NOVARTIS

VOTRIENT

(Pazopanib)

200 and 400 mg film-coated tablets

Patient Information Leaflet

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VOTRIENT ® 200 mg tablets

VOTRIENT ® 400 mg tablets

Pazopanib

Sugar-free

Read all of this leaflet carefully before you start taking VOTRIENT

- **Keep this leaflet. You may need to read it again.**
- **If you have any further questions, please ask your doctor pharmacist, nurse, or other health care providers.**
- **VOTRIENT has been prescribed for you personally and you should not share your medicine with other people. It may harm them, even if their symptoms are the same as yours.**

What is in this leaflet

1. What VOTRIENT is and what it is used for

2. What you need to know before you take VOTRIENT

3. How to take VOTRIENT

4. Possible side effects

5. How to store VOTRIENT

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1. What VOTRIENT is and what it is used for

VOTRIENT is used as a single agent to treat renal cell carcinoma (a form of kidney cancer).

VOTRIENT is used as a single agent to treat certain forms of advanced soft tissue sarcoma (STS), which is a type of cancer that affects the supportive tissues of the body. It can occur in muscles, blood vessels, fat tissue or in other tissues that support, surround, and protect the organs.

2. What you need to know before you take VOTRIENT

Do not take VOTRIENT

If you are allergic (hypersensitive) to pazopanib or to any of the ingredients contained in the product (see What VOTRIENT contains and what it is used for). Check with your doctor if you think this may apply to you.

If you are pregnant or breastfeeding your baby.

Warnings and precautions

Before you take VOTRIENT your doctor needs to know:

- if you have heart disease
- if you have had heart failure or a heart attack
- if you have had prior blood clots in a vein or in a lung
- if you have had prior collapse of a lung

- if you have high blood pressure
- if you have liver disease
- if you have problems with bleeding
- if you have gastrointestinal problems
- if you have thyroid problems
- if you are going to have a 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. You may need extra tests to check that your 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

Other medicines and VOTRIENT

Always tell your health care provider if you are taking any other medicine. (This includes all complementary or traditional medicines.) Some medicines may affect the way VOTRIENT works or VOTRIENT may affect how other medicines work. These include:

- clarithromycin, ketoconazole, itraconazole, telithromycin, voriconazole (used to treat infections)
- atazanavir, indinavir, nelfinavir, ritonavir, saquinavir (used to treat HIV)
- nefazodone (used to treat depression)
- simvastatin (used to treat high cholesterol levels)

- medicines that reduce stomach acid (e.g. esomeprazole)

Tell your doctor if you are taking any of these.

Grapefruit juice should be avoided when taking VOTRIENT, as this may increase concentration of the active ingredient i.e., pazopanib in your blood stream which can cause side effects.

VOTRIENT with food and drink

VOTRIENT is affected by food intake (see How to take VOTRIENT). You should not drink grapefruit juice while you are being treated with VOTRIENT as this may increase the chance of side effects**.**

While you are taking VOTRIENT:

While you are taking VOTRIENT your doctor will take blood samples to check for any liver problems 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.

Pregnancy, breastfeeding and fertility

Use a reliable method of contraception to avoid becoming pregnant while you are taking VOTRIENT.

VOTRIENT should not be taken if you are pregnant. Mothers should not breastfeed their babies while taking VOTRIENT. If you are pregnant or breastfeeding, think you may be pregnant or are planning to have a baby, please consult your doctor, pharmacist, or other healthcare professional for advice before taking this medicine.

Females of child-bearing potential and male patients

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

Male patients (including those who have had vasectomies) with sexual female partners who are pregnant, possibly pregnant, or who could become pregnant should use condoms during sexual intercourse while taking VOTRIENT and for at least 2 weeks after the last dose of drug.

If you become pregnant or think you are pregnant, tell your healthcare provider right away.

Driving and using machines

Do not drive or operate machinery unless you are feeling well.

VOTRIENT may cause side effects such as fatigue or blurred vision, that may impar your ability to handle machines

Patients should ensure that they do not engage in the above activities until they are aware of the measure to which VOTRIENT affects them.

3. How to take VOTRIENT

Always take VOTRIENT 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 VOTRIENT, 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.

