

Pazopanib Teva 200 mg Film-coated tablets

Each film-coated tablet contains:
Pazopanib (as hydrochloride) 200 mg

Pazopanib Teva 400 mg Film-coated tablets

Each film-coated tablet contains:
Pazopanib (as hydrochloride) 400 mg
For information regarding inactive ingredients and allergens, see in section 2 – “Important information about some of the ingredients of the medicine” and section 6 – “Additional information”.
Read the entire leaflet carefully before using the medicine. This leaflet contains concise information about the medicine. If you have additional questions, refer to the doctor or the pharmacist.
This medicine has been prescribed for you. Do not pass it on to others. It may harm them even if it seems to you that their medical condition is similar to yours.

1. WHAT IS THE MEDICINE INTENDED FOR?
Pazopanib Teva is used in adults for treatment of:

- Kidney cancer that is advanced or has spread to other organs.
- Certain types of advanced soft-tissue sarcoma, which is a type of cancer that affects the supportive tissues of the body. Sarcoma can occur in muscles, blood vessels, fat tissues or other tissues that support, surround and protect the organs.

Therapeutic class:
Protein kinase inhibitor.
Pazopanib Teva works by inhibiting the activity of proteins involved in the growth and spread of cancer cells

2. BEFORE USING THE MEDICINE:
Do not use the medicine if:

- **You are sensitive (allergic)** to pazopanib or to any of the other ingredients the medicine contains (listed in section 6 – “Additional information”). **Check with your doctor** if you think you are sensitive (allergic) to pazopanib or to any of the other ingredients the medicine contains.

Special warnings regarding the use of the medicine
Before treatment with Pazopanib Teva, inform the doctor if:

- You have a **heart disease**.
- You have a **liver disease**.
- You have had **heart failure or a heart attack**.
- You have had a **collapsed lung in the past** (loss of lung volume).
- You have had problems with **bleeding, blood clots or narrowing of the arteries**.
- You have had **stomach or bowel problems** such as perforation (hole) or fistula (abnormal passage forming between parts of the intestine).
- You have **thyroid problems**.
- You have **problems with kidney function**.
- You have or have had an **aneurysm** (distension and weakening of a blood vessel wall) or a tear in a blood vessel wall.

Tell your doctor if any of these apply to you. Your doctor will decide whether Pazopanib Teva is suitable for you. You may need to have **extra tests** to check that your kidneys, heart and liver function properly.

High blood pressure and Pazopanib Teva
Pazopanib Teva can increase your blood pressure. Your blood pressure will be checked before and while taking Pazopanib Teva. If you have high blood pressure, you will be treated with medicines to reduce it.

Tell your doctor if you have high blood pressure.
If you are about to undergo surgery
Your doctor will stop the treatment with Pazopanib Teva at least 7 days before your surgery as it may affect wound healing. Your treatment will be restarted when the wound has adequately healed.
Conditions you need to look out for
Pazopanib Teva may worsen certain conditions or cause serious side effects. You must look out for certain symptoms while you are taking Pazopanib Teva to reduce the risk of any problems. See **section 4**.

Children and adolescents
This medicine is not intended for use in children and adolescents under the age of 18.
Drug interactions
If you are taking, or have recently taken, other medicines including non-prescription medicines and nutritional supplements, tell the doctor or the pharmacist.
Certain medicines may affect the way Pazopanib Teva works or increase the probability that you will have side effects.
Pazopanib Teva may also affect the way certain other medicines work. **Inform the doctor or pharmacist** especially if you are taking:

- Clarithromycin, ketoconazole, itraconazole, rifampin, telithromycin, voriconazole (used for **treatment of infection**).
- Atazanavir, indinavir, nelfinavir, ritonavir, saquinavir (used for **treatment of HIV**).
- Nefazodone (used to treat **depression**).
- Simvastatin and possibly other statins (used for **treatment of high cholesterol levels**).
- Medicines that **reduce stomach acid**. Medicines to reduce stomach acid (for example proton pump inhibitors, H2 histamine receptor antagonists or antacids) may affect the way Pazopanib Teva is taken. Please consult your doctor.

