Dr. Reddy's Laboratories (Pty) Ltd.
APPROVED PATIENT INFORMATION LEAFLET
PAZITORZ 200 mg & 400 mg (film-coated tablets)

PATIENT INFORMATION LEAFLET

SCHEDULING STATUS: **S4**

PAZITORZ 200 mg, film-coated tablets

PAZITORZ 400 mg, film-coated tablets

Pazopanib

Sugar free

Read all of this leaflet carefully before you start taking PAZITORZ

- Keep this leaflet. You may need to read it again.
- If you have further questions, please ask your doctor, pharmacist, nurse or other health care provider.
- PAZITORZ 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 PAZITORZ is and what it is used for
2. What you need to know before you take PAZITORZ
3. How to take PAZITORZ
4. Possible side effects
5. How to store PAZITORZ
6. Contents of the pack and other information

1. What PAZITORZ is and what it is used for

PAZITORZ is a type of medicine called a *protein kinase inhibitor.* It works by preventing the activity of proteins that are involved in the growth and spread of cancer cells.

PAZITORZ is used as a single agent in adults to treat renal cell carcinoma (a form of kidney cancer) that is advanced or has spread to other organs.

PAZITORZ is used as a single agent to treat certain forms of advanced soft tissue sarcoma (STS), which is a type of cancer that affects the supportive tissues of the body. It can occur in muscles, blood vessels, fat tissue or in other tissues that support, surround, and protect the organs.

2. What you need to know before you take PAZITORZ

Do not take PAZITORZ

- if you are allergic (hypersensitive) to pazopanib or any of the other ingredients of PAZITORZ (see "What PAZITORZ contains").
- if you are pregnant or breastfeeding your baby.

Warnings and precautions

Talk to your doctor before taking PAZITORZ:

- if you have any conditions that affect blood flow to your brain e.g., stroke, brain aneurysm, brain bleed and carotid artery disease.
- if you have liver disease.
- if you have high blood pressure.

  PAZITORZ can raise your blood pressure. Your blood pressure will

be checked before you take PAZITORZ and while you are taking it.

If you have high blood pressure you will be treated with medicines to reduce it.

- if you have had prior collapse of a lung.
- if you have heart disease.
- if you have had problems with bleeding, blood clots or narrowing of the arteries.
- if you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall.
- if you have had stomach or bowel problems such as *perforation* (hole) or *fistula* (abnormal passages forming between parts of the intestine).
- if you are going to have an operation.

  Your doctor will stop PAZITORZ at least 7 days before your operation (surgical or dental) as it may affect wound healing.

  Your treatment will be restarted when the wound has adequately healed.
- if you have thyroid problems.
- if you have problems with your kidney function.

Tell your doctor if any of these apply to you.

Your doctor will decide whether PAZITORZ is suitable for you.

You may need extra blood tests to check that your heart, thyroid and liver are working properly. Your doctor will also take blood and urine samples to check for any kidney problems. You will also have your blood pressure checked. Your doctor will periodically record your electrocardiogram (ECG) to check your heart's electrical conduction.

Your doctor will also check on any recent surgical or dental procedures to see if you are healing properly.

Children and adolescents

PAZITORZ is not for use in children and adolescents.

Other medicines and PAZITORZ

Always tell your health care provider if you are taking any other medicine.

(This includes complementary or traditional medicines).

Some medicines may affect how PAZITORZ works or make it more likely that you'll have side effects. PAZITORZ can also affect how some other medicines work.

These include:

- clarithromycin, ketoconazole, itraconazole, rifampin, telithromycin, voriconazole (used to treat infection)
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir (used to treat HIV)
- nefazodone (used to treat depression)
- simvastatin and possibly other statins (used to treat high cholesterol levels)
- lapatinib, paclitaxel, irinotecan (used to treat cancer)
- midazolam (used to produce drowsiness before surgery)
- dextromethorphan (used to treat coughs)
- medicines that reduce stomach acid. The type of medicine that you are taking to reduce your stomach acid (e.g., proton pump inhibitor, H_2 antagonists or antacids) may affect how PAZITORZ is taken. Please consult your doctor, nurse or pharmacist for advice.

Tell your doctor or pharmacist if you take any of these.

