

Patient Information Leaflet
Information for the Patient about
CIPLA-PIOGLITAZONE 15 / 30 (TABLETS)

SCHEDULING STATUS:

S3

PROPRIETARY NAME, STRENGTH AND PHARMACEUTICAL FORM:

CIPLA-PIOGLITAZONE 15 (Tablets)

CIPLA-PIOGLITAZONE 30 (Tablets)

Read all of this leaflet carefully before you start taking CIPLA-PIOGLITAZONE

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

The active substance is pioglitazone.

Each **CIPLA-PIOGLITAZONE 15** tablet for oral administration contains pioglitazone hydrochloride equivalent to 15 mg pioglitazone.

Each **CIPLA-PIOGLITAZONE 30** tablet for oral administration contains pioglitazone hydrochloride equivalent to 30 mg pioglitazone.



Inactive ingredients include carboxymethyl cellulose calcium, hydroxypropyl cellulose, lactose monohydrate, and magnesium stearate.

Contains lactose.

WHAT CIPLA-PIOGLITAZONE TABLETS ARE USED FOR:

CIPLA-PIOGLITAZONE tablets belong to a class of medicines called antidiabetics, in other words medicines to lower blood sugar.

CIPLA-PIOGLITAZONE tablets are used to treat diabetes mellitus in addition to diet and exercise. It may be used alone or in combination with other medicines for the treatment of diabetes mellitus, such as insulin, metformin or sulphonylureas.

BEFORE YOU TAKE CIPLA-PIOGLITAZONE

Do NOT take CIPLA-PIOGLITAZONE tablets if you:

- Are known to be hypersensitive or allergic to pioglitazone or any of the other ingredients in the formulation.
- Have impaired liver function or active liver disease.
- Are in heart failure. Please speak to your doctor if you are unsure.
- Are pregnant or breastfeeding (see "**Pregnancy and breastfeeding**").
- Have been diagnosed with type 1 diabetes (you are dependent on insulin).
- Have been diagnosed with diabetic ketoacidosis, a condition characterised by too much acid in the blood. Symptoms include excessive thirst, frequent urination, nausea and vomiting, stomach pain, loss of appetite, weakness or fatigue,



shortness of breath, fruity-scented breath, and confusion. It may proceed to coma and death.

- Are younger than 18 years of age.

Take special care with CIPLA-PIOGLITAZONE tablets

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

- Liver problems
- Previous absence of ovulation in women who have not reached menopause, as ovulation and pregnancy may occur if contraception is not used
- Use other medicines to treat diabetes (see "**Taking other medicines with CIPLA-PIOGLITAZONE**")
- Bladder cancer or a history of bladder cancer
- Tell your doctor that you are on treatment with abiraterone for your prostate cancer

Your doctor will perform blood tests to evaluate your liver function during treatment with **CIPLA-PIOGLITAZONE**. These blood tests will be performed before the start of treatment and regularly for the first year of taking **CIPLA-PIOGLITAZONE**, as well as periodically after that. You should tell your doctor as soon as possible if you experience nausea, vomiting, stomach pain, tiredness, loss of appetite and/or dark urine as this may indicate that your liver is not functioning properly (see "**POSSIBLE SIDE-EFFECTS**").



Taking **CIPLA-PIOGLITAZONE** in combination with insulin may also cause low blood sugar levels. If you develop light-headedness, weakness, jitteriness and tremor accompanied by sweating or feeling hungry or nauseous, your blood sugar levels may be too low. Low blood sugar levels may also result from skipping meals, exercising more than usual or because of physical stress due to illness or fever. Low blood sugar levels may lead to confusion, coma and death. If you do not respond to eating a sweet or drinking a soft drink, you need to obtain medical advice urgently.

CIPLA-PIOGLITAZONE may increase the risk of bone fractures in women. Please report any bone pain to your doctor as soon as possible.

Treatment with **CIPLA-PIOGLITAZONE** may result in fluid retention (keeping water back). This in turn may cause heart failure or worsen existing heart failure. You should not take **CIPLA-PIOGLITAZONE** if you have heart failure (see "**Do NOT take CIPLA-PIOGLITAZONE tablets if you**"). Please report to your doctor immediately if you develop excessively rapid weight gain, shortness of breath and swelling of the body (see "**POSSIBLE SIDE-EFFECTS**"). Using insulin in combination with **CIPLA-PIOGLITAZONE** may further increase your risk of keeping fluid back and of developing heart failure.

