

CONSUMER MEDICINE INFORMATION

PAZOPANIB (TEVA)

Film coated tablets 200 mg & 400 mg

What is in this leaflet

This leaflet answers some common questions about Pazopanib (Teva). It does not contain all the information available on this medicine. It does not take the place of talking to your doctor or pharmacist.

All medicines have risks and benefits.

Your doctor has weighed the risks of using Pazopanib (Teva) against the benefits expected it will have for you. If you have any concerns about using this medicine, ask your doctor or pharmacist.

Keep this leaflet. You may want to read it again.

What Pazopanib (Teva) is used for

Pazopanib (Teva) contains the active ingredient pazopanib which belongs to a anti-cancer group of medicines called protein kinase inhibitors.

Pazopanib (Teva) is used to treat the following conditions:

- 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;
- Certain forms of advanced Soft Tissue Sarcoma (STS), which is a type of cancer that affects the supportive tissue of the body.

It can occur in muscles, blood vessels, fat tissue or other tissues that support, surround and protect organs.

Pazopanib (Teva) works by preventing the activity of proteins that are involved in the growth and spread of cancer cells.

Your doctor may have prescribed Pazopanib (Teva) for another reason.

Ask your doctor if you have any questions about why Pazopanib (Teva) has been prescribed for you.

Pazopanib (Teva) is not addictive.

This medicine is available only with a doctor's prescription.

Before you take Pazopanib (Teva)

When you must not take it

Do not take Pazopanib (Teva) if you have ever had:

- A severe allergic (hypersensitive) reaction to pazopanib.

Check with your doctor if you think this may apply to you.

- An allergic reaction to any of the ingredients listed toward the end of this leaflet. (See "Ingredients").

Some of the symptoms of an allergic reaction may include:

- Shortness of breath
- Wheezing or difficulty breathing
- Swelling of the face, lips, tongue or other parts of the body
- Rash, itching or hives on the skin

Do not take this medicine after the expiry date printed on the pack or if the packaging is torn or shows signs of tampering. Return it to your pharmacist for disposal.

If you are not sure whether you should start taking this medicine, talk to your doctor.

Before you start to take it

Tell your doctor if:

Before you take pazopanib, tell your doctor if you have any of the following conditions:

- Heart disease
- Heart failure or a heart attack in the past
- Blood clots in the vein or in a lung in the past
- Collapse of a lung in the past
- Problems with your blood pressure
- Liver disease
- 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.
- Problems with bleeding, blood clots or narrowing of the arteries in the past
- Stomach or bowel problems such as perforation (hole) or fistula (abnormal passages or tunnels leading out of the gut) in the past.
- thyroid problems
- a planned surgical or dental procedure, or if you have had either recently.

Check with your doctor if you think any of these may apply to you.

Before you take Pazopanib (Teva), your doctor will take blood samples 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

Tell your doctor if you are taking any other medicines including any that you have bought without a prescription from a pharmacy, supermarket or healthfood shop.

Pazopanib can affect some other medicines, or they can affect pazopanib. Taking both together can make it more likely that you'll have side effects. These medicines include:

- those used to treat infections:
 - Clarithromycin
 - Ketoconazole
 - Itraconazole
 - Rifampicin
 - Telithromycin
 - Voriconazole

- Those used to treat HIV:
 - Atazanavir
 - Indinavir
 - Nelfinavir
 - Ritonavir
 - Saquinavir

- Nefazodone (used to treat depression)
- Simvastatin (used to treat high cholesterol levels)
- Medicines that reduce stomach acid (e.g. esomeprazole)

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

Some are not to be taken with pazopanib. For others, the dose or the time you take the medicine may need to be changed.

Taking pazopanib with food and drink

Pazopanib is affected by food intake.

For details, see How do I take Pazopanib (Teva).

Do not drink grapefruit juice while you are being treated with pazopanib as this may increase the chance of side effects.

Children and adolescents

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

Pregnancy

Pazopanib is not recommended if you are pregnant or breast-feeding.

If you are pregnant or breast-feeding, planning to get pregnant or think you might be pregnant, ask your doctor, pharmacist or healthcare provider for advice before taking pazopanib.