Using the medicine with food and drink
Do not take Pazopanib Teva with food, as food affects the way the medicine is absorbed. Take Pazopanib Teva at least two hours after a meal or one hour before a meal. For example, you can take Pazopanib Teva two hours after breakfast or one hour before lunch.
Do not drink grapefruit juice during treatment with Pazopanib Teva, since grapefruit juice may increase the chance of side effects.

Pregnancy, breastfeeding and fertility
Pazopanib Teva is not recommended if you are pregnant. The effect of Pazopanib Teva during pregnancy is not known.

- **Tell your doctor if you are pregnant** or planning to become pregnant.
- **Use a reliable method of contraception** while you are taking Pazopanib Teva, and for at least two weeks after the last dose.
- **If you become pregnant during treatment** with Pazopanib Teva, refer to your doctor.

Do not breastfeed while taking Pazopanib Teva. It is not known whether the components of Pazopanib Teva pass into breast milk. Talk to your doctor about this.

Male patients (including those who have had a vasectomy) 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 using Pazopanib Teva and for at least two additional weeks after the last dose.

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

Driving and operating machinery
Pazopanib Teva can have side effects that may affect your ability to drive or operate machinery.
Avoid driving or using machinery if you feel dizzy, tired or weak or if your energy levels are low.

Important information about some of the ingredients of the medicine

This medicine contains less than 23 mg of sodium in a tablet, and is therefore considered sodium-free.

3. HOW SHOULD YOU USE THE MEDICINE?
Always use Pazopanib Teva according to the doctor's instructions. Check with the doctor or pharmacist if you are uncertain about the dosage and how to use Pazopanib Teva. The dosage and treatment regimen will be determined only by the doctor.
How much to take
The generally accepted dosage is two tablets of Pazopanib Teva 400 mg (800 mg pazopanib) taken once a day. This is the maximum daily dosage. Your doctor may need to reduce your dosage if side effects occur.

Do not exceed the recommended dose.
When to take
Take Pazopanib Teva at about the same time each day. See also in section 2 – “Using the medicine with food and drink”.
How to take the medicine
The tablets should be swallowed 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 accidentally took a higher dosage, consult the doctor or pharmacist. If you took an overdose or a child accidentally swallowed this medicine, go to the doctor or to a hospital emergency room immediately and take the package of the medicine with you.
If you forgot to take Pazopanib Teva
Do not take a double dose to compensate for a missed dose. Take your next dose at the usual time.
Follow the treatment as recommended by the doctor.
Do not stop treatment with Pazopanib Teva without an instruction from your doctor
Take Pazopanib Teva as long as your doctor recommends. Do not stop unless your doctor advises you to.
Do not take medicines in the dark! Check the label and the dose every time you take a medicine. Wear glasses if you need them. If you have any other questions regarding use of the medicine, consult the doctor or the pharmacist.

4. SIDE EFFECTS
As with any medicine, using Pazopanib Teva may cause side effects in some users. Do not be alarmed when reading the list of side effects. You may not experience any of them.
Possible serious side effects
Swelling of the brain (reversible posterior leukoencephalopathy syndrome)
Pazopanib Teva can, in rare cases, cause swelling of the brain, which may be life-threatening. Symptoms include:

- Loss of the ability to speak
- Change in vision
- Convulsions (fits)
- Confusion
- High blood pressure

Stop taking Pazopanib Teva and seek medical assistance immediately if you develop any of these symptoms, or if you develop a headache accompanied by any of these symptoms.
Hypertensive crisis (sudden and severe increase in blood pressure)
Pazopanib Teva can, in certain cases, cause a sudden and severe increase in blood pressure. The phenomenon is called hypertensive crisis. The doctor will monitor your blood pressure while you are taking the medicine. Signs and symptoms of a hypertensive crisis may include:

- Severe chest pain
- Severe headache
- Blurry vision
- Confusion
- Nausea
- Vomiting
- Severe anxiety
- Shortness of breath
- Convulsions (fits)
- Fainting

Stop taking Pazopanib Teva and seek medical assistance immediately if you develop hypertensive crisis.

