

PAZORENE FILM COATED TABLETS

Pazopanib (200mg, 400mg)

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What Pazorene is used for

Pazorene is used as a single agent to treat advanced or metastatic (has spread to other organs) renal cell carcinoma (RCC), which is a form of kidney cancer that involves cancerous changes in the cells of the renal tubule. It prevents the activity of a special group of proteins which are known to be involved in the growth and spread of cancer cells.

Pazorene 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 other tissues that support, surround and protect the organs.

How Pazorene works

Pazorene works by preventing the activity of proteins that are involved in the growth and spread of cancer cells.

Before you use Pazorene

Before you start to use it

If any of these apply to you, tell your doctor before taking Pazorene:

- If you have heart disease
- If you have had heart failure or a heart attack
- If you have problems with your blood pressure
- If you have liver disease
- If you have problems with bleeding
- If you have had prior blood clots in a vein or in a lung
- if you have gastrointestinal problems

- if you have thyroid problems
- If you had prior collapse of a lung
- if you are going to have a surgical or dental procedure, or if you have had either recently
- If you have problems with your kidney function
- If you have or have had an aneurysm (enlargement and weakening of a blood vessel wall) or a tear in a blood vessel wall

Check with your doctor if you think any of these may apply to you. You may need extra tests to check that your kidneys, 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.

Taking other medicines

Before you take Pazorene, tell your doctor or pharmacist or healthcare provider if you are taking or have recently taken or might take any medicines, including medicines obtained without a prescription, because these might interact with Pazorene.

Some medicines may affect the way Pazorene works or Pazorene may affect how other medicines work. These include:

- clarithromycin, ketoconazole, itraconazole, telithromycin, voriconazole (used to treat infections)
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir (used to treat HIV)
- nefazodone (used to treat depression)
- simvastatin (used to treat high cholesterol levels)
- medicines that reduce stomach acid (e.g. esomeprazole)

Ask your doctor, pharmacist or healthcare provider if you are not sure whether your medicine is one of the medicines listed above.

Taking Pazorene with food and drink

Pazorene is affected by food intake (See How to use Pazorene). It is important that you take Pazorene on an empty stomach, either at least

one hour before or at least two hours after food. You should not drink grapefruit juice while you are being treated with Pazorene as this may increase the chance of side effects.

Females of child-bearing potential and male patients

Use a reliable method of contraception to avoid becoming pregnant while you are taking Pazorene and for at least 2 weeks after you stop treatment with Pazorene.

Male patients (including those who have had vasectomies) with female partners who are pregnant, possibly pregnant, or who could become pregnant should use condoms while taking Pazorene and for at least 2 weeks after the last dose. If you become pregnant or think you are pregnant, tell your healthcare provider right away.

Pregnancy and breastfeeding

If you are pregnant or breast-feeding, think you might be pregnant or are planning to have a baby, ask your doctor, pharmacist or healthcare provider for advice before taking this medicine. Your doctor will discuss with you the potential risks of taking Pazorene during pregnancy or breast-feeding.

Breast-feeding is not recommended during treatment with Pazorene. Ask your doctor for advice.

Children and adolescents (under 18 years)

Pazorene is not recommended for use in children and adolescents under 18 years.

How to use Pazorene

Always take this medicine exactly as your doctor, pharmacist or healthcare provider has told you. You should check with your doctor, pharmacist or healthcare provider if you are not sure.

How much to use

The usual dose is 800 mg Pazorene, 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.

Do not break or crush the tablets as this

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affects the way the medicine is absorbed and may increase the chance of side effects. Depending on your response to treatment, your doctor may recommend adjusting your dose or temporarily stopping your treatment.

When to use it

Swallow the tablets whole with water, one after the other, at about the same time each day. It is important that you take Pazorene on an empty stomach, either at least one hour before or at least two hours after food.

How long to use it

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

If you forget to use it

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

If you use too much (overdose)

If you take too much Pazorene you may be more likely to get side effects. Contact your doctor or pharmacist or healthcare provider for advice. If possible show them the Pazorene pack.

