Module 1.3.2: Patient Information Leaflet

Information for the Patient about

CIPLASYL 2 (Tablets)

CIPLASYL 4 (Tablets)

CIPLASYL 8 (Tablets)

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM

CIPLASYL 2 (Tablets)

CIPLASYL 4 (Tablets)

CIPLASYL 8 (Tablets)

Read all of this leaflet carefully before you start taking CIPLASYL.

- **Keep this leaflet, you may need to read it again.**
- **If you have further questions please ask your doctor or your pharmacist.**
- **CIPLASYL 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 CIPLASYL TABLETS CONTAIN:

The active ingredient in **CIPLASYL** is perindopril. Perindopril belongs to a class of medicines known as angiotensin converting enzyme inhibitors (ACE inhibitors).

Each **CIPLASYL 2** mg tablet contains 2 mg perindopril erbumine .

Each **CIPLASYL 4** mg tablet contains 4 mg perindopril erbumine.

Each **CIPLASYL 8** mg tablet contains 8 mg perindopril erbumine.

Inactive ingredients are hypromellose, magnesium stearate, Opadry, polyethylene glycol, sodium carbonate, starch and talc.

Each **CIPLASYL 2** mg contains sugar (43.318 mg mannitol per tablet).

Each CIPLASYL 4 mg contains sugar (86,637 mg mannitol per tablet).

Each CIPLASYL 8 mg contains sugar (173,274 mg mannitol per tablet).

WHAT CIPLASYL IS USED FOR:

CIPLASYL is indicated for the treatment of patients with mild to moderate high blood pressure (hypertension), as well as for patients with heart failure whose condition is not adequately controlled by conventional therapy with water pills (diuretics) and digitalis and who require dilation of their blood vessels. **CIPLASYL** reduces the risk of incidences which can damage the heart muscle in patients with stable coronary artery disease (where blood vessels of the heart are partially blocked) and who does not suffer from heart failure.

BEFORE YOU TAKE CIPLASYL:

Do NOT take CIPLASYL if you:

- Are hypersensitive or allergic to any of the ingredients in **CIPLASYL**
- Have a history of severe swelling (angioedema) after previous therapy with other ACE inhibitors or medicines known as angiotensin receptor blockers (ARBs). You should never use these medicines again
- Suffer from hereditary (inherited) or idiopathic (unknown cause) angioedema (severe swelling of the whole body)
- Narrowing of your aorta
- Suffer from a heart condition known as hypertrophic obstructive cardiomyopathy (HOCM)
- Severe kidney impairment
- Have narrowing of both your renal arteries (blood vessels taking blood to the kidneys)
- Narrowing of the artery taking blood to your kidney if you have only one kidney
- Are also using water pills (diuretics) that keep potassium back (potassium-sparing), such as spironolactone, triamterene or amiloride. (see **"Taking other medicines with CIPLASYL"**). Please speak to your doctor or pharmacist if you are unsure
- Suffer from porphyria
- Are pregnant or breastfeeding, since the use of **CIPLASYL** may harm your baby

- Are also using another product for blood pressure pill that contains aliskiren
- Are taking lithium, as use of **CIPLASYL** with lithium may lead to toxic blood concentrations of lithium
- Have moderate to severe kidney impairment and are using a medicine containing fluoroquinolones, which is used to treat an infection
- CIPLASYL should not be given to children.

Take special care with CIPLASYL:

Tell your doctor if you have any of the following as you may then require a lower dose or special precautions:

- Reduced blood flow to your brain (cerebrovascular disease) or heart (ischaemic heart disease), because a reduction in blood pressure under these circumstances may cause strokes or heart attacks
- Dehydration
- Low blood pressure or salt depletion
- Severe autoimmune disease, such as systemic lupus erythematosus (SLE), other collagen vascular diseases or scleroderma
- Recent heart attack (myocardial infarction)
- Kidney dysfunction
- Bone marrow disease
- Diabetes mellitus
- High blood potassium levels