Heart conditions
The risks of heart problems may be higher for people with an existing heart problem, or for people who are taking other medicines. You will be checked for any heart problems while you are taking Pazopanib Teva.
Heart function problem/heart failure, heart attack
Pazopanib Teva can affect the efficiency of your heartbeats or can increase the probability of a heart attack.
Signs and symptoms include:

- Irregular or fast heartbeat
- Rapid fluttering of the heart
- Fainting
- Pain or tightness in the chest
- Pain in the arms, back, neck or jaw
- Shortness of breath
- Swelling of the leg

Seek medical assistance immediately if you develop any of these symptoms.
Changes in heart rhythm (QT interval prolongation)
Pazopanib Teva can affect the heart rhythm, which in some people may develop into a serious heart condition known as torsade de pointes. This condition can lead to very fast heartbeats causing a sudden loss of consciousness.
Tell your doctor if you notice any **unusual change in your heart rhythm**, such as heartbeats that are too fast or too slow.

Stroke
Pazopanib Teva can increase your probability of having a stroke. Signs and symptoms of a stroke may include:

- Weakness or numbness in one side of the body
- Difficulty speaking
- Headache
- Dizziness

Seek medical assistance immediately if you develop any of these symptoms.
Bleeding
Pazopanib Teva can cause severe bleeding in the digestive system (for example, in the stomach, esophagus, anus or intestine), in the lungs, kidneys, mouth, vagina or brain, although it is uncommon. Symptoms include:

- Bloody or black stool
- Blood in the urine
- Abdominal pain
- Coughing up or vomiting blood

Seek medical assistance immediately if you develop any of these symptoms.

Hole (perforation) in the digestive system and fistula
Pazopanib Teva can cause a tear (perforation) in the stomach or intestinal wall or the formation of abnormal connections between two parts of the digestive system (fistula). Signs and symptoms may include:

- Severe abdominal pain
- Nausea and/or vomiting
- Fever
- Formation of a hole (perforation) in the stomach, small intestine or large intestine, from which bloody or foul smelling pus is released

Seek medical assistance immediately if you develop any of these symptoms.
Liver problems
Pazopanib Teva can cause liver problems which may develop into serious conditions such as impaired liver function and liver failure, which may cause death. The doctor will check your liver enzymes while you are taking the medicine. Signs that the liver is not functioning properly may include:

- Yellowing of the skin or of the whites of the eyes (jaundice)
- Dark urine
- Tiredness
- Nausea
- Vomiting
- Loss of appetite
- Pain in the right side of the abdomen
- Bruising easily

Seek medical assistance immediately if you develop any of these symptoms.

Blood clots
Deep vein thrombosis (DVT) and pulmonary embolism
Pazopanib Teva may cause blood clots in the veins, especially in the legs (deep vein thrombosis or DVT), which may reach your lungs (pulmonary embolism). Signs and symptoms may include:

- Sharp chest pain
- Shortness of breath
- Rapid breathing
- Leg pain
- Swelling of the arms and hands or legs and feet

Seek medical assistance immediately if you develop any of these symptoms.

Tumor lysis syndrome
Pazopanib Teva may cause fast breakdown of cancer cells, resulting in tumor lysis syndrome, which in some people may cause death. Symptoms may include irregular heartbeat, convulsions (fits), confusion, muscle cramps, spasms or reduced urine output.
Seek medical assistance immediately if you develop any of these symptoms.
Infections
Infections that occur while taking Pazopanib Teva may 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 during urination
- Cuts, scrapes or red, warm, swollen or painful wounds

