Applicant : Eurolab (Pty) Ltd
Proprietary name : Pazopanib Eurolab 200 mg & 400 mg
Dosage form and strength : Film-coated tablets; 200 mg & 400 mg
Date of submission : 21 April 2026
Approval date : 21 July 2026

APPROVED PATIENT INFORMATION LEAFLET

SCHEDULING STATUS **S4**

PAZOPANIB 200 MG EUROLAB, 200 mg film-coated tablets

PAZOPANIB 400 MG EUROLAB, 400 mg film-coated tablets

Pazopanib

Sugar-free

Read all of this leaflet carefully before you start taking PAZOPANIB EUROLAB

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

1. What is PAZOPANIB EUROLAB and what it is used for

PAZOPANIB EUROLAB 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. PAZOPANIB EUROLAB is used in adults to treat kidney cancer that is advanced or has spread to other organs. PAZOPANIB EUROLAB 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 PAZOPANIB EUROLAB

Do not take PAZOPANIB EUROLAB:

- if you are hypersensitive (allergic) to pazopanib or any of the other ingredients of PAZOPANIB EUROLAB (listed in section 6).

Warnings and precautions

Talk to your doctor or pharmacist before taking PAZOPANIB EUROLAB.

Special care should be taken with PAZOPANIB EUROLAB:

- if you have liver disease. Your doctor will monitor your liver function closely (with blood tests).
- if you have high blood pressure. PAZOPANIB EUROLAB can raise your blood pressure. Your blood pressure will be monitored before you take PAZOPANIB EUROLAB and while you are taking it. If you have high blood pressure you will be treated with medicines to reduce it.
- if you experience a rapid onset of symptoms including headache, seizures, extreme tiredness and confusion, hypertension, and blindness. PAZOPANIB EUROLAB can cause swelling of the brain. This condition is diagnosed by your doctor and is called posterior reversible encephalopathy syndrome (PRES)/ reversible posterior leukoencephalopathy syndrome (RPLS), which requires immediate medical attention.
- if you have trouble breathing, shortness of breath, cough, chest pain and unexplained weight loss. PAZOPANIB EUROLAB can cause inflammation and scarring of the lungs. This condition is diagnosed by your doctor and is called interstitial lung disease (ILD)/ pneumonitis, which requires immediate medical attention.
- if you have had heart failure or a heart attack.
- if you have been diagnosed with changes in heart rhythm (QT prolongation). PAZOPANIB EUROLAB 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.

- if you have been diagnosed with heart disease or previous stroke.
- If you notice or someone notices in you 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 have had problems with bleeding, blood clots, narrowing of the arteries or weakening of arteries/ aneurysm.
- 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 PAZOPANIB EUROLAB at least 7 days before your operation 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 kidney disease and excess protein in urine (after urine tests).
- if you have been diagnosed with rapid growing tumours, a high tumour burden (large sized tumour/s and/or large number of cancer cells), renal dysfunction, dehydration, high uric acid levels in blood (after blood tests), your doctor will monitor you for a condition called tumour lysis syndrome. This is when tumour cells release their contents into the bloodstream.
- if you experience sudden shortness of breath, chest pain, or difficulty breathing (pneumothorax).
- if you have been diagnosed with serious infection/s.
- If you are taking other anti-cancer medicines.
- if you are pregnant, planning to get pregnant or fall pregnant during treatment with PAZOPANIB EUROLAB.

Children

The safety and efficacy of PAZOPANIB EUROLAB in children have not been established.

Other medicines and PAZOPANIB EUROLAB

Always tell your health care provider if you are taking any other medicine. (This includes all

complementary or traditional medicines.)

Some medicines may affect how PAZOPANIB EUROLAB works or make it more likely that you will have side effects. PAZOPANIB EUROLAB can also affect how some other medicines work. These include:

- ketoconazole, itraconazole, clarithromycin, telithromycin, voriconazole, rifampicin (used to treat infection).
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir (used to treat HIV).
- nefazodone (used to treat depression).
- lapatinib, paclitaxel, irinotecan, cetuximab (used to treat cancers).
- midazolam (used as a sedative).
- simvastatin and possible other statin (used to treat high cholesterol levels).
- dextromethorphan (included in certain cough mixtures or cold and flu medication).
- medicines that reduce stomach acid. e.g. proton pump inhibitor such as esomeprazole, H_2 antagonists or antacids.