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.

It is important that you take VOTRIENT either at least one hour before or at least two hours after food.

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

If you forget to take VOTRIENT:

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

If you take too much VOTRIENT:

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

Do not stop VOTRIENT without advice:

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

4. Possible side effects

VOTRIENT can cause side effects.

Some side effects could be serious

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

- Signs of liver problems (abnormal liver function, liver failure) which may include: yellowing of your skin or the whites of your eyes (jaundice), dark urine, tiredness, nausea and/or vomiting, loss of appetite, pain on the right side of your stomach area (abdomen), bruising easily.
- Signs of sudden and severe rise in blood pressure (hypertensive crisis) which may include: severe chest pain, severe headache, blurred vision, confusion, nausea and/or vomiting, severe anxiety, shortness of breath, seizures, fainting.
- Signs of brain swelling (posterior reversible encephalopathy syndrome, reversible

posterior leukoencephalopathy syndrome) which may include: loss of speech, blindness or changes in vision, seizures, confusion, headache, lack of energy, high blood pressure.

- Signs of lung inflammation (interstitial lung disease, pneumonitis) which may include: cough that will not go away, shortness of breath.
- Signs of heart problems such as abnormal heart rhythm (QT-prolongation, Torsade de Pointes), cardiac dysfunction/heart failure, heart attack which may include: irregular or fast heartbeat, rapid fluttering of your heart, fainting, chest pain or pressure, pain in your arms, back, neck or jaw, shortness of breath, leg swelling.
- Signs of stroke which may include: numbness or weakness on one side of your body, trouble talking, headache, dizziness.
- Signs of blood clots in your veins, especially in your legs (deep vein thrombosis), which may also travel to your lungs (pulmonary embolism) which may include: sharp chest pain, shortness of breath, rapid breathing, leg pain, swelling of your arms/hands or legs/feet.
- Signs of blood clots in the small blood vessels in the kidneys and 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.
- Signs of bleeding problems (haemorrhage) which may include: blood in your stool, black stool, blood in your urine, stomach pain, coughing and/or vomiting up blood.
- Signs of a tear in your stomach or intestinal wall (perforation) or the development of an abnormal connection between two parts of your digestive tract (fistula) which may

include: severe stomach pain, nausea and/or vomiting, fever, bloody or foul-smelling drainage (pus) from an opening in your stomach area (abdomen) or near your anus.

- Signs of tumour lysis syndrome resulting from a fast breakdown of cancer cells which may include: irregular heartbeat, seizures, confusion, muscle cramps or spasms, decrease in urine output.
- Signs of infections (which can become serious) may include: fever, flu-like symptoms such as cough, tiredness and body aches that do not go away, shortness of breath and/or wheezing, pain while urinating, cuts, scrapes or wounds that are red, warm, swollen, or painful.

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

Frequent side effects

- diarrhoea
- feeling or being sick (nausea or vomiting)
- loss of appetite
- stomach pain or discomfort
- high blood pressure
- headache

– loss of strength

– lack of energy

– weakness

– changes in hair colour

– dizziness

– slow heart rate

– cough

– shortness of breath

– chest pain

– swelling of hands, ankles, or feet

– muscle pain

– pain in the bones, muscles, ligaments, joints, and tendons

– mouth sores

– unusual hair loss or thinning

– temporary reduction in blood supply to the brain (mini stroke)

– reduction of blood supply to the heart (angina)

– changes in the heart's electrical conduction (QT-prolongation)

– heart attack

– severe bleeding in the lung

– under-active thyroid gland

– increase in some substances (enzymes) produced by the liver

– indigestion

– flatulence
– nosebleed
– dry skin
– nail disorder
– skin rash
– hoarseness
– blurred vision
– chills
– blood in the urine
– weight loss
– problems with taste
– skin rash
– a skin reaction or pain on the palms of the hands or soles of the feet (including tingling, numbness, pain, swelling or reddening)
– unusual hair loss or thinning
– loss of skin pigment
– sudden collapse of a lung
– heart becomes less effective at pumping blood (cardiac dysfunction)
– inflammation of the lining in the mouth
– muscle spasms
– decrease in albumin (a protein found in the blood)
– severe bleeding in digestive tract (stomach and intestine), lung and brain

