

# VOTRIENT<sup>®</sup>

200 mg and 400 mg film-coated tablets

Pazopanib

## New Zealand Consumer Medicine Information

### What is in this leaflet?

**Please read this leaflet carefully before you take VOTRIENT.**

This leaflet answers some common questions about VOTRIENT (pazopanib hydrochloride). It does not contain all of the available information.

It does not take the place of talking to your doctor or pharmacist.

**You should ensure that you speak to your pharmacist or doctor to obtain the most up to date information on the medicine.**

**You can also download the most up to date leaflet from [www.medsafe.govt.nz](http://www.medsafe.govt.nz)**

The updates may contain important information about the medicine and its use of which you should be aware.

All medicines have risks and benefits. Your doctor has weighed the expected benefits of you taking VOTRIENT against the risks this medicine could have for you.

**If you have any concerns about taking this medicine, ask your doctor or pharmacist.**

**Keep this leaflet with the medicine.**

You may need to read it again.

### What is VOTRIENT used for

VOTRIENT tablets contain the active substance pazopanib, which

belongs to a anti-cancer group of medicines called protein kinase inhibitors.

VOTRIENT 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.

VOTRIENT works by preventing the activity of proteins that are involved in the growth and spread of cancer cells.

Your doctor may have prescribed VOTRIENT for another reason.

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

VOTRIENT is not addictive.

### Before you take VOTRIENT

#### **When you must not take it**

**You must not take VOTRIENT if you have ever had:**

- A severe allergic (hypersensitive) reaction to VOTRIENT (pazopanib hydrochloride).

**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 VOTRIENT, 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 VOTRIENT, 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 VOTRIENT with other medicines***

**Before you take VOTRIENT, tell your doctor, healthcare provider, or pharmacist if you are taking any other medicines, have taken any recently, or if you start new ones.**

**This includes herbal medicines and other medicines you have bought without a prescription.**

VOTRIENT can affect some other medicines, or they can affect VOTRIENT. 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 VOTRIENT. For others, the dose or the time you take the medicine may need to be changed.

### ***Taking VOTRIENT with food and drink***

VOTRIENT is affected by food intake.

**For details, see How do I take VOTRIENT.**

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

### ***Children and adolescents***

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

### ***Pregnancy***

VOTRIENT 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 VOTRIENT.**

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

### ***Breast-feeding***

**Do not breast-feed while taking VOTRIENT.**

Breast-feeding is not recommended during treatment with VOTRIENT. It is not known whether the ingredients in VOTRIENT 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 VOTRIENT and for at least 2 weeks after you stop treatment with VOTRIENT.**

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

### ***Men taking VOTRIENT***

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

### ***Driving and using machines***

VOTRIENT 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.**

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## **How do I take VOTRIENT?**

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It is important that you always take VOTRIENT 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 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.

### **How to take it**

It is important that you take VOTRIENT 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 VOTRIENT**

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 VOTRIENT for as long as your doctor recommends.

Do not stop unless your doctor advises you to.

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## **If you take more VOTRIENT than you should (Overdose)**

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If you take too much VOTRIENT you may be more likely to get side effects.

Immediately telephone your doctor or National Poisons Centre (call 0800 POISON or 0800 764 766) for advice, or go to the nearest hospital if you think you or anyone else may have taken too much

**VOTRIENT. 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.**

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## **Monitoring during your treatment with VOTRIENT**

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While you are taking VOTRIENT, 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 VOTRIENT.**

**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 VOTRIENT 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.**

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## **What are the side effects?**

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

Like all medicines, VOTRIENT 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 VOTRIENT 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.

**Do not be alarmed by this list of possible side effects.**

You may not experience any of them.

### ***If you get side effects***

**Tell your doctor or pharmacist if any of the side effects listed become severe or troublesome, or if you notice any side effects not listed in this leaflet.**

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## **After using VOTRIENT**

### ***Storage***

**Keep this medicine where children cannot reach it, such as in a locked cupboard.**

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

**Keep your tablets in a cool, dry place, where the temperature stays below 30°C.**

**Do not store VOTRIENT or any other medicines in a car, on a window sill, in a bathroom, or near a sink.**

Heat and dampness can destroy some medicines

**Keep VOTRIENT in the original packaging until it is time to take it.**

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

### ***Disposal***

**Dispose of medicines safely.**

**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.

**Do not keep old medicines because you think you may need them in the future.**

Keeping any unwanted or expired medications runs the risk of unintentional poisonings.

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## **Product description**

### ***What VOTRIENT tablets looks like***

VOTRIENT film coated tablets are modified capsule-shaped, available in plastic bottles that have a child resistant closure.

#### **200 mg**

Pink tablets with 'GS JT' debossed on one side.

Available in packs of 30 tablets.

#### **400 mg**

White tablets with 'GS UHL' debossed on one side.

Available in packs of 30 tablets.

### ***Ingredients***

VOTRIENT tablets contain the active ingredient pazopanib hydrochloride.

Each film-coated tablet contains the equivalent of either 200 mg or 400 mg of pazopanib.

VOTRIENT tablets also contain the following inactive ingredients:

- Microcrystalline cellulose (E460)
- Povidone (E1201)
- Sodium starch glycollate
- Magnesium stearate (E572) (vegetable source)
- Hypromellose (E464)
- Titanium dioxide (E171)
- Macrogol (E1521)
- Polysorbate 80 (E433)
- Iron oxide red (E172) (200 mg tablets only).

This medicine does not contain lactose, sucrose, tartrazine, or azo dyes.

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## **Sponsor**

**VOTRIENT is supplied in New Zealand by:**

**Novartis New Zealand Limited**

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Newmarket  
Auckland 1149  
New Zealand  
Telephone: 0800 354 335

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