Seek medical assistance immediately if you develop any of these symptoms.
Pneumonia
Pazopanib Teva can, in rare cases, cause lung inflammation (interstitial lung disease, pneumonitis), which in certain people may cause death. Symptoms include shortness of breath or persistent cough. You will be checked for any lung problems while you are taking Pazopanib Teva.
Seek medical assistance immediately if you develop any of these symptoms.
Thyroid problems
Pazopanib Teva can lower the amount of thyroid hormone produced in your body. This condition can cause weight gain and tiredness. The levels of your thyroid hormones will be checked while you are taking Pazopanib Teva.
Tell your doctor if you notice significant weight gain or tiredness.
Blurry or impaired vision
Pazopanib Teva can cause separation or tear of the inner tissue of the back part of the eye (retinal detachment or tear). This effect can be manifested in blurry or impaired vision.
Tell your doctor if you notice any change in your vision.
Possible side effects (including serious side effects under the relevant frequency)
Very common side effects (effects that occur in **more than 1 user out of ten**):

- High blood pressure
- Diarrhea
- Nausea or vomiting
- Abdominal pain
- Loss of appetite
- Weight loss
- Impairment of taste sensation or loss of sense of taste
- Pain in the mouth
- Headache
- Pain due to a tumor
- Lack of energy, feeling of weakness or tiredness
- Changes in hair color
- Unusual loss or thinning of the hair
- Loss of skin pigment
- Skin rash, possibly in combination with skin peeling
- Redness and swelling of the hands or feet

Refer to your doctor or pharmacist if any of these side effects become troublesome.

Very common side effects that may appear in your blood or urine tests:

- An increase in liver enzyme levels
- A decrease in blood albumin
- Protein in the urine
- A decrease in the number of platelets (cells that help blood clotting)
- A decrease in the number of white blood cells

Common side effects (effects that occur in **1-10 users out of 100**):

- Digestive difficulties, bloating, flatulence
- Nose bleeding
- Dry mouth or mouth ulcers
- Infections
- Unusual drowsiness
- Sleeping difficulties
- Chest pain, shortness of breath, leg pain and swelling of the legs/feet. These effects can be signs of a blood clot in your body (thromboembolism). If the blood clot breaks off, it may travel to your lungs and this may be life-threatening or even cause death.
- The heart becomes less efficient in pumping blood to the body (reduced cardiac function)
- Slow heartbeat
- Bleeding in the mouth, anus or lung
- Dizziness
- Blurry vision
- Hot flashes
- Swelling caused by fluid in the face, hands, ankles, feet or eyelids
- Tingling, weakness or numbness in the hands, arms, legs or feet
- Skin disorders, redness, itch, dry skin
- Nail disorders
- Burning, prickling, itching or tingling sensation in the skin
- Sensation of coldness accompanied by chills
- Increased sweating
- Dehydration
- Muscle, joint, tendon or chest pain, muscle cramps
- Hoarseness
- Shortness of breath
- Cough
- Coughing up blood
- Hiccups
- Collapsed lung (loss of lung volume) with air trapped in the space between the lung and chest, often causing shortness of breath (pneumothorax)

Refer to your doctor or pharmacist if any of these side effects become troublesome.

Common side effects that may appear in your blood or urine tests:

- Underactive thyroid gland
- Abnormal liver function
- An increase in the levels of bilirubin (a substance produced by the liver)
- An increase in the levels of lipase (an enzyme involved in digestion)
- An increase in the levels of creatinine (a substance produced in the muscles)
- Changes in the levels of different chemical substances/other enzymes in the blood. Your doctor will inform you of the results of the blood tests

Uncommon side effects (effects that occur in **1-10 users out of 1,000**):

- Stroke
- Temporary fall in blood supply to the brain (transient ischemic attack)
- Interruption of blood supply to part of the heart or heart attack (myocardial infarction)
- Partial interruption of blood supply to part of the heart (myocardial ischemia)
- Blood clots accompanied by a decrease in red blood cells and cells involved in clotting (thrombotic microangiopathy – TMA). These blood clots may harm organs such as the brain and kidneys
- An increase in the number of red blood cells

Blood clots accompanied by a decrease in red blood cells and cells involved in clotting (thrombotic microangiopathy – TMA)

Pazopanib Teva may cause the formation 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. Signs and symptoms may include:

- Bruising easily
- High blood pressure
- Fever
- Confusion
- Feeling drowsy
- Convulsions (fits)
- Reduced urine output

Seek medical assistance immediately if you develop any of these symptoms.

