VOTRIENT®

Consumer Medicine Information (CMI) summary

The full CMI on the next page has more details. If you are worried about taking this medicine, speak to your doctor or pharmacist.

WARNING: Important safety information is provided in a boxed warning in the full CMI. Read before using this medicine.

1. Why am I taking VOTRIENT?

VOTRIENT contains the active ingredient pazopanib. VOTRIENT is used to treat cancer of the kidney that may have spread to other parts of your body. VOTRIENT may also be used to treat cancer in your surrounding soft tissue including muscles, fat cells or blood vessels. For more information, see Section 1. Why am I taking VOTRIENT? in the full CMI.

2. What should I know before I take VOTRIENT?

Do not take if you have ever had an allergic reaction to pazopanib or any of the ingredients listed at the end of the CMI.

Talk to your doctor if you have any other medical conditions, take any other medicines, or are pregnant or plan to become pregnant or are breastfeeding. For more information, see Section 2. What should I know before I take VOTRIENT? in the full CMI.

3. What if I am taking other medicines?

Some medicines may interfere with VOTRIENT and affect how it works. Food will also affect the way VOTRIENT works so it is important you take it on an empty stomach (see section "How do I take VOTRIENT") and that you not consume grapefruit while taking VOTRIENT. A list of these medicines is in Section 3. What if I am taking other medicines? in the full CMI.

4. How do I take VOTRIENT?

- The usual dose is 800 mg taken once a day in one sitting at generally the same time each day. This may be taken as four (4) 200 mg tablets OR two (2) 400 mg tablets. Your doctor will decide this.
- Swallow tablets whole (do not crush, break, or chew them) with a glass of water either one hour before or at least 2 hours AFTER food. You must take VOTRIENT on an empty stomach.

More instructions can be found in Section 4. How do I take VOTRIENT? in the full CMI.

5. What should I know while taking VOTRIENT?

Things you should do	• Remind any doctor, dentist, surgeon, or pharmacist that you are taking VOTRIENT. • Attend all your appointments and tests so that your progress and overall health can be checked.
Things you should not do	• Do not give this medicine to anyone else. • Do not stop taking this medicine unless your doctor tells you to.
Driving or using machines	• VOTRIENT may make you feel tired, weak, or like you don't have much energy. It may impact your ability to drive, concentrate or use machinery.
Drinking alcohol	• VOTRIENT may make you feel tired, weak, or like you don't have much

	energy. Alcohol may increase this effect.
Looking after your medicine	• Store in a cool, dry, place below 30°C away from moisture, heat, and direct sunlight. • Store in its original packaging until it is time to take it.

For more information, see Section 5. What should I know while taking VOTRIENT? in the full CMI.

6. Are there any side effects?

More common side effects include feeling tired, sick, anxious, dizzy; hair loss, cracked, dry, nails/skin, tummy discomfort, cramps, hair loss, weight loss, headaches, muscle or joint pain, weakness, nosebleeds, diarrhoea, no energy. More serious side effects include signs of: an allergic reaction including wheezing, difficulty breathing, hives or swelling of face, mouth, lips; heart attack or stroke including problems speaking, balancing, sudden tight chest pain or numbness/swelling in arms, legs, hands or feet; signs of liver/tummy distress including yellowing of eyes, severe tummy pain, blood in stool; kidney distress including difficulty going to the toilet; lung problems including persistent cough and signs of fever or flu-like symptoms. You may also have some abnormal test results from your heart, lungs, blood, urine, kidneys, pancreas, and eyes that your doctor may want to investigate. For more information, including what

to do if you have any side effects, see Section 6. Are there any side effects? in the full CMI.