- Any disease affecting the blood vessels that supply blood to your kidneys
- Dialysis
- Are prone to allergic reactions or have previously suffered from allergic reactions to medicines
- Sever chest pains (unstable angina pectoris)
- Liver failure
- Narrowing of two of the valves in the heart, the aorta or mitral valves or a disease called hypertrophic cardiomyopathy (when a part of the heart becomes thickened without an obvious cause)
- If you need to go for a procedure called low-density lipoproteins (LDL) apheresis, tell your doctor that you are taking **CIPLASYL**
- If you need to go for a procedure called desensitizing, involving for example insect venom, tell your doctor that you are taking **CIPLASYL**
- If you are receiving treatment that suppresses the immune system, or have a sickness called collagen vascular disease, or take medicine that contains procainamide or allupurinol
- If you need to take a medicine containing fluoroquinolones, which is used to treat an infection, and have moderate to severe kidney disease
- If you need to take medicines called sirolimus, everolimus and temsirolimus which could incresas swelling of the throat or tongue.

The safety of **CIPLASYL** in children has not been established.

Therapy with **CIPLASYL** may lead to low blood pressure, which may lead to dizziness or tiredness. This is especially important if you are also taking water pills, if you suffer from heart failure, are elderly or if you develop diarrhoea or any other condition that may cause water or salt depletion. Your doctor will monitor you for this condition.

Use of **CIPLASYL** may also cause a fall in haemoglobin, a component of your red blood cells, decrease white blood cells and blood platelets, while blood potassium levels may increase, as may blood urea and creatinine (markers of kidney function). You may have to undergo periodic blood tests to determine this.

If you are elderly or if you suffer from kidney disease, your doctor may decide to alter the dosage of **CIPLASYL**.

If you are scheduled to undergo surgery, please inform the anaesthetist that you are taking **CIPLASYL**.

CIPLASYL causes a higher rate of swelling (angioedema) and be less effective in lowering blood pressure in black patients than in other ethnic groups.

Use of **CIPLASYL** may cause cough which disappears when you stop treatment with CIPLASYL.

Taking CIPLASYL with food and drink:

CIPLASYL should be taken in the morning *before* breakfast.

Pregnancy and breastfeeding:

You should *not* take **CIPLASYL** if you are pregnant, contemplating pregnancy or if you are breastfeeding your baby. If you are pregnant or breastfeeding your baby while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

Driving and using machinery:

CIPLASYL may make you feel dizzy. You should refrain from driving a car or operating machinery should you experience dizziness.

Important information about some of the ingredients of CIPLASYL

CIPLASYL contains mannitol. If you have been told that you have an intolerance to some sugars, you should not take **CIPLASYL**.

Taking other medicines with CIPLASYL:

If you are taking other medicines on a regular basis, including complementary or traditional medicines, the use of **CIPLASYL** with these medicines may cause undesirable interactions. Please consult your doctor, pharmacist or other healthcare professional for advice.

If you are taking any of the following medicines, please discuss this with your treating doctor or pharmacist, as you may require dosage adjustments or other precautions:

- Water pills (diuretics)
- Other medicines for high blood pressure, including medicines for widening the blood vessels (vasodilators), and medicines called angiotensin II receptor blockers and aliskiren
- Alcohol, because this may cause too low blood pressure
- Non-steroidal anti-inflammatory medicines (NSAIDs) for the treatment of pain and inflammation, since these medicines may make **CIPLASYL** less effective
- Potassium-sparing water pills, non-potassium sparing water pills, potassium containing salt substitutes or potassium supplements (see **"Do NOT take CIPLASYL if you"**)
- Lithium (see **"Do NOT take CIPLASYL if you"**)
- Medicine to treat diabetes
- Medicines for depression (tricyclic antidepressants), mental disorders (antipsychotics) and a medicine which eliminates the feeling of pain by putting you to sleep (anaesthetic)
- Medicines belonging to a group called sympathomimetics, which my decrease the blood pressure lowering effect of **CIPLASYL**
- A medicine called co-trimoxazole which is used to treat infections