Tumor lysis syndrome
Pazopanib Teva may cause fast breakdown of cancer cells, resulting in tumor lysis syndrome, which in some people may cause death. Symptoms may include irregular heartbeat, convulsions (fits), confusion, muscle cramps, spasms or reduced urine output.

Seek medical assistance immediately if you develop any of these symptoms.

Infections
Infections that occur while taking Pazopanib Teva may 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 during urination
- Cuts, scrapes or red, warm, swollen or painful wounds

Seek medical assistance immediately if you develop any of these symptoms.

Pneumonia
Pazopanib Teva can, in rare cases, cause lung inflammation (interstitial lung disease, pneumonitis), which in certain people may cause death. Symptoms include shortness of breath or persistent cough. You will be checked for any lung problems while you are taking Pazopanib Teva.

Seek medical assistance immediately if you develop any of these symptoms.

Thyroid problems
Pazopanib Teva can lower the amount of thyroid hormone produced in your body. This condition can cause weight gain and tiredness. The levels of your thyroid hormones will be checked while you are taking Pazopanib Teva.

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

Blurry or impaired vision
Pazopanib Teva can cause separation or tear of the inner tissue of the back part of the eye (retinal detachment or tear). This effect can be manifested in blurry or impaired vision.

Tell your doctor if you notice any change in your vision.

Possible side effects (including serious side effects under the relevant frequency)
Very common side effects (effects that occur in **more than 1 user out of ten**):

- High blood pressure
- Diarrhea
- Nausea or vomiting
- Abdominal pain
- Loss of appetite
- Weight loss
- Impairment of taste sensation or loss of sense of taste
- Pain in the mouth
- Headache
- Pain due to a tumor
- Lack of energy, feeling of weakness or tiredness
- Changes in hair color
- Unusual loss or thinning of the hair
- Loss of skin pigment
- Skin rash, possibly in combination with skin peeling
- Redness and swelling of the hands or feet

Refer to your doctor or pharmacist if any of these side effects become troublesome.

Very common side effects that may appear in your blood or urine tests:

- An increase in liver enzyme levels
- A decrease in blood albumin
- Protein in the urine
- A decrease in the number of platelets (cells that help blood clotting)
- A decrease in the number of white blood cells

Common side effects (effects that occur in **1-10 users out of 100**):

- Digestive difficulties, bloating, flatulence
- Nose bleeding
- Dry mouth or mouth ulcers
- Infections
- Unusual drowsiness
- Sleeping difficulties
- Chest pain, shortness of breath, leg pain and swelling of the legs/feet. These effects can be signs of a blood clot in your body (thromboembolism). If the blood clot breaks off, it may travel to your lungs and this may be life-threatening or even cause death.
- The heart becomes less efficient in pumping blood to the body (reduced cardiac function)
- Slow heartbeat
- Bleeding in the mouth, anus or lung
- Dizziness
- Blurry vision
- Hot flashes
- Swelling caused by fluid in the face, hands, ankles, feet or eyelids
- Tingling, weakness or numbness in the hands, arms, legs or feet
- Skin disorders, redness, itch, dry skin
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- Increased sweating
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Refer to your doctor or pharmacist if any of these side effects become troublesome.

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- Underactive thyroid gland
- Abnormal liver function
- An increase in the levels of bilirubin (a substance produced by the liver)
- An increase in the levels of lipase (an enzyme involved in digestion)
- An increase in the levels of creatinine (a substance produced in the muscles)
- Changes in the levels of different chemical substances/other enzymes in the blood. Your doctor will inform you of the results of the blood tests

Uncommon side effects (effects that occur in **1-10 users out of 1,000**):