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

PAZOPANIB EUROLAB with food and drink

Don’t take PAZOPANIB EUROLAB 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 section 3). Do not drink grapefruit juice while you are being treated with PAZOPANIB EUROLAB as this may increase the chance of side effects.

Pregnancy, breastfeeding and fertility

Pregnancy

PAZOPANIB EUROLAB is not recommended if you are pregnant. The effect of PAZOPANIB EUROLAB during pregnancy is not known. Tell your doctor if you are pregnant, planning to get pregnant or fall pregnant during treatment with PAZOPANIB EUROLAB.

Women

If you are able to become pregnant:

- you must use an effective method of contraception while receiving treatment with PAZOPANIB EUROLAB to avoid becoming pregnant and for at least 6 months after the last dose.

Men

- If your partner is pregnant or able to become pregnant, you must use condoms for the entire time you are taking PAZOPANIB EUROLAB and for 3 months after the end of treatment.
- If your partner becomes pregnant while you are taking PAZOPANIB EUROLAB, tell your doctor immediately.
- Your partner should also tell her doctor right away.

Breastfeeding

The effect of PAZOPANIB EUROLAB during breastfeeding is not known. Do not breast feed while taking PAZOPANIB EUROLAB. Talk to your doctor about this.

Fertility

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

Driving and using machines

The effect of PAZOPANIB EUROLAB when driving or using machines is not known. Avoid driving or using machines if you feel dizzy, tired or weak, or if your energy levels are low.

3. How to take PAZOPANIB EUROLAB

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

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

The usual dose is PAZOPANIB EUROLAB 800 mg taken once a day (4 tablets of PAZOPANIB 200 MG EUROLAB or 2 tablets of PAZOPANIB 400 MG EUROLAB). This is the maximum dose per day. Your doctor may need to reduce your dose if you get side effects.

Do not take PAZOPANIB EUROLAB with food. Take it at least two hours after a meal, or one hour before a meal. For example, you could take it two hours after breakfast or one hour before lunch. Take PAZOPANIB EUROLAB at about the same time each day. Swallow the tablets whole with water, one after the other. Do not break or crush the tablets as this affects the way the medicine is absorbed and may increase the chance of side effects.

If you take more PAZOPANIB EUROLAB than you should

If you take too many tablets, contact a doctor or pharmacist for advice. If possible show them the pack, or this leaflet.

If you forget to take PAZOPANIB EUROLAB

Do not take a double dose to make up for a forgotten dose. Just take your next dose at the usual time.

If you stop taking PAZOPANIB EUROLAB

Do not stop PAZOPANIB EUROLAB without advice. Take PAZOPANIB EUROLAB for as long as your doctor recommends. Do not stop unless your doctor advises you to.

4. Possible side effects

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

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

- Swelling of the brain (reversible posterior leukoencephalopathy syndrome):
  PAZOPANIB EUROLAB can, on rare occasions, cause swelling of the brain, which may be life threatening. Symptoms include loss of speech, change of vision, seizure (fits), confusion and high blood pressure. Stop taking PAZOPANIB EUROLAB and seek medical help if you get any of these symptoms, or if you get headache accompanied with any of these symptoms.

- Hypertensive crisis (sudden and severe rise in blood pressure):
  PAZOPANIB EUROLAB 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 PAZOPANIB EUROLAB. 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) and fainting. Stop taking PAZOPANIB EUROLAB and seek medical help if you develop hypertensive crisis.

- Heart conditions, such as cardiac dysfunction/ heart failure, heart attack:
  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 PAZOPANIB EUROLAB. PAZOPANIB EUROLAB 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 and leg swelling. Seek medical help if you get any of these symptoms.

- Changes in heart rhythm (QT prolongation):
  PAZOPANIB EUROLAB 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. Tell your doctor if you notice any unusual changes in your heart beat, such as beating too fast or too slow.

- Stroke:

  PAZOPANIB EUROLAB 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 and dizziness. Seek medical help if you get any of these symptoms.

- Bleeding:

  PAZOPANIB EUROLAB 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 and coughing or vomiting up blood. Seek medical help if you get any of these symptoms.

- Perforation and fistula:

  PAZOPANIB EUROLAB 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 and development of a hole (perforation) in the stomach, intestine or bowel from which bloody or foul smelling pus is released. Seek medical help if you get any of these symptoms.

