ethnic differences:**

MYLAN CAPTOPRIL causes a higher rate of angioedema (swelling underneath the skin) in black patients than in non-black patients.

- **Children/ and adolescents:**

  Do not give MYLAN CAPTOPRIL to children.

Other medicines and MYLAN CAPTOPRIL

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

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

- Diuretics (medicines to increase the excretion of urine), alcohol and hypotension-producing (low blood pressure) medicines – The anti-hypertensive (blood pressure lowering) effect is additive. Dosage adjustment may be necessary during concurrent use or when one medicine is discontinued.
- Loop, thiazide or related diuretics (medicines to increase the excretion of urine) – “First dose hypotension” may occur (speak to your doctor or pharmacist regarding the meaning of this).
- ~~Indomethacin and –~~ Non-steroidal anti-inflammatory painkiller (NSAIDS) (e.g. indometacin, and ibuprofen). These can cause a reduction in the antihypertensive effects of MYLAN CAPTOPRIL. Blood pressure monitoring should be increased when any NSAID is added or discontinued in a patient treated with MYLAN CAPTOPRIL.
- Potassium supplements, salt substitutes containing potassium or potassium sparing diuretics such as spironolactone, triamterene or amiloride. Concurrent administration may result in hyperkalaemia (too much potassium in the blood).
- Lithium – Increases in lithium concentrations have been reported. Frequent monitoring of serum lithium concentrations is recommended.

- Medicines that cause dilation of the blood vessels (e.g. nitroglycerin, clonidine).
- Medicines to treat mental problems including manic depression or depression (e.g. lithium and amitriptyline).
- Immuno-suppressants (e.g. azathioprine, cyclophosphamide and everolimus).
- Medicines to treat gout (e.g. allopurinol and probenecid).
- Medicines to treat irregular heartbeats (e.g. procainamide).
- Medicines to treat diabetes (e.g. oral antidiabetics and insulin).
- Medicines to treat high blood pressure (e.g. beta-blockers such as propranolol, atenolol or calcium channel blockers such as amlodipine and nifedipine).
- Concomitant use of fluoroquinolones and ACE inhibitors/renin-angiotensin receptor blockers may precipitate acute kidney injury *(see section Do not take MYLAN CAPTOPRIL*).
- The combined use of andangiotensin converting enzyme (ACE) inhibitors, as in MYLAN CAPTOPRIL, angiotensin II receptor blockers or aliskiren is associated with a higher frequency of side effects such as low blood pressure, levels of potassium that are too high, and decreased kidney function. Ask your doctor or pharmacist if you are unsure.
- Other medicines to help lower your blood pressure, including betablockers, diazoxide, andangiotensin converting enzyme (ACE) inhibitors, as mentioned above, such as enalapril, captopril, lisinopril or ramipril. *(see 'Do not take MYLAN CAPTOPRIL' and 'Take special care with MYLAN CAPTOPRIL')*.
- Sacubitril/valsartan (medicine for high blood pressure). Do not take this medicine with MYLAN CAPTOPRIL as it increases the risk of angioedema (*see 'Do not take'*).

MYLAN CAPTOPRIL with food and drink and alcohol

MYLAN CAPTOPRIL should be taken 1 hour before meals.

Pregnancy and breastfeeding and fertility

- The use of MYLAN CAPTOPRIL is contraindicated during pregnancy. Pregnant women should be informed of the potential hazards to the foetus and must not take MYLAN CAPTOPRIL during pregnancy (*see Do not take MYLAN CAPTOPRIL*). Patients planning pregnancy should be changed to alternative anti-hypertensive treatments which have an established safety profile for use in pregnancy. When pregnancy is diagnosed, treatment with MYLAN CAPTOPRIL should be stopped immediately and if appropriate, alternative therapy should be started.
- Exposure of the foetus to ACE inhibitors during the first trimester of pregnancy has been reported to be associated with an increased risk of malformations of the heart and blood vessels (atrial and/or ventricular septal defect, pulmonic stenosis, patent ductus arteriosus) and brain (microcephaly spina bifida), and of kidney malformations.
- MYLAN CAPTOPRIL crosses the placenta and can be presumed to cause disturbance in the mechanisms that regulate the blood pressure of the foetus.
- Oligohydramnios as well as hypotension, oliguria and anuria in newborns, have been reported after administration of MYLAN CAPTOPRIL during the second and third trimesters. Cases of defective skull ossification have been observed.
- Prematurity and low birth mass can occur.
- Do not use MYLAN CAPTOPRIL if you are breastfeeding.

