

Package leaflet: Information for the patient

Pazopanib CF 200 mg, filmomhulde tabletten
Pazopanib CF 400 mg, filmomhulde tabletten

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

1. What <Product name> is and what it is used for

<Product name> 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.

<Product name> 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 <Product name>

Do not take <Product name>

- **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 <Product name>:

- 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 <Product name> is suitable for you. You may need **extra tests** to check that your kidneys, heart and liver are working properly.

High blood pressure and <Product name>

<Product name> can raise your blood pressure. Your blood pressure will be checked before you take <Product name> 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 <Product name> 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

<Product name> can make some conditions worse or cause serious side effects. You must look out for certain symptoms while you are taking <Product name> to reduce the risk of any problems. **See section 4.**

Children and adolescents

<Product name> 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 <Product name>

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 <Product name> works or make it more likely that you'll have side effects. <Product name> 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 <Product name> is taken. Please consult your doctor or nurse for advice.

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

<Product name> with food and drink

Don't take <Product name> 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 <Product name> as this may increase the chance of side effects.

Pregnancy, breast-feeding and fertility

<Product name> **is not recommended if you are pregnant**. The effect of <Product name> 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 <Product name>, and at least for 2 weeks after, to prevent pregnancy.
- **If you do become pregnant during treatment** with <Product name>, tell your doctor.

Don't breast-feed while taking <Product name>. It is not known whether the ingredients in <Product name> 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 <Product name> and for at least 2 weeks after the last dose.

Fertility may be affected by treatment with <Product name>. Talk to your doctor about this.

Driving and using machines

<Product name> 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.

<Product name> 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 <Product name>

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

<Product name> 200 mg film-coated tablets:

The usual dose is four <Product name> 200 mg tablets (800 mg pazopanib) taken once a day. This is the maximum dose per day. Your doctor may need to reduce your dose if you get side effects.

<Product name> 400 mg film-coated tablets:

The usual dose is two <Product name> 400 mg tablets (800 mg pazopanib) taken once a day. This 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 <Product name> 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 <Product name> 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 <Product name> 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 <Product name>

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 <Product name> without advice

Take <Product name> 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)

<Product name> 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 <Product name> 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)

<Product name> 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 <Product name>.

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 <Product name> 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 <Product name>.

Cardiac dysfunction/heart failure, heart attack

<Product name> 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)

<Product name> 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

<Product name> 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

<Product name> 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

<Product name> 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

<Product name> 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 <Product name>. 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

<Product name> 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)

<Product name> 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

<Product name> 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 <Product name> 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

<Product name> 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 <Product name>.

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

Thyroid problems

<Product name> 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 <Product name>.

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

Blurry or impaired vision

<Product name> 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 **the national reporting system listed in Appendix V**. By reporting side effects you can help provide more information on the safety of this medicine.

5. How to store <Product name>

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

Do not use this medicine after the expiry date which is stated on the bottle or blister and the carton after EXP. 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 <Product name> contains

<Product name> 200 mg film-coated tablets:

- The active substance is pazopanib (as hydrochloride).
Each film-coated tablet contains 200 mg pazopanib.
- The other ingredients are:
Tablet core: cellulose, microcrystalline (E460), sodium starch glycolate (type A), povidone K30 (E1201), magnesium stearate (E470b).
Tablet coating: hypromellose (E464), titanium dioxide (E171), macrogol 400 (E1521), iron oxide red (E172), polysorbate 80 (E433).

<Product name> 400 mg film-coated tablets:

- The active substance is pazopanib (as hydrochloride).
Each film-coated tablet contains 400 mg pazopanib.
- The other ingredients are:
Tablet core: cellulose, microcrystalline (E460), sodium starch glycolate (type A), povidone K30 (E1201), magnesium stearate (E470b).
Tablet coating: hypromellose (E464), titanium dioxide (E171), macrogol 400 (E1521), polysorbate 80 (E433).

What <Product name> looks like and contents of the pack

<Product name> 200 mg film-coated tablets:

<Product name> 200 mg film-coated tablets are capsule-shaped, pink, with “200” marked on one side with dimensions 14.3 mm x 5.7 mm approximately.