Your doctor will discuss with you the potential risks of taking pazopanib during pregnancy or breast-feeding.

Breast-feeding

Do not breast-feed while taking pazopanib.

Breast-feeding is not recommended during treatment with pazopanib. It is not known whether the ingredients in Pazopanib (Teva) pass into breast milk, and so may harm your baby.

Talk to your doctor about this.

Females of child-bearing potential and male patients

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

If you become pregnant or think you are pregnant, tell your doctor immediately.

Men taking pazopanib

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 pazopanib and for at least 2 weeks after the last dose.

Driving and using machines

Pazopanib can have side effects such as fatigue, weakness and loss of energy that may affect your ability to drive.

Do not drive or use machines unless you are feeling well.

How to take Pazopanib (Teva)

It is important that you always take pazopanib exactly as your doctor 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 pazopanib, 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.

How to take it

It is important that you take pazopanib on an empty stomach, either at least one hour before or at least two hours after food.

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.

Taking the drug with food increases the amount absorbed into the body, which may increase side effects.

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

If you forget to take Pazopanib

Do not take a double dose to make up for a missed dose.

Take the next dose at the scheduled time.

How long to take it for

Take Pazopanib for as long as your doctor recommends.

Do not stop unless your doctor advises you to.

If you take too much (overdose)

Immediately telephone your doctor or Poisons Information Centre (0800 POISON [0800 764 766]), or go to your nearest accident and emergency centre, if you think that you or anyone else may have taken too much Pazopanib (Teva). Do this even if there are no signs of discomfort or poisoning. This may need urgent medical attention.

Take your medications with you. Do this even if there are no signs of discomfort or poisoning.

You may need urgent medical attention.

If you are not sure what to do, contact your doctor or pharmacist.

While you are taking Pazopanib (Teva)

While you are taking pazopanib, 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

Tell your doctor if, for any reason, you have not taken your medicine exactly as directed.

Otherwise, your doctor may think that it was not working as it should and change your treatment unnecessarily.

If you are about to be started on any new medicine, remind your doctor and pharmacist that you are taking pazopanib.

Tell any other doctors, dentists, nurses and pharmacists who treat you that you are taking this medicine.

Things you must not do

Do not give this medicine to anyone else, even if their symptoms seem similar to yours.

Do not use pazopanib to treat any other complaints unless your doctor says to.

Do NOT stop taking your medicine or lower the dosage without checking with your doctor.

Side Effects

Check with your doctor as soon as possible if you think you are experiencing any side effects or allergic reactions due to taking pazopanib, even if the problem is not listed below.

Like all medicines, pazopanib can cause side effects, although not everybody gets them. If they occur, they are most likely to be minor and temporary. However, some may be serious and need medical attention.

Serious side effects

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

LIVER PROBLEMS

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 which occurs easily.

BLOOD PRESSURE PROBLEMS

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.

BRAIN SWELLING

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
- symptoms of high blood pressure.

LUNG INFLAMMATION

Signs of lung inflammation (interstitial lung disease, pneumonitis) which may include:

- cough that will not go away
- shortness of breath.

HEART PROBLEMS

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.

STROKE

Signs of stroke, which may include:

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

BLOOD CLOTS (VEINS)

Signs of blood clots in your veins, especially in your legs (deep vein thrombosis), and which may also go to your lungs (pulmonary embolism). These may include:

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

BLOOD CLOTS (SMALL BLOOD VESSELS)

Signs of 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) which may include:

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

BLEEDING PROBLEMS

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.

GI TEAR OR FISTULA

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.

TUMOUR LYSIS SYNDROME

Signs resulting from a fast breakdown of cancer cells may include:

- irregular heartbeat
- seizures
- confusion
- muscle cramps or spasms
- decrease in urine output.

INFECTIONS

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.