PAZITORZ with food and drink

- Do not take PAZITORZ with food, as it affects the way the medicine is absorbed. Take it at least two hours after a meal or one hour before a meal (see "How to take PAZITORZ").
- Grapefruit juice should be avoided when taking PAZITORZ, as this may increase the concentration of the active ingredient i.e., pazopanib in your blood stream which may increase the chance of side effects.

Pregnancy, breastfeeding and fertility

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

PAZITORZ should not be used if you are pregnant.

- Use a reliable method of contraception while you are taking PAZITORZ, and at least for 2 weeks after the last dose, to prevent pregnancy.
- If you do become pregnant during treatment with PAZITORZ, tell your doctor.

Do not breastfeed while taking PAZITORZ. It is not known whether the ingredients in PAZITORZ pass into breast milk.

Male patients (including those who have had vasectomies) who have partners who are either pregnant or who could become pregnant (including those who use other methods of contraception) should use condoms during sexual intercourse while taking PAZITORZ and for at least 2 weeks after the last dose.

Fertility may be affected by treatment with PAZITORZ. Talk to your doctor about this.

Driving and using machines

PAZITORZ can have side effects that may affect your ability to drive or use machines.

- Avoid driving or using machines if you feel dizzy, tired or weak, or if your energy levels are low.

3. How to take PAZITORZ

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

Always take PAZITORZ exactly as your doctor or pharmacist has told you. You should check with your doctor or pharmacist if you are not sure.

How much to take:

The usual dose is 800 mg PAZITORZ, taken once a day.

Your doctor may decide to give you two 400 mg tablets or four 200 mg tablets to make up the 800 mg dose.

When to take:

Swallow the tablets whole with water, one after the other, at about the same time each day.

Do not break or crush the tablets as this affects the way the medicine is absorbed and may increase the chance of side effects.

Do not take PAZITORZ with food. Take it at least two hours after a meal, or one hour before a meal.

Depending on your response to treatment, your doctor may recommend adjusting your dose or temporarily stopping treatment.

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

If you take more PAZITORZ than you should

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

If you take too many tablets, you may be more likely to get side effects. Contact your doctor or pharmacist for advice. If possible, show them the PAZITORZ pack.

If you forget to take PAZITORZ

Do not take a double dose to make up for a missed dose. Take the next dose at the scheduled time.

Do not stop taking PAZITORZ without advice

Take PAZITORZ for as long as your doctor recommends. Do not stop unless your doctor advises you to.

4. Possible side effects

PAZITORZ can have side effects.

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

If any of the following happens, stop taking PAZITORZ 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 PAZITORZ. 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 possible serious side effects:

Swelling of the brain (reversible posterior leukoencephalopathy syndrome)

PAZITORZ can, on rare occasions, cause swelling of the brain, which may be life threatening.

Symptoms include:

- headache
- lack of energy (lethargy)
- loss of speech
- change of vision
- seizure (fits)
- confusion
- high blood pressure
- blindness.

Hypertensive crisis (sudden and severe rise in blood pressure)

PAZITORZ can on occasion cause a sudden and severe rise in blood pressure. This is known as a hypertensive crisis. Your doctor will monitor your blood pressure while you are taking PAZITORZ.

Signs and symptoms of a hypertensive crisis may include:

- severe chest pain
- severe headache

- blurred vision
- confusion
- nausea
- vomiting
- severe anxiety
- shortness of breath
- seizures (fits)
- fainting.

Heart conditions

The risks of these problems may be higher for people with an existing heart problem, or who are taking other medicines. You will be checked for any heart problems while you are taking PAZITORZ.

Cardiac dysfunction/heart failure, heart attack

PAZITORZ can affect how well your heart pumps or can increase the likelihood of having a heart attack.

Signs and symptoms include:

- irregular or fast heartbeat
- rapid fluttering of your heart
- fainting
- chest pain or pressure
- pain in your arms, back, neck or jaw
- shortness of breath
- leg swelling.

Changes in heart rhythm (QT prolongation)

PAZITORZ can affect heart rhythm which in some people 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.

Stroke

PAZITORZ can increase your likelihood of having a stroke.

Signs and symptoms of stroke may include:

- numbness or weakness on one side of your body
- difficulty talking
- headache
- dizziness.

Bleeding

PAZITORZ can cause severe bleeding in the digestive system (such as stomach, oesophagus, rectum or intestine), or the lungs, kidneys, mouth, vagina and brain, although this is uncommon.

