

1.3 Product Information

1.3.1 SPC, labelling and package leaflet

1.3.1.3 Package Leaflet

Package leaflet: Information for the patient

Pazopanib Accord 200 mg film-coated tablets Pazopanib Accord 400 mg film-coated tablets

pazopanib

Read all of this leaflet carefully before you start taking this medicine because it contains important information for you.

- Keep this leaflet. You may need to read it again.
- If you have any further questions, ask your doctor or pharmacist.
- This medicine has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.
- If you get any side effects, talk to your doctor or pharmacist. This includes any possible side effects not listed in this leaflet. See section 4.

What is in this leaflet

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

1. What Pazopanib Accord is and what it is used for

Pazopanib Accord 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 Accord is used in adults to treat:

- kidney cancer that is advanced or has spread to other organs.
- certain forms of soft-tissue sarcoma, 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.

2. What you need to know before you take Pazopanib Accord

Do not take Pazopanib Accord

- **if you are allergic** to pazopanib or any of the other ingredients of this medicine (listed in section 6).

Check with your doctor if you think this applies to you.

Warnings and precautions

Talk to your doctor before taking Pazopanib Accord:

- if you have **heart disease**.
- if you have **liver disease**.
- if you have had **heart failure or a heart attack**.
- if you have had prior **collapse of a lung**.
- if you have had problems with **bleeding, blood clots or narrowing of the arteries**.
- if you have had **stomach or bowel problems** such as *perforation* (hole) or *fistula* (abnormal passages forming between parts of the intestine).
- if you have **thyroid problems**.
- 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.

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

High blood pressure and Pazopanib Accord

Pazopanib Accord can raise your blood pressure. Your blood pressure will be checked before you take Pazopanib Accord and while you are taking it. 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 going to have an operation

Your doctor will stop Pazopanib Accord at least 7 days before your operation 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 Accord can make some conditions worse or cause serious side effects. You must look out for certain symptoms while you are taking Pazopanib Accord to reduce the risk of any problems. See **section 4**.

Children and adolescents

Pazopanib Accord is not recommended for people aged under 18. It is not yet known how well it works in this age group. Moreover it should not be used in children younger than 2 years of age because of safety concerns.

Other medicines and Pazopanib Accord

Tell your doctor or pharmacist if you are taking, have recently taken, or might take any other medicines. This includes herbal medicines and other medicines you've bought without a prescription.

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

- clarithromycin, ketoconazole, itraconazole, rifamicin, 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**).
- medicines that **reduce stomach acid**. The type of medicine that you are taking to reduce your stomach acid (e.g. proton pump inhibitor, H₂ antagonists or antacids) may affect how Pazopanib Accord is taken. Please consult your doctor or nurse for advice.

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

Pazopanib Accord with food and drink

Don't take Pazopanib Accord 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 Accord as this may increase the chance of side effects.

Pregnancy, breast-feeding and fertility

Pazopanib Accord is not recommended if you are pregnant. The effect of Pazopanib Accord during pregnancy is not known.

- **Tell your doctor if you are pregnant** or planning to get pregnant.
- **Use a reliable method of contraception** while you're taking Pazopanib Accord, and at least for 2 weeks after, to prevent pregnancy.
- **If you do become pregnant during treatment** with Pazopanib Accord, tell your doctor.

Don't breast-feed while taking Pazopanib Accord. It is not known whether the ingredients in Pazopanib Accord pass into breast milk. Talk to your doctor about this.

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 Pazopanib Accord and for at least 2 weeks after the last dose.

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

Driving and using machines

Pazopanib Accord 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.

Pazopanib Accord contains sodium

This medicine contains less than 1 mmol sodium (23 mg) per film-coated tablet, that is to say essentially 'sodium-free'.

3. How to take Pazopanib Accord

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

How much to take

The usual dose is 800 mg taken once a day. The dose can be taken as 2 tablets of 400 mg or as 4 tablets of 200 mg. The dose of 800 mg once a day is the maximum dose per day. Your doctor may need to reduce your dose if you get side effects.

When to take

Don't take Pazopanib Accord 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 Accord 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 Accord 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 Accord

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

Don't stop Pazopanib Accord without advice

Take Pazopanib Accord for as long as your doctor recommends. Don't stop unless your doctor advises you to.

4. Possible side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Possible serious side effects

Swelling of the brain (reversible posterior leukoencephalopathy syndrome)

Pazopanib Accord 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
- high blood pressure

Stop taking Pazopanib Accord and seek medical help immediately 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 Accord 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 Accord. 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

Stop taking Pazopanib Accord and seek medical help immediately if you develop hypertensive crisis.

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 Pazopanib Accord.

Cardiac dysfunction/heart failure, heart attack

Pazopanib Accord 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

Seek medical help immediately if you get any of these symptoms.

Changes in heart rhythm (QT prolongation)

Pazopanib Accord 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 Accord 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

Seek medical help immediately if you get any of these symptoms.