- Liver problems:

  PAZOPANIB EUROLAB 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 PAZOPANIB EUROLAB. 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) and bruising easily. Seek medical help immediately if you get any of

these symptoms.

- Blood clots (Deep vein thrombosis (DVT) and pulmonary embolism):

  PAZOPANIB EUROLAB 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 and swelling of your arms and hands or legs and feet.

- Thrombotic microangiopathy (TMA):

  PAZOPANIB EUROLAB 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 (thrombotic microangiopathy, TMA). 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.

- Tumour lysis syndrome

  PAZOPANIB EUROLAB 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 if you get any of these symptoms.

- Infections

  Infections occurring while you take PAZOPANIB EUROLAB 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 and scrapes or wounds that are red, warm, swollen or painful. Seek medical help if you get any of these symptoms.

- Lung inflammation

  PAZOPANIB EUROLAB 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 PAZOPANIB EUROLAB. Seek medical help if you get any of these symptoms.

- Thyroid problems

  PAZOPANIB EUROLAB 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 PAZOPANIB EUROLAB. Tell your doctor if you notice significant weight gain or tiredness.

- Blurry or impaired vision

  PAZOPANIB EUROLAB 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 change in your vision.

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

Tell your doctor if you notice any of the following:

Frequent side effects:

- infections
- decrease in the number of blood platelets (seen in blood tests)
- decrease in the number of white blood cells (seen in blood tests)
- underactive thyroid gland (seen in blood tests)
- loss of appetite
- abnormally low body weight (anorexia)
- decrease in phosphate in the blood (seen in blood tests)

- changes in the levels of other different chemicals / enzymes in the blood. (seen in blood tests)
- dehydration
- difficulty sleeping
- taste disturbance or loss of taste
- headache
- dizziness
- lack of energy, feeling weak or tired
- tingling or prickling, “pins-and-needles” sensation often in the arms, hands, legs or feet
- numbness of hands or feet
- blurred vision
- high blood pressure
- hot flushes
- nose bleeds
- diarrhoea
- dry mouth or mouth ulcers
- increase in bilirubin (a substance produced by the liver) (seen in blood tests)
- changes in hair colour
- loss of skin pigment
- muscle, joint, tendon or chest pain, muscle spasms
- protein in the urine (seen in urine tests)
- feeling or being sick (nausea or vomiting)
- stomach pain
- weight loss
- sore mouth
- unusual hair loss or thinning
- skin rash, possibly involving peeling of the skin
- redness and swelling of the palms of the hands or soles of the feet
- increase in liver enzymes (seen in blood tests)
- decrease in albumin in the blood (seen in blood tests)

- indigestion, bloating, flatulence
- abnormal drowsiness
- 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.
- heart becomes less effective at pumping blood around the body (cardiac dysfunction)
- slow heartbeat
- high blood pressure
- hot flush / flushing of skin
- sudden shortness of breath, especially when accompanied with sharp pain in the chest and /or rapid breathing (pulmonary embolism)
- hoarseness
- shortness of breath
- cough
- coughing up blood
- nausea
- vomiting
- stomach pain
- sores in the mouth (stomatitis)
- heartburn (dyspepsia)
- gassiness
- bloating
- mouth ulcers
- dry mouth
- increase in bilirubin levels in the blood (see in blood tests)
- liver disease
- change in hair colour
- redness, swelling, pain, blisters on the palms of the hands and/or the soles of the feet (hand-foot syndrome)

- hair loss
- rash
- skin lightening
- skin dryness, redness or itchiness
- excessive sweating
- severe skin rash with peeling (exfoliative rash)
- loss of hair colour (hair depigmentation)
- nail disorders
- skin disorder
- joint and muscle pain
- muscle twitch or spasm
- pain experienced in bones, muscles, ligaments, tendons, and nerves (musculoskeletal pain)
- increase protein levels in urine (seen in urine tests)
- swelling caused by fluid of face, hands, ankles, feet or eyelids
- chest pain
- chills
- abnormal liver function (seen in blood tests)
- increase in creatinine (a substance produced in muscles) (seen in blood or urine tests)
- increase in lipase (an enzyme involved in digestion) (seen in blood tests)
- decrease in white blood cell count (seen in blood tests)
- increase in thyroid stimulating hormone (see in blood tests)
- abnormal results for ear, nose and throat
- abnormal blood cholesterol levels
- increase in urea in the blood (see in blood tests)
- tumour pain
- decrease in heart rate
- partial interruption of blood supply to part of the heart (myocardial ischaemia)
- reduced pumping ability of the left side of the heart (left ventricular dysfunction)
- bleeding in the stomach or bowels

