

**PROPOSED PATIENT INFORMATION LEAFLET FOR
PAZOPANIB 200 CIPLA**

SCHEDULING STATUS:

S4

PAZOPANIB 200 CIPLA, 200 mg, film-coated tablets

Pazopanib

Sugar free

Read all of this leaflet carefully before you start taking PAZOPANIB 200 CIPLA

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor, pharmacist, nurse or other health care provider.
- PAZOPANIB 200 CIPLA 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.
- 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, Page 5)

What is in this leaflet:

1. What PAZOPANIB 200 CIPLA is and what it is used for
2. What you need to know before you take PAZOPANIB 200 CIPLA
3. How to take PAZOPANIB 200 CIPLA
4. Possible side effects
5. How to store PAZOPANIB 200 CIPLA
6. Contents of the pack and other information

1. What PAZOPANIB 200 CIPLA is and what it is used for

PAZOPANIB 200 CIPLA contains an active substance pazopanib. It is classified as a cytostatic medicine (medicine that can cause cell death or stop cell growth and cell multiplication) and is used to treat renal cell carcinoma (a form of kidney cancer).

PAZOPANIB 200 CIPLA is indicated for the treatment of advanced and/or metastatic renal cell carcinoma (RCC).

2. What you need to know before you take PAZOPANIB 200 CIPLA**Do not take PAZOPANIB 200 CIPLA:**

If you are hypersensitive (allergic) to pazopanib or any of the other ingredients of PAZOPANIB 200 CIPLA (listed in **section 6**).

Warnings and precautions

Tell your doctor or health care provider before taking PAZOPANIB 200 CIPLA:

- If you have heart disease
- If you have a history of blockage of blood vessels due to blood clots
- If you previously suffered a heart attack or stroke, heart failure, heart palpitations
- If you have a history of aneurysm (weakening of the artery that causes a bulge that can rupture the artery)
- If you have or are developing a condition in which parts of the brain are affected by swelling, this usually results in headaches, changes in vision, confusion, weakness and seizures
- If you have high blood pressure
- If you have liver disease
- If you have a condition whereby there is progressive scarring and inflammation of the lung tissue. Tell your doctor if you experience shortness of breath, dry cough and fatigue
- If you have gastrointestinal problems
- If you have thyroid problems
- If you have problems with wound healing especially if you are going to have surgery, PAZOPANIB 200 CIPLA should be stopped 7 days before the surgery
- If you have problems with your kidneys resulting in protein in the urine
- If you have a rapidly growing tumour or a very large tumour, your doctor will monitor you for a condition called Tumour lysis syndrome (large amounts of cell contents are released into the bloodstream)
- If you have had a history of pneumothorax (collapsing of the lung resulting in difficulty breathing)
- Serious infections can occur during treatment with PAZOPANIB 200 CIPLA. Tell your doctor if you experience fever, chills, fatigue, sore throat

- If you experience bruising, bleeding, fever, fatigue and confusion when taking PAZOPANIB 200 CIPLA, contact your doctor. This may be a sign of damage to blood vessels known as thrombotic microangiopathy (TMA)
- If you notice any stroke-like symptoms, such as trouble walking, speaking and understanding, as well as paralysis or numbness of the face, arm or leg, weakness on one side of the body, vision problems and slurred speech
- If you are taking any other medicine including complementary medicine.

Check with your doctor if you think any of these may apply to you or if you are unsure. You may need extra tests to check that your heart, liver and thyroid are working properly. Your doctor may decide to adjust your dose or stop treatment based on the results of these tests.

Children and adolescents

Do not give PAZOPANIB 200 CIPLA to children. The safety and efficacy of PAZOPANIB 200 CIPLA in children has not yet been established.

Other medicines and PAZOPANIB 200 CIPLA

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines).

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

- Clarithromycin, telithromycin, voriconazole (used to treat infections) as it may increase the effects of PAZOPANIB 200 CIPLA.