Bleeding

Pazopanib Accord 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

Seek medical help immediately if you get any of these symptoms.

Perforation and fistula

Pazopanib Accord 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

Seek medical help immediately if you get any of these symptoms.

Liver problems

Pazopanib Accord 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 Accord. 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

Seek medical help immediately if you get any of these symptoms.

Blood clots

Deep vein thrombosis (DVT) and pulmonary embolism

Pazopanib Accord 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)

Pazopanib Accord 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)
- decrease in urine output

Seek medical help immediately if you get any of these symptoms.

Tumour lysis syndrome

Pazopanib Accord 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 Pazopanib Accord 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

Seek medical help immediately if you get any of these symptoms.

Lung inflammation

Pazopanib Accord 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 Accord. **Seek medical help immediately** if you get any of these symptoms.

Thyroid problems

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

Blurry or impaired vision

Pazopanib Accord 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.

Possible side effects (including possible serious side effects under the relevant frequency category).

Very common side effects (may affect more than 1 in 10 people):

- high blood pressure
- diarrhoea
- feeling or being sick (nausea or vomiting)
- stomach pain
- loss of appetite
- weight loss
- taste disturbance or loss of taste
- sore mouth
- headache
- tumour pain
- lack of energy, feeling weak or tired
- changes in hair colour
- unusual hair loss or thinning
- loss of skin pigment
- skin rash, possibly involving peeling of the skin

- redness and swelling of the palms of the hands or soles of the feet

Tell your doctor or pharmacist if any of these side effects becomes troublesome.

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

- increase in liver enzymes
- decrease in albumin in the blood
- protein in the urine
- decrease in the number of blood platelets (cells that help blood to clot)
- decrease in the number of white blood cells

Common side effects (may affect **up to 1 in 10** people):

- indigestion, bloating, flatulence
- nose bleed
- dry mouth or mouth ulcers
- infections
- abnormal drowsiness
- difficulty sleeping
- 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 heart beat
- bleeding in the mouth, rectum or lung
- dizziness
- blurred vision
- hot flushes
- swelling caused by fluid of face, hands, ankles, feet or eyelids
- tingling, weakness or numbness of the hands, arms, legs or feet
- skin disorders, redness, itching, dry skin
- nail disorders
- burning, prickling, itching or tingling skin sensation
- sensation of coldness, with shivering
- excessive sweating
- dehydration
- muscle, joint, tendon or chest pain, muscle spasms
- hoarseness
- shortness of breath
- cough
- coughing up blood
- hiccups
- collapsed lung with air trapped in the space between the lung and chest, often causing shortness of breath (pneumothorax)

Tell your doctor or pharmacist if any of these effects become troublesome.

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

- underactive thyroid gland
- abnormal liver function
- increase in bilirubin (a substance produced by the liver)
- increase in lipase (an enzyme involved in digestion)
- increase in creatinine (a substance produced in muscles)
- changes in the levels of other different chemicals / enzymes in the blood. Your doctor will inform you of the results of the blood tests

Uncommon side effects (may affect **up to 1 in 100** people):

- stroke
- temporary fall in blood supply to the brain (transient ischaemic 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 ischaemia)
- blood clots accompanied by a decrease in red blood cells and cells involved in clotting (thrombotic microangiopathy, TMA). These may harm organs such as the brain and kidneys.
- increase in the number of red blood cells
- sudden shortness of breath, especially when accompanied with sharp pain in the chest and /or rapid breathing (pulmonary embolism)
- severe bleeding in the digestive system (such as stomach, oesophagus or intestine), or the kidneys, vagina and brain
- heart rhythm disturbance (QT prolongation)
- hole (perforation) in stomach or intestine
- abnormal passages forming between parts of the intestine (fistula)
- heavy or irregular menstrual periods
- sudden sharp increase in blood pressure (hypertensive crisis)
- inflammation of the pancreas (pancreatitis)
- liver inflamed, not working well or damaged
- yellowing of the skin or whites of the eyes (jaundice)
- inflammation of the lining of the abdominal cavity (peritonitis)
- runny nose
- rashes which may be itchy or inflamed (flat or raised spots or blisters)
- frequent bowel movements
- increased sensitivity of the skin to sunlight
- decreased feeling or sensitivity, especially in the skin
- skin wound which does not heal (skin ulcer)

Rare side effects (may affect **up to 1 in 1,000** people):

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

Not known (frequency cannot be estimated from the available data):

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

Reporting of side effects

If you get any side effects, **talk to your doctor or pharmacist**. This includes any possible side effects not listed in this leaflet. You can also report side effects directly via

HPRA Pharmacovigilance

Website: www.hpra.ie.

By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store Pazopanib Accord

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date (EXP) which is stated on the blister, the bottle and the carton. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help protect the environment.