WARNING: Treatment with VOTRIENT can cause life-threatening and fatal liver damage

VOTRIENT (Vot-ree-ent)

Active ingredient(s): *pazopanib* (Paz-OH-pa-nib)

Consumer Medicine Information (CMI)

This leaflet provides important information about taking VOTRIENT. **You should also speak to your doctor or pharmacist if you would like further information or if you have any concerns or questions about using VOTRIENT.**

Where to find information in this leaflet:

1. Why am I taking VOTRIENT?
2. What should I know before I take VOTRIENT?
3. What if I am taking other medicines?
4. How do I take VOTRIENT?
5. What should I know while taking VOTRIENT?
6. Are there any side effects?
7. Product details

1. Why am I taking VOTRIENT?

VOTRIENT contains the active ingredient pazopanib. VOTRIENT is a 'protein kinase inhibitor' meaning it can block unusual activity in the body that is responsible for the growth and spread of cancer.

VOTRIENT is used to treat cancer that has originated in the kidney and may have spread to other parts of the body ('metastatic') where surgery may no longer be an option.

VOTRIENT is also used to treat a type of cancer known as 'advanced soft tissue sarcoma' which is where the cancer is in your supporting tissue and is advanced. This means you may have had this cancer before, and it came back, or it may have started somewhere else in the tissue and spread further in the same tissue. This may be in your muscles, fat cells and blood vessels that are around your organs.

2. What should I know before I take VOTRIENT?

Warnings

Do not take VOTRIENT if:

- you are allergic to pazopanib, or any of the ingredients listed at the end of this leaflet. Always check the ingredients to make sure you can use this medicine.
- the expiry date printed on the packaging has passed.

- the packaging is torn or shows signs of tampering.
- you are under 18 years of age. VOTRIENT is not safe in this group.

Check with your doctor if you:

- have had a heart attack or heart failure before.
- have high blood pressure or other heart disease.
- have had an aneurysm (weakening or bulging of blood vessel wall) or tear in blood vessel wall.
- have had a blood clot in your veins or lungs.
- have a bleeding disorder.
- have a neurological disorder that causes swelling of the brain or seizures.
- have had a collapsed lung before or other lung disease or lung infection at present.
- have a liver condition.
- have had stomach or bowel problems before including a hole or other passage created leading out of your gut (fistula).
- have a thyroid condition.
- are going to have surgery soon including dental procedures.

During treatment, you may be at risk of developing certain side effects. It is important you understand these risks and how to monitor for them. See additional information under Section 6. Are there any side effects?

Risk of liver damage/existing liver conditions

Your doctor will want to know if you have a liver condition and will want to monitor your liver closely before and during treatment (see section below on "Monitoring and altering of treatment plans). Treatment with VOTRIENT can cause life-threatening and fatal liver damage. Your doctor may choose to alter your treatment plan accordingly by starting you on a lower daily dose or may decide to stop your treatment altogether.

Risk of blood vessel damage and bleeding events

Your doctor will want to know if you have had or are at a higher risk of developing damage in your blood vessels.

VOTRIENT, along with other medicines that work the same way may cause or promote an aneurysm or other blood vessel weakening/damage which can be life-threatening or fatal. If you have high blood pressure or have had an aneurism, blood clot, embolism, or other internal bleeding event previously, your doctor may want to carefully consider your treatment plan based on this as you may be at higher risk of it happening again while on treatment.

Monitoring and altering of treatment plans

Your doctor will send you for a blood test to check your blood counts and baseline liver, or thyroid function before taking VOTRIENT. Your doctor may also send you for other tests to check your kidney, heart, pancreas,

or lungs prior to initiating treatment which may involve specialist care.

Your doctor will also want to monitor these along with your blood pressure throughout your treatment with VOTRIENT if you have an existing condition or are not responding to treatment well.

If your blood pressure becomes too high for example, it may put extra pressure on your heart and blood vessels which can be life-threatening or fatal. Your doctor may start you on medication for high blood pressure if this happens and may want to monitor your heart closely by sending you for an "ECG".

Your doctor will also be interested in whether you are healing properly from recent surgery including dental work.