Symptoms include:

- passing blood in the stools or passing black stools
- passing blood in the urine
- stomach pain
- coughing or vomiting up blood.

Perforation and fistula

PAZITORZ can cause a tear (perforation) in your stomach or intestinal wall or the development of an abnormal connection between two parts of your digestive tract (a fistula).

Signs and symptoms may include:

- severe stomach pain
- nausea and/or vomiting
- fever
- development of a hole (perforation) in the stomach, intestine or bowel from which bloody or foul-smelling pus is released.

Liver problems

PAZITORZ can cause problems with your liver which may develop into serious conditions such as liver dysfunction and liver failure, which may be fatal. Your doctor will be checking your liver enzymes while you are taking PAZITORZ.

Signs that your liver may not be working properly may include:

- yellowing of your skin or the whites of your eyes (jaundice)
- dark urine
- tiredness
- nausea
- vomiting
- loss of appetite
- pain on the right side of your stomach area (abdomen)
- bruising easily.

Blood clots

Deep vein thrombosis (DVT) and pulmonary embolism

PAZITORZ may cause blood clots in your veins, especially in your legs (deep vein thrombosis or DVT), which may also travel to your lungs (pulmonary embolism).

Signs and symptoms may include:

- sharp chest pain
- shortness of breath
- rapid breathing
- leg pain
- swelling of your arms and hands or legs and feet.

Thrombotic microangiopathy (TMA)

PAZITORZ may cause blood clots in the small blood vessels in the kidneys and brain accompanied by a decrease in red blood cells and cells involved in clotting (TMA).

Signs and symptoms may include:

- bruising easily
- high blood pressure
- fever
- confusion
- drowsiness
- seizures (fits)
- decrease in urine output.

Tumour lysis syndrome

PAZITORZ can cause a fast breakdown of cancer cells resulting in tumour lysis syndrome, which in some people may be fatal. Symptoms may include irregular heartbeat, seizures (fits), confusion, muscle cramps or spasms, or decrease in urine output. **Seek medical help immediately** if you get any of these symptoms.

Infections

Infections occurring while you take PAZITORZ may possibly become serious.

Symptoms of infections may include:

- fever
- flu-like symptoms such as cough, tiredness and body aches that do not go away
- shortness of breath and/or wheezing
- pain while urinating
- cuts, scrapes or wounds that are red, warm, swollen or painful.

Lung inflammation

PAZITORZ can, on rare occasions, cause lung inflammation (interstitial lung disease, pneumonitis), which in some people can be fatal. Symptoms include shortness of breath or cough that will not go away. You will be checked for any lung problems while you are taking PAZITORZ.

Thyroid problems

PAZITORZ can lower the amount of thyroid hormone produced in your body. This can result in weight increase and tiredness. You will be checked for thyroid hormone levels while you are taking PAZITORZ.

Blurry or impaired vision

PAZITORZ can cause separation or tear of the lining of the back part of the eye (retinal detachment or tear). This can result in blurry or impaired vision.

Tell your doctor if you notice any of the following possible side effects (including possible serious side effects under the relevant frequency category):

Frequent side effects:

- tumour pain
- infections – you may experience fever, chills and tiredness

- loss of appetite
- loss of weight
- problems sleeping
- taste disturbance or loss of taste
- headache
- dizziness
- temporary reduction in blood supply to the brain (transient ischemic attack)

- slow heart rate
- decreased blood flow to the heart – which may cause chest pain
- abnormal electrocardiogram reading (QT prolonged) – changes in heart rhythm 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.
- nose bleeds
- bleeding in digestive tract (stomach and intestine)
- high blood pressure
- chest pain, shortness of breath, 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.
- hoarseness
- shortness of breath
- collapsed lung with air trapped in the space between the lung and chest, often causing shortness of breath (pneumothorax)

- stomach pain
- loose stools (diarrhoea)
- indigestion, bloating
- increase in lipase (an enzyme involved in digestion)
- feeling or being sick (nausea or vomiting)
- sore mouth due to redness and inflammation of the mouth (stomatitis)
- unusual hair loss or thinning
- dry skin
- skin disorders, redness, itching, dry skin
- changes in hair colour
- nail disorder
- redness and swelling of the palms of the hands or soles of the feet including tingling, numbness, pain, swelling or reddening
- skin rash, peeling of the skin
- loss of skin pigment
- muscle and bone pain
- lack of energy, feeling weak or tired
- chest pain
- chills
- swelling caused by fluid of face, hands, ankles, feet or eyelids
- blurred vision