- blood in the urine (hematuria)
- bleeding in the lung
- collapsed lung with air trapped in the space between the lung and chest, often causing shortness of breath (pneumothorax)
- hiccups
- bleeding from the rectum
- bleeding from the mouth

Less frequent side effects:

- infection of the gums
- inflammation of the lining of the abdominal cavity (peritonitis)
- increase in the number of red blood cells (seen in blood tests)
- decrease in magnesium in the blood (seen in blood tests)
- tumour lysis syndrome resulting from a fast breakdown of cancer cells
- loss of sensation or feeling in one or more parts of your body (hypoaesthesia)
- temporary fall in blood supply to the brain (transient ischaemic attack)
- sleepiness
- stroke
- swelling of the brain (posterior reversible encephalopathy/ reversible posterior leukoencephalopathy syndrome)
- change in the colour of eyelashes
- retinal tear (detachments)
- interruption of blood supply to part of the heart or heart attack (myocardial infarction)
- heart failure
- sudden sharp increase in blood pressure (hypertensive crisis)
- severe bleeding in the digestive system (such as stomach, oesophagus or intestine), or the kidneys, vagina and brain
- an enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)

- runny nose
- inflammation of the lung (pneumonitis)
- pain in the mouth or throat (oropharyngeal pain)
- inflammation of the pancreas (pancreatitis)
- bloody stools
- frequent bowel movements
- hole (perforation) in stomach or intestine
- severe infection inside the abdomen (peritonitis)
- abnormal passages forming between parts of the intestine (fistula)
- vomiting blood
- yellowing of the skin or whites of the eyes (jaundice)
- liver failure/ damage
- change in nail colour
- peeling of skin
- increased sensitivity of the skin to sunlight
- rashes which may be itchy or inflamed (flat or raised spots or blisters)
- an open sore on the skin (skin ulcer)
- bleeding in the bladder
- heavy or irregular menstrual periods
- sensation of coldness, with shivering
- increased in liver enzymes (seen in blood tests)
- decrease in blood sugar level (see in blood tests)
- heart rhythm disturbance (QT prolongation)
- abnormal thyroid function test (seen in blood tests)

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 Med Safety APP (Medsafety X SAHPRA) and eReporting platform (who-umc.org)

found on SAHPRA website or to Eurolab (Pty) Ltd. by email: drug-safety@eurolab.co.za. By reporting side effects, you can help provide more information on the safety of PAZOPANIB EUROLAB.

5. How to store PAZOPANIB EUROLAB

Store at or below 25 °C.

Store all medicines out of reach of children.

Store in the original package / container.

Do not use this medicine after the expiry date which is stated on the packaging after "EXP". The expiry date refers to the last day of the month.

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 EUROLAB contains:

The active substance is pazopanib (as hydrochloride).

The other ingredients are microcrystalline cellulose, povidone K-30, sodium starch glycolate, magnesium stearate, purified water, coating material (titanium dioxide E171, hypromellose E464, macrogol 400 E1521, polysorbate 80 E433, iron oxide red E172).

What PAZOPANIB EUROLAB looks like and contents of the pack

PAZOPANIB 200 MG EUROLAB is a capsule-shaped, pink, film-coated tablet with “200” debossed on one side. It is packed in white HDPE bottles with a polypropylene child-resistant cap of 30 or 90 tablets or in clear/transparent Aluminium-PVC/PE/PVDC blisters of 30, 60 or 90 tablets.

PAZOPANIB 400 MG EUROLAB is a capsule-shaped, white, film-coated tablet with “400” debossed on one side. It is packed in white HDPE bottles with a polypropylene child-resistant cap of 30 or 60 tablets or in clear/transparent Aluminium-PVC/PE/PVDC blisters of 30, 60 or 90 tablets.

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Proprietary name	: Pazopanib Eurolab 200 mg & 400 mg
Dosage form and strength	: Film-coated tablets; 200 mg & 400 mg
Date of submission	: 21 April 2026
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Holder of Certificate of Registration

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