Your doctor may alter your dose or stop your treatment altogether depending on results from your blood/urine tests and any specialist equipment to monitor your heart, lungs, kidney, or pancreas. See section 6 "Are there any side effects".

Wound healing

VOTRIENT belongs to a class of medicines that may impair wound healing. Internal bleeds and sores/wounds on your skin may take longer to heal and stop bleeding. Your doctor will want to know if you have upcoming surgery (including dental procedures) as treatment with VOTRIENT should cease at least 7 days prior to surgery.

Contraception

Use a reliable method of contraception (birth control) to avoid becoming pregnant while you are taking VOTRIENT and for at least two (2) weeks AFTER you stop treatment with it if your doctor has told you to stop taking it.

Male patients (including those who have had vasectomies) with 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.

Pregnancy and breastfeeding

Check with your doctor if you are pregnant, think you may be pregnant, or intend to become pregnant. It is not recommended that you take VOTRIENT if you are pregnant.

Talk to your doctor if you are breastfeeding or intend to breastfeed. You should not take VOTRIENT if you are breast-feeding as it may pass into breast milk and harm your baby.

3. What if I am taking other medicines?

Tell your doctor or pharmacist if you are taking any other medicines, including any medicines, vitamins, or supplements that you buy without a prescription from your pharmacy, supermarket, or health food shop.

Some medicines may interfere with VOTRIENT and affect how it works or how much and when you should take it. VOTRIENT may also affect how other medicines work. These may include:

- common antibiotic or anti-fungal medicines such as clarithromycin, ketoconazole, itraconazole, rifampicin, telithromycin, voriconazole.
- medicines used to treat HIV (human immunodeficiency virus) including atazanavir, indinavir, nelfinavir, ritonavir, saquinavir.
- nefazodone (used to treat depression).
- simvastatin (used to treat high cholesterol).
- esomeprazole (used to reduce stomach acid).
- anti-cancer therapies such as medicines containing lapatinib, pemetrexed, pembrolizumab, bevacizumab and topotecan.
- some heart medications

VOTRIENT may also be affected by grapefruit ingestion. Do not consume grapefruit (including grapefruit juice) while taking VOTRIENT as it may affect how it works.

Check with your doctor or pharmacist if you are not sure about what medicines, vitamins or supplements you are taking and if these affect VOTRIENT.

4. How do I take VOTRIENT?

How much to take

- The usual dose is up to 800 mg of VOTRIENT, taken once a day in one sitting. Your doctor will decide whether this is appropriate for you.
- Your doctor may for example decide for you to take this as two (2) 400 mg VOTRIENT tablets or four (4) 200 mg VOTRIENT tablets to make up this 800 mg dose.
- Depending on how well you respond to your treatment, your doctor may adjust your dose or stop your treatment with VOTRIENT altogether.
- Always follow the instructions provided to you by your doctor and keep taking VOTRIENT until your doctor tells you to stop.

When to take VOTRIENT

- Your dose of VOTRIENT should be taken once a day in the same sitting.
- Take VOTRIENT at the same time each day to help you remember.

How to take VOTRIENT

- You must take VOTRIENT on an empty stomach either at least one hour before or at least two hours after food.

- Swallow the required amount of VOTRIENT tablets whole with a glass of water, one after the other. Do not exceed the amount as directed by your doctor.
- Do not break, crush, or chew the tablets as it may affect how well VOTRIENT works and increase the chances of unwanted side effects.

If you forget to take VOTRIENT

Your VOTRIENT tablets should be taken at the same time each day in one sitting. If you miss your dose, take it as soon as you remember.

If it is almost time for your next dose (less than 12 hours), skip the dose you missed and take your next dose when you are meant to.

Do not take a double dose to make up for the dose you missed.

If you take too much VOTRIENT

If you think that you have taken too much VOTRIENT, you may need urgent medical attention.

You should immediately:

- phone the Poisons Information Centre (**by calling 13 11 26**), or
- contact your doctor, or
- go to the Emergency Department at your nearest hospital.