Driving and using machinery

MYLAN CAPTORIL may cause dizziness and it is not always possible to predict to what extent MYLAN CAPTOPRIL 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 MYLAN CAPTOPRIL affects them.

MYLAN CAPTOPRIL contains lactose

MYLAN CAPTOPRIL contains lactose which may have an effect on the control of your blood sugar if you have diabetes mellitus.

Patients with the rare hereditary conditions of lactose/fructose or galactose intolerance should not take MYLAN CAPTOPRIL.

Sodium warning:

MYLAN CAPTOPRIL contains less than 1 mmol sodium (23 mg) per dose, that is to say essentially 'sodium-free'.

3. How to take MYLAN CAPTOPRIL

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

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

The usual dose is:

Adults:

- Take the medicine 1 hour before meals.
- The recommended initial dose for adults is 25 mg two or three times a day.
- This is increased as necessary, after 2 weeks to 50 mg three times daily.
- The maximum daily dosage should not exceed 150 mg daily.
- ***Congestive heart failure:***

  MYLAN CAPTOPRIL must start under close medical supervision. It should be added to conventional therapy with diuretic (and digitalis where indicated). A much smaller dosage, 6,25 mg-12,5 mg, three times daily, is appropriate for the initiation of therapy

in patients with heart failure, or in others who have received intensive therapy with diuretics.

- Reduced dosage is also indicated for patients with impaired renal function.

  After the desired therapeutic effect has been achieved, the total daily dose should be reduced, or the dose intervals increased.

  The following maximum daily doses are suggested as a guide to minimise accumulation:

Creatinine clearance (mℓ/min/1,75 mm^3)	Maximum total daily dose (mg)
more than 80	450
80-41	300
40-21	150
20-11	75
less than 10	37,5

Your doctor will tell you how long your treatment with MYLAN CAPTORPIL will last.

If you have the impression that the effect of MYLAN CAPTORPIL is too strong or too weak, tell your doctor or pharmacist.

Children:

This medicine should not be given to children.

If you take more MYLAN CAPTORPIL 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 MYLAN CAPTOPRIL

If you forget to take a dose, take it as soon as you remember. If it is almost time for your next dose though, do not double the dose but carry on as before.

4. Possible side effects

MYLAN CAPTOPRIL can have side effects.

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

If any of the following happens, stop taking MYLAN CAPTOPRIL 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;
- fainting;
- severe skin disorders such as pemphigus (blistering of skin and mucous membranes, toxic epidermal necrolysis (serious illness with blistering of the skin);
- Stevens-Johnson Syndrome (serious illness with blistering of the skin, mouth, eyes and genitals);
- erythema multiforme (eruption of lesions on the skin).

These are all very serious side effects. If you have them, you may have had a serious allergic reaction to MYLAN CAPTOPRIL. 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:

- If you feel unusually tired, look pale, bruise easily, or suffer from frequent nosebleeds, sore throats or fever.
- If you suspect liver disease, if you notice yellowing of your skin or the whites of your eyes (jaundice) or unusual bruising or bleeding of your skin.
- If you experience difficulty in breathing or constriction of the airways (dyspnoea).
- If you have inflammation of the pancreas with symptoms such as upper abdominal pain, nausea and vomiting.

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

Tell your doctor if you notice any of the following:

The following side effects have been reported frequently:

- Increases in urea and creatinine in the blood;
- mood alterations;
- sleep disturbances;
- confusion
- dizziness;
- dry, irritating cough;
- diarrhoea;
- nausea and vomiting;
- stomach pain and indigestion;
- dry mouth and taste disturbances.