- Medicines called fluoroquinolones which are used to treat infections, and which may cause kidney injury
- A medicine called racecadotril which is used to treat diarroea
- Medicines that belongs to a group called mTOR inhibitors and estramustine, which are all used to treat cancer
- Baclofen, a medicine which is a muscle relaxer
- Medicines causing increase blood levels of potassium, including the following: ACE inhibitors, angiotensin-II receptors antagonists, aliskiren, potassium salts, potassium-sparing diuretics, NSAIDs, heparins, medicines suppressing the immune system such as ciclosporin or tacrolimus and trimethoprim
- Medicines called gliptins, which are used for diabetes and which may make the swelling of the face, lips, hands, feet, tongue or throat worse
- Gold a medicine which is injected and used to treat cancer and arthritis, which can cause, vomiting, feeling sick, becoming red in the face or other parts of the body.

CIPLASYL may be used with a medicine called acetylsalicylic acid (when used to dissolve blood clots), other medicines used to dissolve blood clots (thrombolytics) and manage abnormal heart rhythms (betablockers).

HOW TO TAKE CIPLASYL:

For patients with mild to moderate high blood pressure:

Take one 4 mg tablet in the morning before breakfast.

If your blood pressure remains high, your doctor may decide to increase the dosage to 8 mg after one month.

If you are elderly or if you suffer from heart failure, your doctor may decide to use a lower dose. Diabetic patients usually do not require dosage adjustments. If you are already on a water tablet, talk to doctor or pharmacist.

If you have the impression that the effect of **CIPLASYL** is too strong or too weak, talk to your doctor or pharmacist.

Your doctor will decide how long therapy with **CIPLASYL** will last. Patients with high blood pressure usually require life-long therapy.

Patients with heart failure:

The usual dose is 2 mg in the morning before breakfast. Your doctor may increase this to 4 mg if necessary.

Decreasing risk of incidents affecting the heart and blood vessels:

In patients with stable coronary artery disease (where the flow of blood to the heart muscle is reduced due to the blood vessels which are partially blocked), the initial dose should be 4 mg once daily for two weeks. The dose should then be increased to 8 mg once daily, depending on kidney function. Elderly patients

should receive 2 mg once daily for one week, then 4 mg once daily the next week, before increasing the dose up to 8 mg once daily depending on kidney function.

Use of water pills (diuretics), potassium-sparing pills and potassium containing tablets with CIPLASYL:

Care should be taken if you are already a water tablet. Water pills should be stopped before starting therapy with **CIPLASYL**, as the effects of **CIPLASYL** may be increased if used with a water pill. Please speak to your doctor if you are using a water pill or a potassium containing tablet or a potassium sparing pill.

Special populations:

Patients with impaired kidney function:

Your doctor will decide the most appropriate dosage of **CIPLASYL** for you, based on your kidney function.

If you take more CIPLASYL than you should:

In the event of an overdosage, or if someone has taken your medicine by mistake, you, or this person, may experience side-effects such as those listed below. Symptoms resulting from overdose are those associated with low blood pressure, salt and water disturbances and impaired kidney function. In the event of an overdosage, consult your doctor or pharmacist. If neither is available, seek help at the nearest hospital or poison control centre.

If you forget to take CIPLASYL:

Always take **CIPLASYL** exactly as prescribed. If you miss a dose, take it as soon as you remember. If you do not remember the missed dose until the next day, skip the missed dose and go back to your regular dosing schedule. Do not take a double dose to compensate for the forgotten individual dose. Continue with your normal dose on the regular schedule as prescribed by your doctor.

POSSIBLE SIDE-EFFECTS:

CIPLASYL may have unintended or undesirable effects. Not all side-effects reported for this medicine are included in this leaflet. Should your general health worsen while taking this medicine, please consult your doctor, pharmacist or other healthcare professional for advice.