You may gain weight while taking **CIPLA-PIOGLITAZONE**. The mechanism of weight gain is unclear, but may be due to a combination of fluid retention (keeping water back) and fat accumulation. You should strictly stick to your calorie-controlled diet.



If you notice that your vision is deteriorating or if you experience any visual disturbances (see "**POSSIBLE SIDE-EFFECTS**"), you should report it to your doctor immediately.

Taking CIPLA-PIOGLITAZONE tablets with food and drink

CIPLA-PIOGLITAZONE tablets can be taken with or without food. However, once you have taken **CIPLA-PIOGLITAZONE**, you should not skip meals (see "**HOW TO TAKE CIPLA-PIOGLITAZONE**").

Each tablet should be swallowed whole with fluid. Do not divide, crush, chew or place the tablets in water.

Pregnancy and breastfeeding

Do not take **CIPLA-PIOGLITAZONE** if you are pregnant or breastfeeding your baby (see "**Do NOT take CIPLA-PIOGLITAZONE tablets if you**").

If you are pregnant or breastfeeding your baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking CIPLA-PIOGLITAZONE.

Driving or using machinery:

CIPLA-PIOGLITAZONE tablets have not been shown to impair judgement, thinking or motor skills. However, if you experience blurred vision or any other visual disturbances,



you must be cautious about operating hazardous machinery and driving until you are certain that **CIPLA-PIOGLITAZONE** does not affect you adversely.

Important information about some of the ingredients in CIPLA-PIOGLITAZONE

CIPLA-PIOGLITAZONE contains lactose. If you are lactose intolerant, please speak to your doctor or pharmacist before taking **CIPLA-PIOGLITAZONE**, as you may experience unwanted side-effects, such as nausea, cramping, bloating, diarrhoea (runny stomach), and flatulence. If you suffer from rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption, you should not take **CIPLA-PIOGLITAZONE**.

Taking other medicines with CIPLA-PIOGLITAZONE:

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

Please consult your doctor if you are using any of the following medicines:

- Oral contraceptives (the pill), as combination with **CIPLA-PIOGLITAZONE** may make the pill less effective.
- Ketoconazole for fungal infections, since you may require more frequent monitoring of your blood sugar levels.
- Midazolam (used as a sedative), as **CIPLA-PIOGLITAZONE** may lower blood levels of midazolam.



- Rifampicin, an antibiotic, as you may require an increase in the dosage of **CIPLA-PIOGLITAZONE**.
- Gemfibrozil for high blood cholesterol levels, as it may be necessary to reduce your dose of **CIPLA-PIOGLITAZONE**.
- Insulin, since combination with **CIPLA-PIOGLITAZONE** may increase your risk of developing heart failure or low blood sugar levels (see "**Take special care with CIPLA-PIOGLITAZONE tablets**").
- Abiraterone (used to treat prostate cancer): You may develop a low blood glucose (hypoglycaemia) if you use **CIPLA-PIOGLITAZONE** concurrently with abiraterone. You should monitor your blood glucose frequently.

HOW TO TAKE CIPLA-PIOGLITAZONE TABLETS

Always take CIPLA-PIOGLITAZONE exactly as your doctor has instructed you.

You should check with your doctor or pharmacist if you are unsure.

Do not share medicines prescribed for you with others.

The usual dose is one **CIPLA-PIOGLITAZONE 15** or one **CIPLA-PIOGLITAZONE 30** tablet once a day, with or without a meal. However, once you have taken **CIPLA-PIOGLITAZONE 15** or **30**, you should not skip a meal.

The maximum daily dose is 45 mg per day (3 **CIPLA-PIOGLITAZONE 15** tablets).

Diabetes mellitus requires life-long treatment. Your doctor will decide how long treatment



with **CIPLA-PIOGLITAZONE** should last and whether or not you require additional medicines or dosage adjustments. Do not abruptly stop taking **CIPLA-PIOGLITAZONE** without your doctor's permission.