They are supplied in white bottles (HDPE) with child-resistant cap of 30, 90, multipack of 90 (3 packs of 30) tablets.

They are supplied in clear/transparent Aluminium-PVC/PE/PVDC blisters of 30, 60, multipack of 60 (2 packs of 30), 90, multipack of 90 (3 packs of 30) tablets.

They are supplied in clear/transparent Aluminium-PVC/PE/PVDC perforated unit dose blisters of 30 x 1, 60 x 1, multipack of 60 x 1 (2 packs of 30 x 1), 90 x 1, multipack of 90 x 1 (3 packs of 30 x 1) tablets.

<Product name> 400 mg film-coated tablets:

<Product name> 400 mg film-coated tablets are capsule-shaped, white, with “400” marked on one side with dimensions 18.0 mm x 7.1 mm approximately.

They are supplied in white bottles (HDPE) with child-resistant cap of 30, 60 tablets.

They are supplied in clear/transparent Aluminium-PVC/PE/PVDC blisters of 30, 60, multipack of 60 (2 packs of 30), 90, multipack of 90 (3 packs of 30) tablets.

They are supplied in clear/transparent Aluminium-PVC/PE/PVDC perforated unit dose blisters of 30 x 1, 60 x 1, multipack of 60 x 1 (2 packs of 30 x 1), 90 x 1, multipack of 90 x 1 (3 packs of 30 x 1) tablets.

Not all pack sizes may be marketed.

Marketing Authorisation Holder and Manufacturer

Marketing Authorisation Holder:

Centrafarm B.V.
Van de Reijtstraat 31-E
4814 NE Breda
Nederland

Manufacturer:

Remedica Ltd
Aharnon Street
Limassol Industrial Estate
Limassol 3056
Cyprus

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

STADA Arzneimittel AG
Stadastrasse 2-18,
61118 Bad Vilbel
Duitsland

In het register ingeschreven onder

RVG 127761 Pazopanib CF 200 mg, filmomhulde tabletten
RVG 127762 Pazopanib CF 400 mg, filmomhulde tabletten

This medicinal product is authorised in the Member States of the EEA under the following names:

Hungary:

Pazopanib Stada 200 mg filmtabletta
Pazopanib Stada 400 mg filmtabletta

Belgium

Pazopanib EG 200 mg filmomhulde tabletten
Pazopanib EG 400 mg, filmomhulde tabletten

Germany:

Pazopanib STADA 200 mg filmtabletten
Pazopanib STADA 400 mg filmtabletten

Denmark:

Pazopanib STADA
Pazopanib STADA

Greece:

Pazopanib/Stada 200 mg επικαλυμμένα με λεπτό υμένιο δισκία

Pazopanib/Stada 400 mg επικαλυμμένα με λεπτό υμένιο δισκία

Spain:

Pazopanib STADA 200 mg comprimidos recubiertos con película EFG

Pazopanib STADA 400 mg comprimidos recubiertos con película EFG

Finland:

Pazopanib STADA 200 mg kalvopäällysteiset tabletit

Pazopanib STADA 400 mg kalvopäällysteiset tabletit

France:

PAZOPANIB STADA 200 mg, comprimé pelliculé

PAZOPANIB STADA 400 mg, comprimé pelliculé

Iceland:

Pazopanib STADA 200 mg filmuhúðaðar töflur

Pazopanib STADA 400 mg filmuhúðaðar töflur

Luxembourg:

Pazopanib EG 200 mg comprimé pelliculé

Pazopanib EG 400 mg comprimé pelliculé

The Netherlands:

Pazopanib CF 200 mg, filmomhulde tabletten

Pazopanib CF 400 mg, filmomhulde tabletten

Norway:

Pazopanib STADA

Pazopanib STADA

Poland

Pazopanib STADA

Pazopanib STADA

Portugal:

Pazopanib STADA

Pazopanib STADA

Sweden:

Pazopanib STADA 200 mg filmdragerade tabletter

Pazopanib STADA 400 mg filmdragerade tabletter

Slovakije:

Pazopanib STADA 200 mg

Pazopanib STADA 400 mg

Deze bijsluiter is voor de laatste keer goedgekeurd in februari 2024