- Atazanavir, indinavir, nelfinavir, ritonavir, saquinavir (used to treat HIV) as it may increase the effects of PAZOPANIB 200 CIPLA.
- Nefazodone (used to treat depression) as it may increase the effects of PAZOPANIB 200 CIPLA.
- Lapatinib (used to treat breast cancer), as it may increase the effects of PAZOPANIB 200 CIPLA.
- Paclitaxel (used to treat cancers), as co-administration of PAZOPANIB 200 CIPLA may increase the effects of paclitaxel.
- Cetuximab (used to treat cancers), as co-administration of PAZOPANIB 200 CIPLA may increase the effects of cetuximab.
- Irinotecan (used to treat cancers), as co-administration of PAZOPANIB 200 CIPLA may increase the effects of irinotecan.
- Rifampin (used to treat infections), as the effects of PAZOPANIB 200 CIPLA may be decreased.
- Esomeprazole (used to treat stomach acid), as the effects of PAZOPANIB 200 CIPLA may be decreased.
- Simvastatin or any other 'statin'(used to treat high cholesterol levels), as coadministration of PAZOPANIB 200 CIPLA may cause an increase in a certain liver enzyme, which could result in liver failure).
- Midazolam (used to treat anxiety), as co-administration of PAZOPANIB 200 CIPLA may increase the effects of midazolam.
- Dextromethorphan (used to temporarily relieve cough), as co-administration of PAZOPANIB 200 CIPLA may increase the effects of dextromethorphan.

PAZOPANIB 200 CIPLA with food and drink

PAZOPANIB 200 CIPLA when taken with a high-fat or low-fat meal may increase the amount of medicine that is available in the body. (See **section 3** for dosage and directions for use)

Avoid grapefruit juice as it may increase the effect of PAZOPANIB 200 CIPLA.

Pregnancy and breastfeeding

If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist or other health care provider for advice before taking this medicine.

PAZOPANIB 200 CIPLA should not be used during pregnancy or be used if you are planning on becoming pregnant.

The safe use of PAZOPANIB 200 CIPLA during breastfeeding has not been established.

Breastfeeding should be discontinued during treatment with PAZOPANIB 200 CIPLA.

Women of childbearing potential should use adequate contraception during treatment and for at least 2 weeks after the last dose of PAZOPANIB 200 CIPLA and to avoid becoming pregnant while receiving treatment with PAZOPANIB 200 CIPLA.

Male patients (including those who have had vasectomies) should use condoms during sexual intercourse while taking PAZOPANIB 200 CIPLA and for at least 2 weeks after the last dose of PAZOPANIB 200 CIPLA to avoid potential exposure to the medicine for pregnant partners and female partners of reproductive potential.

Driving and using machines

Patients should avoid driving or using machines if they feel dizzy, tired or weak as the ability to drive and use machines while using PAZOPANIB 200 CIPLA has not been established.

It is not always possible to predict to what extent PAZOPANIB 200 CIPLA may interfere with your daily activities. You should ensure that you do not engage in the above activities until you are aware of the measure to which PAZOPANIB 200 CIPLA affects you.

3. How to take PAZOPANIB 200 CIPLA

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

Always take PAZOPANIB 200 CIPLA exactly as your doctor or pharmacist has told you. Check with your doctor or pharmacist if you are not sure.

PAZOPANIB 200 CIPLA should be taken orally without food (at least one hour before or two hours after a meal).

The usual dose is 800 mg (4 tablets of 200 mg tablet) orally once daily.

Your doctor will tell you how long your treatment with PAZOPANIB 200 CIPLA will last. Do not stop treatment early. If you have the impression that the effect of PAZOPANIB 200 CIPLA is too strong or too weak, tell your doctor or pharmacist.

If you take more PAZOPANIB 200 CIPLA than you should

An overdose of PAZOPANIB 200 CIPLA may result in fatigue and hypertension.

In the event of overdosage, consult your doctor or pharmacist. If neither is available, contact the nearest hospital or poison centre.

If you forget to take PAZOPANIB 200 CIPLA

Do not take a double dose to make up for forgotten individual doses. If you miss a dose, take it as soon as you remember. Do not take it if it is close (within 12 hours) to your next dose.

4. Possible side effects

PAZOPANIB 200 CIPLA can have side effects.

Not all side effects reported for PAZOPANIB 200 CIPLA are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking PAZOPANIB 200 CIPLA, please consult your health care provider for advice.

If any of the following happens, stop taking PAZOPANIB 200 CIPLA and tell your doctor immediately or go to the casualty department at your nearest hospital:

- Swelling of the hands, feet, ankles, face, lips and mouth or throat, which may cause difficulty in swallowing or breathing
- Rash or itching
- Fainting.