- Stroke
- Temporary fall in blood supply to the brain (transient ischemic attack)
- Interruption of blood supply to part of the heart or heart attack (myocardial infarction)
- Partial interruption of blood supply to part of the heart (myocardial ischemia)
- Blood clots accompanied by a decrease in red blood cells and cells involved in clotting (thrombotic microangiopathy – TMA). These blood clots may harm organs such as the brain and kidneys
- An increase in the number of red blood cells

Pazopanib PIL MW1224

- Sudden shortness of breath, especially when accompanied by sharp pain in the chest and/or rapid breathing (pulmonary embolism)
- Severe bleeding in the digestive system (for example, in the stomach, esophagus or intestine), in the kidneys, vagina or brain
- Heart rhythm disturbance (QT interval prolongation)
- Hole (perforation) in the stomach or intestine
- Abnormal passages forming between parts of the intestine (fistula)
- Heavy or irregular menstrual bleeding
- Sudden sharp increase in blood pressure (hypertensive crisis)
- Inflammation of the pancreas (pancreatitis)
- Inflamed, dysfunctional or damaged liver
- Yellowing of the skin or of the whites of the eyes (jaundice)
- Inflammation of the lining of the abdominal cavity (peritonitis)
- Rhinitis
- Rash which may be itchy or inflamed (flat or raised spots or blisters)
- Frequent bowel movements
- Increased sensitivity of the skin to sunlight
- A decrease in sensation or in sensitivity, especially in the skin
- Skin wounds which do not heal (skin ulcers)

Rare side effects (effects that occur in **1-10 users out of 10,000**):

- Inflammation of the lungs (pneumonitis)
- Distension and weakening of a blood vessel wall or a tear in a blood vessel wall (aneurysm and arterial dissection)

Side effects with unknown frequency (effects whose frequency cannot be estimated from the available data):

- Tumor lysis syndrome as a result of fast breakdown of cancer cells
- Liver failure

If a side effect occurs, if one of the side effects worsens, or if you suffer from a side effect not indicated in the leaflet, consult with the doctor.

Reporting side effects
Side effects may be reported to the Ministry of Health by clicking on the link “Report side effects due to medicinal treatment” found on the Ministry of Health website homepage (www.health.gov.il), which will direct you to the online form for reporting side effects, or by clicking on the following link: <https://sideeffects.health.gov.il>

5. HOW TO STORE THE MEDICINE?

- **Avoid poisoning!** This medicine and any other medicine must be kept in a closed place out of the reach and sight of children and/or infants to avoid poisoning. Do not induce vomiting without an explicit instruction from the doctor.
- Do not use the medicine after the expiry date (exp. Date) appearing on the package. The expiry date refers to the last day of that month.
- **Store below 25°C.**

6. ADDITIONAL INFORMATION

In addition to the active ingredient the medicine also contains:

Tablet core:
Pazopanib Teva 200 mg, Pazopanib Teva 400 mg
Microcrystalline cellulose, Sodium starch glycolate (type A), Povidone K-30, Magnesium stearate.

Tablet coating:
Pazopanib Teva 200 mg, Pazopanib Teva 400 mg
Hypromellose (E464), Titanium dioxide (E171), Macrogol 400 (E1521), Polysorbate 80 (E433)
Pazopanib Teva 200 mg
Iron oxide red (E172)

What does the medicine look like and what are the contents of the package?

Pazopanib Teva 200 mg – film-coated capsule-shaped pink tablets, marked with “200” on one side.
Pazopanib Teva 400 mg – film-coated capsule-shaped white tablets, marked with “400” on one side.

Package sizes: 30, 60 or 90 tablets in a tray (blister) package.
Not all package sizes may be marketed

Name and address of the license holder:
Teva Israel Ltd., 124 Dvora HaNevi’a St., Tel Aviv 6944020

Name and address of the manufacturer:
Remedica Ltd, Aharon Street, Limassol Industrial Estate, 3056 Limassol, Cyprus

The leaflet was revised in December 2024 in accordance with the Ministry of Health guidelines.

Registration numbers of the medicines in the National Drug Registry of the Ministry of Health:

Pazopanib Teva 200 mg: 178-30-37216-99
Pazopanib Teva 400 mg: 178-31-37217-99