You should do this even if there are no signs of discomfort or poisoning.

5. What should I know while taking VOTRIENT?

Things you should do

- Attend all your appointments and complete all blood tests and any other body function tests so that your progress can be checked.
- Tell your doctors if you have recently had surgery including any dental work so that they can check you are healing properly.
- Tell your doctor if you have not been taking VOTRIENT regularly or it has been making you feel worse.

Call your doctor straight away if you:

- Are pregnant or think you may be pregnant.

Remind any doctor, dentist, surgeon, or pharmacist you visit that you are taking VOTRIENT.

Things you should not do

- Do not stop taking this medicine unless your doctor tells you to.
- Do not give this medicine to anyone else.
- Do not consume grapefruit or grapefruit juice while taking VOTRIENT.

Driving or using machines

Be careful before you drive or use any machines or tools until you know how VOTRIENT affects you.

VOTRIENT may make you feel tired, weak, or without much energy and so may impair your ability to drive.

Drinking alcohol

Tell your doctor if you drink alcohol.

VOTRIENT may make you feel tired, weak, or without much energy. Alcohol may increase this effect.

Looking after your medicine

- Store below 30°C
- Keep VOTRIENT tablets in its original packaging until it is time to take them.

Store it in a cool dry place away from moisture, heat, or direct sunlight; for example, do not store it:

- in the bathroom or near a sink, or
- in the car or on windowsills.

Keep it where young children cannot reach it such as in a locked cupboard off the ground.

When to discard your medicine

You must keep taking VOTRIENT for as long as your doctor tells you to. Discard VOTRIENT only when all your tablets are gone, or the expiry date printed on the packaging has passed.

Getting rid of any unwanted medicine

If your doctor tells you that you no longer need to take this medicine; it is out of date or looks like it has been damaged or tampered with, take it to any pharmacy for safe disposal.

Do not take this medicine after the expiry date.

6. Are there any side effects?

All medicines can have side effects. If you do experience any side effects, most of them are minor and temporary. However, some side effects may need medical attention.

See the information below and, if you need to, ask your doctor or pharmacist if you have any further questions about side effects.

Less serious side effects

Less serious side effects	What to do
General wellness: • Headaches, feeling dizzy or anxious. • Feeling or being sick, no energy • Problems sleeping • Cough/nosebleed • Weight loss or feeling gassy • Changes to taste • Hair loss, changes to hair colour • Feeling hoarse when trying to speak/dry throat **Skin/soft tissue/nail problems** • Pale skin, or red, dry itchy skin or scaly rash • Tingling, numbness, pain or swelling on hands/soles of feet accompanied by redness. • Cracked or dry nails.	**Speak to your doctor if you have any of these less serious side effects and they worry you.** **If they become worse over time speak to your doctor.**

Less serious side effects	What to do
• Cuts, scrapes, or wounds that are read, swollen and painful. • Mouth sores, redness in mouth **Tummy problems** • Minor tummy discomfort, cramps, or indigestion. • Diarrhoea **Muscle/joint problems** • Pain or weakness, loss of strength, cramps, or sudden movement (spasm).	

Serious side effects

Serious side effects	What to do
Signs of an allergic reaction • Wheezing, difficulty breathing, shortness of breath, swelling of the face, tongue, lips, hives, or nasty, angry, red rash.	**Call your doctor straight away, or go straight to the Emergency Department at your nearest hospital if you notice any of these serious side effects.**

Serious side effects	What to do
Liver problems • Yellowing of skin/eyes, dark wee when going to the toilet. • Feeling tired, sick and vomiting/loss of appetite and pain/bruising in your tummy. **Heart and lung problems** • Chest pain, fast or irregular heartbeat or changes to heart rhythm. Sudden high blood pressure (hypertensive crisis). • Pain in your arms/legs/ jaw. • Feeling of tightness or sudden breathlessness, sudden low heart rate or blood pressure, may also be fainting. • Blood in lung, persistent cough. • Changes to blood supply to heart or lungs (you may have bluish or pale skin or lips).	**These side effects may become life threatening or fatal.**