These are all very serious side effects. If you have them, you may have had a serious reaction to PAZOPANIB 200 CIPLA. 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:

- Chest pain
- Angina - you may experience chest pain, discomfort or a burning sensation
- Changes in the way your heart beats, for example, if you notice it beating faster
- Difficulty breathing.

It is also worth noting that the use of PAZOPANIB 200 CIPLA may increase the risk of the following fatal events:

- Bleeding anywhere in the digestive tract (from the mouth to the rectum),
- Bleeding from the lung,
- Coughing up blood,
- Abnormal liver function,
- Breakage in the intestine which leads to spillage of intestinal contents outside the digestive tract and in the body causing infection,
- Ischaemic stroke (type of stroke caused by a blockage in an artery that supplies blood to the brain).

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- Infections, you may experience fever, chills, fatigue

- Low levels of blood platelet - you may experience difficulty stopping bleeding
- The thyroid gland does not produce enough thyroid hormone, resulting in fatigue, lethargy, cold sensitivity, constipation, dry skin and unexplained weight gain
- Decreased desire to eat food
- Decrease in body weight
- Low levels of phosphate in the blood, a blood test will be needed to determine this but you may experience muscle or bone pain, weakness, confusion or irritability
- Lack of body water resulting in dehydration
- Not able to sleep efficiently
- Headache, dizziness, lethargy, distortion of the sense of taste
- Tingling or prickling, "pins-and-needles" sensation; usually temporary, often occurs in the arms, hands, legs or feet
- Weakness, numbness and pain from nerve damage, usually in the hands and feet
- Blurred vision
- Increased blood pressure
- Hot flushes
- Leg pain and swelling of the legs/feet. These could be signs of a blood clot in your body (thromboembolism). If the clot breaks off, it may travel to your lungs and this may be life threatening or even fatal
- Coughing up blood
- Chest pain
- Bleeding from the nose
- Difficulty breathing
- Hoarseness of voice
- Presence of blood in the urine

- Diarrhoea, nausea, vomiting
- Abdominal bloating and pain
- Painful swelling and sores inside the mouth
- Indigestion (upper abdominal discomfort, described as burning sensation, bloating or gassiness)
- Increased gassiness (farting)
- Dry mouth
- Abnormal increase of bilirubin in the blood - you may notice yellowing of skin and eyes, accompanied with fatigue
- Hair colour changes
- Loss of hair from the head
- Skin rash
- Dry and/or itchy skin
- Redness, swelling, and pain on the palms of the hands and/or the soles of the feet
- Patches of skin that are lighter than your overall skin tone
- Redness of the skin
- Abnormally excessive sweating
- Painful joints and muscles
- Muscle spasms
- Presence of protein in the urine - a urine test will be needed to confirm this but you may notice swelling of your face, feet or ankles, more frequent urination, shortness of breath
- Vaginal bleeding
- Bleeding from the uterus that occurs in between periods (the tube that allows urine to pass outside the body)
- Menstrual periods with abnormally heavy or prolonged bleeding

- Fluid retention in the body characterised by swelling
- Feeling of body fatigue or tiredness
- Swelling of the mucosal lining of the digestive tract resulting in burning and tingling sensations
- Abnormal Electrocardiogram test reading (QT prolonged) – changes in heart rhythm which can develop into a potentially serious heart condition known as torsade de pointes. This can result in a very fast heartbeat causing a sudden loss of consciousness. Tell your doctor if you notice any unusual changes in your heart beat, such as beating too fast or too slow.

Less Frequent side effects:

- Retinal detachment (part of the eye (the retina) pulls away from supportive tissue)
- Infection and inflammation of the gums
- Infection and inflammation of the peritoneum (abdominal cavity) - you may experience bloating, tenderness or pain accompanied by fever, fatigue, nausea or vomiting
- Tumour pain
- High concentration of red blood cells in your blood. Symptoms may include headaches, dizziness and vision problems
- Blood disorders affecting blood vessels, blood clots forming in small blood vessels throughout the body, destruction of blood platelets (clotting cells), low red blood cell count, kidney failure. Signs and symptoms may include bruising easily, high blood pressure, fever, confusion, drowsiness, seizures (fits) and decrease in urine output. Seek medical help if you get any of these symptoms
- Low levels of magnesium in the blood. Symptoms may include muscle cramps, lack of energy, weakness, pins and needles feeling in the muscles