You should check with your doctor *immediately* if you develop:

- Bleeding from the nose or gums, easy bruising, or pinpoint red spots on your skin, since this may indicate low platelet counts
- Fever, cough, sore throat, skin lesions, generally feeling unwell or chills, since this may indicate low white cell counts
- Swelling of the face, lips, hands, feet, tongue or throat, as this may indicate a serious (and life-threatening) allergic reaction. This may include fever, inflammation of the blood vessels, sore muscles, pain in the joints. Tell you doctor if you experience these symptoms. He may have to test for

positive antinuclear antibodies (ANA), high levels of red blood cells, an increase in types of certain white blood cells

- Chest pain or weakness of one side of the body, or difficulty speaking.
- Difficulty breathing
- Bloating, chills, fast heartbeat, fever, indigestion, pain in the stomach, possibly radiating to the back, inability to pass stools and yellow eyes, as this combination of symptoms may be associated with inflammation of the pancreas (pancreatitis)
- Yellow discolouration of the skin or white of the eyes (jaundice)
- Pain over the liver area, accompanied by loss of appetite, nausea, vomiting and/or jaundice, as this may indicate inflammation of the liver (hepatitis)
- Blistering skin rash
- Difficulty urinating or passing very little urine, as this may indicate kidney failure.

Check with your doctor or pharmacist if any of the following side-effects develop, continue or become bothersome:

- Dizziness or headache
- Fatigue (tiredness), mood alterations, confusion, pins and needles, vertigo, sleepiness and sleep disturbances
- Low blood pressure, swelling of the feet or palpitations
- Cough, runny nose and inflammation of the sinuses, pneumonia

- Diarrhoea, taste disturbances, nausea, stomach pain, indigestion, dry mouth, constipation and vomiting.
- Impotence
- Skin rash, perspiration which could be profuse, hives, hair loss, itching, and psoriasis or aggravation of psoriasis, sensitivity to the ultraviolet rays of the sun or other light sources
- Abnormal tiredness and weakness or joint pain, muscle cramps, muscle ache
- Fainting
- Low blood sugar
- Trouble with seeing
- Trouble with ringing in the ears
- Fall
- Dizziness when suddenly standing up from a sitting of lying position

Other side-effects with **CIPLASYL** include:

- Low white and red blood cell counts
- Low platelet counts
- High blood potassium levels
- Low blood sodium levels
- Abnormal kidney function tests
- Increases in blood levels of liver enzymes
- Increases in blood levels of urea, creatinine and bilirubin

- Inflammation of the blood vessels
- Irregular or abnormal heart rhythm

Not all side-effects reported for this medicine are included in this leaflet. Please tell your doctor or pharmacist of any other undesirable effects you think may be due to taking **CIPLASYL**, especially if not mentioned in this leaflet.

STORAGE AND DISPOSING OF CIPLASYL:

Store at or below 25°C.

STORE OUT OF REACH OF CHILDREN.

Keep the blisters in the outer carton until required for use.

Do not use after the expiry date stated on the packaging material.

Return all unused medicine to your pharmacist.

Do not dispose of unused medicine in drains or sewerage systems, for example toilets.

PRESENTATION OF CIPLASYL:

CIPLASYL 2 mg: Aluminium blister pack of 30 tablets.

CIPLASYL 4 mg: Aluminium blister pack of 30 tablets.

CIPLASYL 8 mg: Aluminium blister pack of 30 tablets.

IDENTIFICATION OF CIPLASYL:

CIPLASYL 2:	White to off-white, circular, biconvex, film-coated tablets plain on both sides.
CIPLASYL 4:	White to off-white, barrel-shaped, biconvex, film-coated tablets with central breakline on both the sides.
CIPLASYL 8:	White to off-white, barrel-shaped, biconvex, film-coated tablets with central breakline on both the sides.

REGISTRATION NUMBERS:

CIPLASYL 2: 41/7.1.3/0673

CIPLASYL 4: 41/7.1.3/0674

CIPLASYL 8: 41/7.1.3/0675

NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATES OF REGISTRATION:

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