Side effects that may show up in your blood or urine tests:

- decrease in the number of blood platelets (cells that help blood to clot) – you may

experience difficulty stopping bleeding

- decrease in the number of white blood cells
- underactive thyroid gland where thyroid gland does not produce enough thyroid hormone, resulting in tiredness, lethargy, cold sensitivity, constipation, dry skin and unexplained weight gain
- increase in lipase (an enzyme involved in digestion)
- increase in bilirubin (a substance produced by the liver) – you may notice yellowing of skin and eyes, accompanied with fatigue
- abnormal liver function
- increase in liver enzymes
- protein in the urine

Your doctor will inform you of the results of the blood tests.

Less frequent side effects:

- stroke
- heart becomes less effective at pumping blood around the body (cardiac dysfunction)
- interruption of blood supply to part of the heart or heart attack (myocardial infarction)
- a dangerous rapid fluttering of the heart (Torsade de Pointes)
- bleeding in the brain and lungs
- cough
- hole (perforation) in stomach or intestine
- abnormal passages forming between parts of the intestine (fistula)
- yellowing of the skin or whites of the eyes (jaundice)

Side effects with unknown frequencies:

- tumour lysis syndrome resulting from a fast breakdown of cancer cells
- increase in the number of red blood cells – you may have headaches, dizziness and vision problems
- swelling of the brain causing headache, seizures, visual disturbances, and altered mental status, stroke
- retinal tear (tear to the innermost layer of the eye)
- inflammation of the lung (interstitial lung disease/ pneumonitis)
- passing gas
- inflammation of the pancreas (pancreatitis)
- liver failure
- increase in gamma-glutamyl transpeptidase (a liver enzyme)
- joint pain
- muscle spasms

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, pharmacist or nurse. You can also report side effects to SAHPRA via the Med SafetyAPP (Medsafety X SAHPRA) and eReporting platform (who-umc.org) found on SAHPRA website.

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

5. How to store PAZITORZ

Store at or below 25 °C.

Keep the containers well closed, protect from light.

This medicine does not require any special storage conditions.

Do not store in a bathroom.

Do not dispose medicines in drains or sewerage systems (e.g., toilets).

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

Store all medicines out of reach of children.

6. Contents of the pack and other information

What PAZITORZ contains

The active substance is pazopanib hydrochloride.

PAZITORZ 200 mg:

Each film-coated tablet contains pazopanib hydrochloride equivalent to 200 mg pazopanib.

PAZITORZ 400 mg:

Each film-coated tablet contains pazopanib hydrochloride equivalent to 400 mg pazopanib.

PAZITORZ 200 mg:

The other ingredients are magnesium stearate, microcrystalline cellulose, povidone (K-30) and sodium starch glycolate (Type A).

The tablet coating ingredients are hypromellose, iron oxide red (E172), macrogol 400, polysorbate 80 and titanium dioxide (E171).

PAZITORZ 400 mg:

The other ingredients are magnesium stearate, microcrystalline cellulose, povidone (K-30) and sodium starch glycolate (Type A).

The tablet coating ingredients are hypromellose, macrogol 400, polysorbate 80 and titanium dioxide (E171).

What PAZITORZ looks like and contents of the pack

PAZITORZ 200 mg:

Capsule-shaped, pink, film-coated tablet with "200" debossed on one side.

PAZITORZ 400 mg:

Capsule-shaped, white, film-coated tablet with "400" debossed on one side.

Holder of Certificate of Registration

Dr. Reddy's Laboratories (Pty) Ltd.

Block C, Woodmead North Office Park

54 Maxwell Drive

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2191

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Registration numbers

PAZITORZ 200 mg: 57/26/0641

PAZITORZ 400 mg: 57/26/0642

Access to the corresponding Professional Information

For any information about this medicine, please contact the local representative of the Holder of Certificate of Registration:

Dr. Reddy's Laboratories (Pty) Ltd. Tel: +27 11 324 2100

Other sources of information

Detailed information on this medicine is available on the Dr. Reddy's Laboratories website:

http://www.drreddys.co.za