– under-active thyroid gland

– protein in urine

– difficulty sleeping

– heart becomes less effective at pumping blood (cardiac dysfunction)

– a decrease in the number of cells involved in blood clotting (thrombocytopenia)

– nosebleed

– hoarseness

– indigestion

– increase in bilirubin (a substance produced by the liver)

– muscle spasms

– dry skin

– flatulence

– chills

–chest pain, shortness of breath, leg pain, and swelling of the legs/feet.
These could be signs of a blood clot in your body (thromboembolism including deep vein thrombosis). If the clot breaks off, it may travel to your lungs (pulmonary embolism) and this may be life threatening or even fatal.

– increase in gamma-glutamyl transpeptidase (a liver enzyme)

– abnormal liver function

– blurred vision

– low white blood cell count (neutropenia)

– nail disorder

– blood in the urine

– increase in lipase (an enzyme from the pancreas)

– sudden collapse of a lung (pneumothorax)

– infections, with or without changes in white blood cells (cells that fight infection)

– 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 (transient ischemic attack)

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

Less frequent side effects

– severe bleeding (*haemorrhage*) in brain

– abnormal connection between parts of the digestive tract (*fistula*)

– stroke

– inflammation of the pancreas (*pancreatitis*)

– hole (*perforation*) in digestive tract

– a dangerous rapid fluttering of the heart (*Torsade de Pointes*)

– abnormal increase in concentration of haemoglobin in the blood

– separation or tear of the lining of the back part of the eye (*retinal detachment or tear*).

This can result in blurry or impaired vision.

– blood clots accompanied by a decrease in red blood cells and cells involved in clotting. These clots may harm organs such as the brain and kidneys (*thrombotic microangiopathy)*.
– liver failure
– a sudden and severe rise in blood pressure which may be life-threatening (*hypertensive crisis*)
– 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
– tumour lysis syndrome resulting from a fast breakdown of cancer cells

Not all side effects reported for VOTRIENT are included in this leaflet. Should your general health worsen or if you experience any untoward effects while taking this medicine, please consult your doctor, pharmacist, or other healthcare professional for advice.
If you notice any side effects not mentioned in this leaflet, please inform your doctor or pharmacist.

Reporting of side effects

You can also report side effects to SAHPRA via the "**6.04 Adverse Drug Reaction Reporting Form**", found online under SAHPRA's publications: https://www.sahpra.org.za/Publications/Index/8. By reporting side effects, you can help provide more information on the safety of VOTRIENT.

5. How to store VOTRIENT

Store all medicines out of reach of children.

Do not use VOTRIENT after the expiry date.

Store at or below 30 °C.

Keep the container tightly closed.

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

6. Contents of the pack and other information

What VOTRIENT contains

The active ingredient is pazopanib hydrochloride. Each film-coated tablet contains either 200 or 400 mg of pazopanib.

The other ingredients are hypromellose, macrogol/PEG 400, magnesium stearate, microcrystalline cellulose, povidone (K30), polysorbate 80, sodium starch glycollate, titanium dioxide (E171), iron oxide red (E172)

What VOTRIENT looks like and contents of the pack

What VOTRIENT looks like:

200 mg: A modified capsule-shaped, pink, film-coated tablet. One side plain and the opposite side debossed with an identifying code, GS JT.

400 mg: A modified capsule-shaped, white, film-coated tablet. One side plain and the opposite side debossed with an identifying code, GS UHL.

Contents of the pack:

200 mg tablet: Opaque, white high-density polyethylene (HDPE) round bottles with polypropylene (PP) child resistant closures and sealed with a polyethylene faced foil induction heat seal liner containing 30 or 90 tablets.

400 mg tablet: Opaque, white high-density polyethylene (HDPE) round bottles with polypropylene (PP) child resistant closures and sealed with a polyethylene faced foil induction heat seal liner containing 30 or 60 tablets.

Holder of Certificate of Registration

Novartis South Africa (Pty) Ltd

Magwa Crescent West

Waterfall City, Jukskei View

Johannesburg

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011 347 6600

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