- Tumour lysis syndrome (large amounts of cell contents are released into the bloodstream due to cell death) Symptoms may include irregular heartbeat, seizures (fits), confusion, muscle cramps or spasms, or decrease in urine output. Seek medical help if you get any of these symptoms
- Numbness (decreased sense of touch or sensation)
- Brief stroke like attack (weakness on one side of the body, vision problems and slurred speech)
- Parts of the brain are affected by swelling, this usually results in headaches, changes in vision, confusion, weakness and seizures
- Strong desire for sleep and feeling of drowsiness
- Eyelash discolouration
- Retinal tear (tear to the innermost layer of the eye)
- Slow heart rate
- Heart attack (tightness or pain in the chest, neck, back or arms, as well as fatigue, light-headedness, abnormal heartbeat and anxiety)
- Heart pumps blood abnormally (shortness of breath upon lying down or physical activity, fatigue and weakness, rapid or irregular heartbeat, coughing or wheezing with pink blood-tinged mucous)
- Irreversible death of heart muscle cells (Neck, jaw, shoulder or arm pain, fast heartbeat, shortness of breath when engaging physical activity, sweating, fatigue)
- Heart palpitations, light-headedness, fainting
- Runny nose
- Bleeding from the lungs - you may notice low blood pressure, rapid heart rate
- Collapsing of the lung (painful chest, fast shallow breathing, shortness of breath)

- Progressive scarring and inflammation of the lung tissue (dry cough with shortness of breath or fast breathing)
- Bleeding from mouth to rectum (the gums, oesophagus, stomach, intestines)
- Internal bleeding or swallowing of blood which results in the production of dark sticky stools
- Bleeding from the rectum and anus including bleeding
- Bleeding from haemorrhoids
- Vomiting of blood
- Bleeding in the retroperitoneal space (space in the back of the belly), you may experience stomach pain, bloating, severe lower back pain
- Inflammation of pancreas - stomach pain that radiates to your back, fever
- Frequent-bowel movements
- Rupture of intestines which may cause severe stomach pain or cramping, bloating, fever, chills
- Abnormal communication between the small or large bowel and the skin that allows the contents of the stomach or intestines to leak through an opening in the skin - you may notice diarrhoea, pain, fever, chills, rapid heart rate
- Yellow tint to the skin or eyes caused by an excess of bilirubin, a substance created when red blood cells break down
- Nail discolouration
- Peeling of the skin
- Breakouts in rash due to sunlight sensitivity
- Itchy skin
- Red of the skin and soles of the feet
- Different types of rashes

- Painful muscles and bones
- Presence of blood when urinating
- Feeling of being cold
- Sores that occurs on the mucous membrane of the mouth and eyes
- Decreased blood glucose.

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

Reporting of side effects

If you get side effects, talk to your doctor or pharmacist or nurse. You can also report side effects to SAHPRA via the “Adverse drug reaction and quality problem reporting form”, found online under SAHPRA’s publications: <https://www.sahpra.org.za/Publications/Index/8> or to Cipla Medpro (Pty) Ltd. by e-mail: drugsafetysa@cipla.com or telephone: 080 222 6662 (toll free). By reporting side effects, you can help provide more information on the safety of PAZOPANIB 200 CIPLA.

5. How to store PAZOPANIB 200 CIPLA

Store all medicines out of reach of children.

Store at or below 25 ° C.

Store in the original container.

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

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 PAZOPANIB 200 CIPLA contains

The active substance is pazopanib.

The other ingredients are:

Magnesium stearate

Microcrystalline cellulose

Povidone K-30

Sodium starch glycolate

Opadry pink composed of:

Hypromellose (E464)

Iron oxide red (E172)

Macrogol

Polysorbate 80

Titanium dioxide (E171)

What PAZOPANIB 200 CIPLA looks like and contents of the pack

PAZOPANIB 200 CIPLA are pink, film-coated, capsule-shaped tablets, with a length of 14,5 mm and a width of 5,6 mm, debossed with "173" on one side and plain on the other side.

CIPLA MEDPRO (PTY) LTD.

Pazopanib 200 Cipla, 200 mg film-coated tablets

PAZOPANIB 200 CIPLA film-coated tablets is packed in HDPE containers with child-resistant PP caps (with liner), or child-resistant HDPE/PP caps (with liner), and a desiccant cylinder containing 30, 90 or 120 tablets.

Not all pack sizes are necessarily marketed.

Holder of Certificate of Registration

CIPLA MEDPRO (PTY) LTD.

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