If you have any further questions on the use of this medicine ask your doctor, pharmacist or healthcare provider.

While you are using it

While you are taking Pazorene, your doctor will take blood samples to check for any liver or thyroid problems. 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.

Things you must do

Take your medicine exactly as your doctor has told you. Tell all the

doctors, dentist and pharmacists treating you that you are taking Pazorene. Tell your doctor immediately if you become pregnant while taking this medication.

Things you must not do

Do not stop taking the medicine unless advised by your doctor. Do not take any new medicines without consulting your doctor. Do not give Pazorene to anyone else, even if they have the same symptoms or condition as you.

Things to be careful of

Tell your doctor immediately if you experience any of the serious side effects listed below while taking Pazorene as they may become life threatening or fatal.

- Signs of liver problems (abnormal liver function, liver failure) which may include: yellowing of your skin or the whites of your eyes (jaundice), dark urine, tiredness, nausea and/or vomiting, loss of appetite, pain on the right side of your stomach area (abdomen), bruising easily.
- Signs of sudden and severe rise in blood pressure (hypertensive crisis) which may include: severe chest pain, severe headache, blurred vision, confusion, nausea and/or vomiting, severe anxiety, shortness of breath, seizures, fainting.
- Signs of brain swelling (posterior reversible encephalopathy syndrome, reversible posterior leukoencephalopathy syndrome) which may include: loss of speech, blindness or changes in vision, seizures, confusion, headache, lack of energy, high blood pressure.
- Signs of lung inflammation (interstitial lung disease, pneumonitis) which may include: cough that will not go away, shortness of breath.
- Signs of heart problems such as abnormal heart rhythm (QT-prolongation, Torsade de Pointes), cardiac dysfunction/heart failure, heart attack which may 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.

- Signs of stroke which may include: numbness or weakness on one side of your body, trouble talking, headache, dizziness.
- Signs of blood clots in your veins, especially in your legs (deep vein thrombosis), which may also travel to your lungs (pulmonary embolism) which may include: sharp chest pain, shortness of breath, rapid breathing, leg pain, swelling of your arms/hands or legs/feet.
- Signs of blood clots in the small blood vessels in the kidneys and brains accompanied by a decrease in red blood cells and cells involved in clotting (thrombotic microangiopathy) which may include: bruising easily, high blood pressure, fever, confusion, drowsiness, seizures, decrease in urine output.
- Signs of bleeding problems (haemorrhage) which may include: blood in your stool, black stool, blood in your urine, stomach pain, coughing and/or vomiting up blood.
- Signs of a tear in your stomach or intestinal wall (perforation) or the development of an abnormal connection between two parts of your digestive tract (fistula) which may include: severe stomach pain, nausea and/or vomiting, fever, bloody or foul-smelling drainage (pus) from an opening in your stomach area (abdomen) or near your anus.
- Signs of tumour lysis syndrome resulting from a fast breakdown of cancer cells which may include: irregular heartbeat, seizures, confusion, muscle cramps or spasms, decrease in urine output.
- Signs of infections (which can become serious) 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.

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Side effects

Possible side effects include the following listed below. If these side effects become severe, please tell your doctor, pharmacist or healthcare provider.

Very common:

- lack of energy
- diarrhoea
- feeling or being sick (nausea or vomiting)
- weight loss
- high blood pressure
- loss of appetite
- change in hair colour
- decrease in albumin (a protein found in blood)
- tumour pain
- stomach pain or discomfort
- problems with taste
- headache
- pain in the bones, muscles, ligaments, joints and tendons
- muscle pain
- shortness of breath
- increase in some substances (enzymes) produced by the liver
- skin rash, possibly involving peeling of the skin
- cough
- weakness/loss of strength (*asthenia*)
- swelling of hands, ankles or feet
- slow heart rate
- unusual hair loss or thinning
- loss of skin pigment
- dizziness
- mouth sores/inflammation of the lining in the mouth (*stomatitis*)
- a skin reaction or pain on the palms of the hands or soles of the feet (including tingling, numbness, pain, swelling or reddening)
- chest pain