6. Contents of the pack and other information

What Pazopanib Accord contains

Pazopanib Accord 200 mg film-coated tablets

- The active substance is pazopanib (as hydrochloride).
Each film-coated tablet contains pazopanib hydrochloride equivalent to 200 mg pazopanib.
- The other ingredients are:
Tablet core: cellulose, microcrystalline (E460), sodium starch glycolate (type A), povidone (E1201), magnesium stearate (E470b).
Tablet coating (Opadry 13B540026 Pink): hypromellose (E464), titanium dioxide (E171), macrogol (E1521), iron oxide red (E172), polysorbate 80 (E433). (see section 2 "Pazopanib Accord contains sodium").

Pazopanib Accord 400 mg film-coated tablets

- The active substance is pazopanib (as hydrochloride).
Each film-coated tablet contains pazopanib hydrochloride equivalent to 400 mg pazopanib.
- The other ingredients are:
Tablet core: cellulose, microcrystalline (E460), sodium starch glycolate (type A), povidone (E1201), magnesium stearate (E470b).
Tablet coating (Opadry 13B58802 White): hypromellose (E464), titanium dioxide (E171), macrogol (E1521), polysorbate 80 (E433). (see section 2 "Pazopanib Accord contains sodium").

What Pazopanib Accord looks like and contents of the pack

Pazopanib Accord 200 mg film-coated tablets

Pazopanib Accord 200 mg film-coated tablets are capsule-shaped, pink, film-coated tablet with "200" debossed on one side, with approximate dimensions 14.3 mm × 5.7 mm.

Pazopanib Accord is packed in cartons containing 10, 30, 60 or 90 film-coated tablets in transparent PVC/PE/PVDC//Alu blisters,

Or

Cartons containing 10×1, 30×1, 60×1 or 90×1 film-coated tablets in transparent PVC/ PE/PVDC//Alu perforated unit dose blisters,

Or

White HDPE bottles with a child-resistant PP closure containing 30, 90 film-coated tablets and multipacks containing 90 (3 packs of 30) film-coated tablets in a carton.

Pazopanib Accord

Pazopanib Accord 400 mg film-coated tablets

Pazopanib Accord 400 mg film-coated tablets are capsule-shaped, white, film-coated tablet with "400" debossed on one side, with approximate dimensions 18.0 mm × 7.1 mm.

Pazopanib Accord is packed in cartons containing 10, 30, 60 or 90 film-coated tablets in transparent PVC/PE/PVDC//Alu blisters,

Or

Cartons containing 10×1, 30×1, 60×1, 90×1 film-coated tablets in transparent PVC/ PE/PVDC//Alu perforated unit dose blisters,

Or

White HDPE bottles with a child-resistant PP closure containing 30, 60 film-coated tablets in a carton.

Pazopanib Accord

Not all pack sizes may be marketed.

Marketing Authorisation Holder

Accord Healthcare Ireland Limited,
Euro House, Euro Business Park,
Cork, T45 K857,
Ireland

Manufacturer

Remedica Ltd
Aharnon Street, Limassol Industrial Estate,
Limassol 3056, Cyprus

PharOS MT Ltd.
HF62X, Hal Far Industrial Estate,
Birzebbugia BBG3000, Malta

This medicine is authorised in the Member States of the European Economic Area under the following names:

Member States	Proposed (Invented) Names
Hungary	Pazopanib Accord 200/400 mg filmtabletta
Bulgaria	Pazopanib Accord 200/400 mg филмирани таблетки
Czech republic	Pazopanib Accord
Croatia	Pazopanib Accord 200/400 mg filmom obložene tablete
Poland	Pazopanib Accord
Romania	Pazopanib Accord 200/400 mg comprimate filmate
Slovenia	Pazopanib Accord 200/400 mg filmsko obložene tablete
Slovakia	Pazopanib Accord 200/400 mg filmom obalené tablety
Spain	Pazopanib Accord 200/400 mg comprimidos recubiertos con película
Italy	Pazopanib Accord
Portugal	Pazopanib Accord 200/400 mg comprimidos revestidos por película
Greece	Pazopanib Accord 200/400 mg επικαλυμμένα με λεπτό υμένιο δισκία
France	PAZOPANIB ACCORD 200/400 mg, comprimé pelliculé
Belgium	Pazopanib Accord 200/400 mg Filmtabletten
Denmark	Pazopanib Accord 200/400 mg filmovertrukne tabletter
Estonia	Pazopanib Accord
Finland	Pazopanib Accord 200/400 mg tabletti, kalvopäällysteinen
Lithuania	Pazopanib Accord 200/400 mg plėvele dengtos tabletės
Latvia	Pazopanib Accord 200/400 mg apvalkotās tabletes
Netherlands	Pazopanib Accord 200/400 mg filmomhulde tabletten
Norway	Pazopanib Accord
Sweden	Pazopanib Accord 200/400 mg filmdragerade tabletter
Ireland	Pazopanib Accord 200/400 mg film-coated tablets

This leaflet was last revised in 10/2023.