The following side effects have been reported less frequently:

- Potassium levels that are too high;
- decrease in white blood cell count, haemoglobin and haematocrit;
- suppression of bone marrow;

- pins and needles or tingling in the fingers and toes;
- headache;
- reduction in blood platelets (thrombocytopenia);
- severe decrease in a particular type of white blood cells which makes infections more likely (agranulocytosis);
- lack of red blood cells due to destruction of circulating cells (haemolytic anaemia);
- effects when upright in posture, such as drop in blood pressure causing dizziness when standing up, heart attack, stroke, irregular heartbeat or rapid heartbeat;
- irritation and inflammation of the lining in the nose and sinuses;
- increased sweating, hair loss;
- psoriasis (skin disease with raised rough scaly areas);
- abnormal physical weakness;
- retention of waste products in the blood (uraemia), reduced urine production, no urine production, disfunction of the kidneys and kidney failure,
- loss of male sexual ability;
- a group of symptoms including fever, inflammation of blood vessels, muscle pain, joint pain and increased white blood cells have been reported;
- sensitivity to sunlight;
- peptic ulcer (a sore on the lining of your stomach, small intestine or esophagus);
- muscle cramps;
- tiredness;
- feeling sick;
- irregular heartbeat;
- weakness or heaviness of legs;
- impaired liver function and raised liver enzymes;
- blurred vision;

- joint pain;
- chest infections;
- swelling of breast tissue in men;
- changes in levels of chemicals in the blood or lymphatic systems (e.g. sugars).

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

Reporting of side effects

Reporting suspected adverse reactions after authorisation of the medicine is important. It allows continued monitoring of the benefit/risk balance of the medicine. Healthcare providers are asked to report any suspected adverse reactions 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.

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

5. How to store MYLAN CAPTOPRIL

Store all medicines out of reach of children.

Store well closed at or below 25 °C in a cool, dry place.

Store in the original package / container.

Do not store in a bathroom.

Do not use after the expiry date stated on the label / carton / bottle.

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 MYLAN CAPTOPRIL contains:

There are three strengths of MYLAN CAPTOPRIL tablets available containing either 12,5 mg, 25 mg or 50 mg of the active ingredient captopril (D-3-mercapto-2-methylpropanoyl-L-proline).

The other ingredients are microcrystalline cellulose, lactose anhydrous, maize starch, stearic acid and sodium starch glycollate.

What MYLAN CAPTOPRIL looks like and contents of the pack:

What MYLAN CAPTOPRIL looks like:

MYLAN CAPROPRIL 12,5 mg: White capsule-shaped tablet with a partial bisect and “G” on one side and partial bisect and “C 12,5” on the other.

MYLAN CAPROPRIL 25 mg: White, round, biconvex tablets with “C 25” on one side and quadrisected on the other side.

MYLAN CAPROPRIL 50 mg: White oval biconvex tablets approximately 11,3 mm by 5,8 mm.

Contents of the pack:

MYLAN CAPTOPRIL 12,5:

White opaque high-density polypropylene containers with a coated metal closure with liner and polystyrene foam inner seal.

Pack size; 100

MYLAN CAPTOPRIL 25:

1.3.2.1 Patient Information Leaflet

White opaque high-density polypropylene containers with a coated metal closure with liner and polystyrene foam inner seal.

Pack size: 30, 100

Not all pack sizes may be marketed.

MYLAN CAPTOPRIL 50:

White opaque high-density polypropylene containers with a coated metal closure with liner and polystyrene foam inner seal.

Pack size: 100, 500

Not all pack sizes may be marketed.

Holder of Certificate of Registration and Manufacturer

Viatris Healthcare (Pty) Ltd

4 Brewery Street

Isando

1600

Republic of South Africa

This leaflet was last revised in

Date of publication: 11 December 2009

Date of revision of text: 27 September 2024

Registration number

MYLAN CAPTOPRIL 12,5: 32/7.1/0545

MYLAN CAPTOPRIL 25: 29/7.1/0228

MYLAN CAPTOPRIL 50: 32/7.1/0528

Access to the corresponding Professional Information

Can be obtained on the SAHPRA website