Use in children

Safety and efficacy in individuals below 18 years of age has not been established. Children should not take **CIPLA-PIOGLITAZONE** tablets (see "**Do NOT take CIPLA-PIOGLITAZONE tablets if you**").

If you feel that the effect of **CIPLA-PIOGLITAZONE** is too strong or too weak for you, please discuss this with your treating doctor.

If you take more CIPLA-PIOGLITAZONE than you should

In the event of an overdose (if you take too many tablets), or if someone else has taken your medicine by mistake, you, or this other person, may experience light-headedness, weakness, jitteriness and tremor accompanied by sweating or feeling hungry or nauseous. **In the event of overdose, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison control centre.**

If you forget to take CIPLA-PIOGLITAZONE

Always take **CIPLA-PIOGLITAZONE** as prescribed. If you miss a dose, take it as soon as possible. However, if you do not remember the missed dose until the next dose is



due, skip the missed dose and go back to your regular dosing schedule of one tablet daily. Do not take a double dose to compensate for the forgotten individual dose.

POSSIBLE SIDE-EFFECTS

CIPLA-PIOGLITAZONE can have side-effects.

Not all side-effects reported for CIPLA-PIOGLITAZONE are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking CIPLA-PIOGLITAZONE, please consult your doctor, pharmacist or other healthcare professional for advice.

If you develop any of the following, consult your doctor immediately:

- Loss of vision or reduced vision
- Swelling of the feet, ankles, or legs accompanied by tiredness, weakness, loss of appetite, palpitations, shortness of breath or inability to lie flat accompanied by excessively rapid weight gain as these symptoms may indicate fluid retention which may lead to heart failure (see "**Take special care with CIPLA-PIOGLITAZONE tablets**")
- A combination of light-headedness, weakness, jitteriness and tremor accompanied by sweating or feeling hungry or nauseous that does not respond to eating a snack or drinking a cool drink (see "**Take special care with CIPLA-PIOGLITAZONE tablets**")



- A combination of nausea, vomiting, stomach pain, tiredness or weakness, loss of appetite and/or dark urine as this may indicate inflammation of the liver or liver damage (see "**Take special care with CIPLA-PIOGLITAZONE tablets**")

Please report to your doctor as soon as possible if you develop any of the following side-effects:

- Blood in the urine
- Pallor, tiredness, shortness of breath, lack of energy, or chest pain with exertion
- Reduced sense of touch or sensation
- Bone pain

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

- Sore throat, coughing, sneezing, runny or blocked nose or pain over the sinuses
- Weight gain (see "**Take special care with CIPLA-PIOGLITAZONE tablets**") or increased appetite
- Headache, sleeplessness, dizziness, or a sensation of motion when you are keeping still
- Muscle aches, joint pain, or back ache
- Tooth disorders
- Flatulence (passing winds)
- Impotence or erectile dysfunction
- Sweating



- Fatigue

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

STORING AND DISPOSING OF CIPLA-PIOGLITAZONE:

Store at or below 30 °C in blister packs. Protect from moisture and humidity.

Keep blisters in the outer carton until required for use.

STORE ALL MEDICINES OUT OF REACH OF CHILDREN.

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 CIPLA-PIOGLITAZONE:

CIPLA-PIOGLITAZONE 15: Supplied in clear, colourless, transparent, PVC/PVDC and aluminium foil blister strips of 10 tablets, packed in 30.

CIPLA-PIOGLITAZONE 30: Supplied in clear, colourless, transparent, PVC/PVDC and aluminium foil blister strips of 10 tablets, packed in 30.

IDENTIFICATION OF CIPLA-PIOGLITAZONE:

CIPLA-PIOGLITAZONE 15: White, circular, flat bevelled edge, uncoated tablet with 'P15' debossed on one side and plain on the other side.



CIPLA-PIOGLITAZONE 30: White, circular, flat bevelled edge, uncoated tablet with
'P30' debossed on one side and plain on the other side.

REGISTRATION NUMBERS:

CIPLA-PIOGLITAZONE 15: A40/21.2/0149

CIPLA-PIOGLITAZONE 30: A40/21.2/0150

NAME AND ADDRESS OF THE REGISTRATION HOLDER:

CIPLA MEDPRO (PTY) LTD.

Building 9

Parc du Cap

Mispel Street

Bellville

7530

RSA

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