Common:

- under-active thyroid gland
- protein in urine
- difficulty sleeping
- heart becomes less effective at pumping blood (*cardiac dysfunction*)
- a decrease in the number of cells involved in blood clotting (*thrombocytopenia*)
- nose bleed
- hoarseness

- indigestion
- increase in bilirubin (a substance produced by the liver)
- muscle spasms
- dry skin
- flatulence
- chills
- 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* including *deep vein thrombosis*). If the clot breaks off, it may travel to your lungs (*pulmonary embolism*) and this may be life threatening or even fatal.
- increase in gamma-glutamyl transpeptidase (a liver enzyme)
- abnormal liver function
- blurred vision
- low white blood cell count (*neutropenia*)
- nail disorder
- blood in the urine
- increase in lipase (an enzyme from the pancreas)
- severe bleeding (*haemorrhage*) in digestive tract (stomach and intestine)
- sudden collapse of a lung (*pneumothorax*)
- infections, with or without changes in white blood cells (cells that fight infection)
- changes in the hearts' electrical conduction (*QT-prolongation*)
- heart attack
- severe bleeding (*haemorrhage*) in the lung
- reduction of blood supply to the heart (*angina*)
- temporary reduction in blood supply to the brain (*transient ischemic attack*)

Uncommon:

- severe bleeding (*haemorrhage*) in brain
- abnormal connection between parts of the digestive tract (*fistula*)
- stroke
- inflammation of the pancreas (*pancreatitis*)
- hole (*perforation*) in digestive tract
- a dangerous rapid fluttering of the heart (*Torsade de Pointes*)

- abnormal increase in concentration of haemoglobin in the blood
- 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.
- blood clots accompanied by decrease in red blood cells and cells involved in clotting. These clots may harm organs such as the brain and kidneys (*thrombotic microangiopathy*).
- a sudden and severe rise in blood pressure which may be life-threatening (hypertensive crisis)
- skin wound with no healing tendency (skin ulcer)

Rare:

- inflammation of the lung (*pneumonitis*)
- swelling of the brain that may be associated with high blood pressure, headache, loss of speech or vision, and/or seizure which may be life threatening

Not known:

- tumour lysis syndrome resulting from a fast breakdown of cancer cells
- liver failure
- an enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)

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

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [Consumer→Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)].

Storage and Disposal of Pazorene

Storage

- Keep this medicine out of the sight and reach of children.
- Store below 30°C.
- Do not take this medicine after the expiry date, which is stated on the pack.

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Disposal

If you have any unwanted tablets do not put them in wastewater or household rubbish. Ask your pharmacist how to dispose of tablets you do not need. This will help to protect the environment.

Product Description

What it looks like

Pazorene 200mg Film Coated Tablets–Grey, modified capsule-shaped, film-coated tablets, debossed with “P 200” on one side and plain on the other side.

Pazorene 400mg Film Coated Tablets–White, modified capsule-shaped, film-coated tablets, debossed with “P 400” on one side and plain on the other side.

Ingredients

• Active ingredients

The active substance of Pazorene 200 mg Film Coated Tablets is 200 mg Pazopanib.

The active substance of Pazorene 400 mg Film Coated Tablets is 400 mg Pazopanib.

• Inactive ingredients

Tablet core:

- Microcrystalline cellulose
- Povidone
- Sodium Starch Glycolate
- Magnesium Stearate

Film coat:

Pazorene 200 mg Film Coated Tablet: Opadry Complete Film Coating System 15B675001 Grey

Pazorene 400 mg Film Coated Tablet: Opadry Complete Film Coating System 15B680006 White

MAL number(s):

Pazorene 200 mg Film Coated Tablet: MALXXXXXXXX

Pazorene 400 mg Film Coated Tablet: MALXXXXXXXX

Manufacturer

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Product Registration Holder

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