Serious side effects	What to do
Bleeding/circulation problems • Swelling or sharp pain in arms/legs or hands/feet • Bruising more easily. • Blood in your stool, wee, severe tummy pain and coughing or vomiting up blood. • Signs of stroke or brain swelling including balance loss, vision loss, trouble speaking or communicating, numbness or loss of movement on one side of your body, trouble balancing. **Tummy problems** • Blood in tummy, severe tummy pain or pus in your tummy, coming out of your bum (signs of tear to tummy or intestine). **Signs of infection or kidney problems**	

Serious side effects	What to do
• Fever or flu-like symptoms, body aches, chills and general tiredness that does not improve. • Pain or difficulty/unable to do a wee along with muscle weakness, tiredness, numbness, or twitching.	

Tell your doctor or pharmacist if you notice anything else that may be making you feel unwell.

- Other side effects not listed here may occur in some people.

Other side effects that may only turn up in your blood/urine or other body function tests

It is important that you attend all tests your doctor requests so that your response to treatment and overall well-being can be checked. It is important that you discuss your results with your doctor.

Test results for example may indicate that you have:

- Bleeding in the brain, heart, lungs, or tummy which you may not be immediately aware of.
- Suffered from a blood clot or mini/major stroke, or have a weakening or tear of blood vessel wall (aneurism).

- Internal tummy sores, or gut problems (fistula) or a hole in your digestive tract.
- Vision problems such as a detached retina or eye tear
- Inflammation of the pancreas.
- Problems with your heart including a heart flutter, changes to heart rhythm or heart function in general.
- Changes to liver function (for example, changes to liver enzymes or a substance called 'bilirubin').
- Changes to your thyroid gland which affects hormone production and metabolism (how much energy you have or weight changes for example).
- Changes to your kidney function (more protein than usual or higher/abnormal waste products in your wee) which may indicate kidney damage.
- Changes to blood cells - having less red blood cells than normal may for example explain why you are feeling tired, weak, short of breath or are pale. It may also be causing you to bleed or bruise more easily. Less white blood cells (essential for fighting infection) may explain why you are sick more often or not healing well from cuts/sores.

Your doctor may alter your treatment plan accordingly or stop treatment with VOTRIENT altogether.

Reporting side effects

After you have received medical advice for any side effects you experience, you can report side effects to the Therapeutic Goods Administration online at www.tga.gov.au/reporting-problems. By reporting side

effects, you can help provide more information on the safety of this medicine.

Always make sure you speak to your doctor or pharmacist before you decide to stop taking any of your medicines.

7. Product details

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

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

What VOTRIENT contains

Active ingredient **(main ingredient)**	Pazopanib (as hydrochloride)
Other ingredients **(inactive ingredients)**	• Microcrystalline cellulose (E460) • Povidone (E1201) • Sodium starch glycolate • Magnesium stearate (E572) • Hypromellose (E464) • Titanium dioxide (E171) • Macrogol (E1521) • Polysorbate 80

	• Iron oxide red (E172) (200 mg tablets only).
Potential allergens	

Do not take this medicine if you are allergic to any of these ingredients.

What VOTRIENT looks like

VOTRIENT film-coated tablets are shaped like capsules and are available in plastic bottles with a child resistant closure.

VOTRIENT 200 mg: Pink tablets with 'GS JT' debossed on one side. Available in packs of 30 tablets and 90 tablets (AUST R 161282).

VOTRIENT 400 mg: White tablets with 'GS UHL' debossed on one side. Available in packs of 30 tablets and 60 tablets (AUST R 161281).

Who distributes VOTRIENT

VOTRIENT is supplied in Australia by:

Novartis Pharmaceuticals Australia Pty Limited

ABN 18 004 244 160

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