Possible 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 side effects:

These may affect more than 1 in 10 people:

- Lack of energy
- Diarrhoea
- Feeling or being sick (nausea or vomiting)
- Weight loss
- Loss of appetite
- Changes in hair colour
- Decrease in albumin (a protein found in the 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
- Skin rash, possibly involving peeling of the skin
- Cough
- Weakness/Loss of strength
- Swelling of hands, ankles or feet
- Unusual hair loss or thinning
- Loss of skin pigmentation
- Dizziness
- Mouth sores/ inflammation of the lining in the mouth (stomatitis)
- Skin reaction or pain on the palms of the hands or soles of the feet (including tingling, numbness, pain, swelling or reddening)

- Chest pain.

Very common side effect that may show up in your tests:

- High blood pressure
- Increase in some substances (enzymes) produced by the liver
- Slow heart rate.

Common side effects:

These may affect up to 1 in 10 people:

- Difficulty sleeping
- Nose bleed
- Hoarseness
- Indigestion
- 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). If the clot breaks off, it may travel to your lungs and this may be life threatening or even fatal.
- Blurred vision
- Nail disorder
- Severe bleeding (haemorrhage) in digestive tract (stomach and intestine)
- Sudden collapse of a lung(pneumothorax), causing shortness of breath
- Infections, with or without changes in white blood cells (cells that fight infection)

Common side effect that may show up in your tests:

- Under-active thyroid gland
- Protein in urine
- Your heart becomes less effective at pumping blood (cardiac dysfunction)
- Decrease in the number of cells involved in blood clotting (thrombocytopenia)
- Increase in bilirubin (a substance produced by the liver)
- Increase in gamma-glutamyl transpeptidase (a liver enzyme)
- Abnormal liver function
- Low white blood cell count (neutropenia)

- Blood in the urine
- Increase in lipase (an enzyme from the pancreas)
- Changes in the heart's 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 (mini-stroke).

Uncommon side effects

These may affect up to 1 in 100 people:

- Liver failure.

Uncommon side effect that may show up in your tests:

- 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
- Dangerous rapid fluttering of the heart (Torsade de Pointes)
- Abnormal increase in the 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.
- skin wound with no healing tendency (skin ulcer)
- Blood clots accompanied by a 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)

Rare side effects:

Rare side effects have occurred, at an uncommon rate (these may affect up to 1 in 1,000 people) in tests:

- 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
- an enlargement and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysms and artery dissections)

Frequency unknown:

- tumour lysis syndrome (resulting from a fast breakdown of cancer cells).
- liver failure

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

This is not a complete list of all possible side effects. Others may occur in some people and there may be some side effects not yet known.

Tell your doctor if you notice anything else that is making you feel unwell, even if it is not on this list.

Ask your doctor or pharmacist if you don't understand anything in this list.

Do not be alarmed by this list of possible side effects. You may not experience any of them.

Storage conditions

Storage

Keep your Pazopanib (Teva) tablets in the container until it is time to take them.

If you take the tablets out of their pack they may not keep well.

Keep Pazopanib (Teva) in a cool dry place where the temperature stays below 25°C.

Do not store Pazopanib (Teva), or any other medicine, in the bathroom or near a sink.

Do not leave it in the car or on window sills.

Heat and dampness can destroy some medicines.

Keep Pazopanib (Teva) where young children cannot reach it.

A locked cupboard at least one-and-a-half metres above ground is a good place to store medicines.

Disposal

If your doctor tells you to stop taking Pazopanib (Teva) or if the tablets have passed the expiry date, ask your pharmacist what to do with the remaining medicine.

Product Description

What Pazopanib (Teva) tablets look like

Pazopanib (Teva) 200 mg tablets are capsule-shaped, pink, film-coated tablet with "200" debossed on one side.

Pazopanib (Teva) 400 mg tablets are capsule-shaped, white, film-coated tablet with “400” debossed on one side.

Ingredients

Microcrystalline cellulose
Sodium starch glycollate
Povidone
Magnesium stearate
The film coating comprises of:
Hypromellose
Titanium dioxide
Macrogol 400
Iron oxide red (200 mg only)
Polysorbate 80

Who supplies this medicine

Distributed in New Zealand by:
Teva Pharma (New Zealand) Limited
PO Box 128 244
Remuera
Auckland 1541
Telephone: 0800 800 097

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