

VOTRIENT[®]

film-coated tablets

Pazopanib hydrochloride

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.

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 is an anti-cancer drug, of a type called protein kinase inhibitors.

VOTRIENT is used as a single agent to treat kidney cancer that is advanced or has spread to other organs. It 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

Do not take if:

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.
- you have ever had an allergic reaction to any of the ingredients listed toward the end of this leaflet. (See "Ingredients")
- the expiry date (EXP) printed on the pack has passed.
- the packaging is torn or shows signs of tampering.

Tell your doctor if:

Before you take VOTRIENT your doctor needs to know:

- if you have heart disease
- if you had heart failure or a heart attack
- if you have had prior blood clots in the 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 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 or tunnels leading out of the gut).
- if you have thyroid problems
- if you are going to have an operation, or if you have had an operation 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

Tell your doctor 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've 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:

- clarithromycin, ketoconazole, itraconazole, rifampicin,

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)

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

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 the food you eat. 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.

Pregnancy and breast-feeding

VOTRIENT is not recommended if you are pregnant.

If you are pregnant, planning to get pregnant or think you might be pregnant, talk to your doctor about the risks and potential benefits of taking VOTRIENT in pregnancy.

Use a reliable method of contraception to prevent pregnancy while you're taking VOTRIENT.

Don't breast-feed while taking 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.

Driving and using machines

VOTRIENT can have side effects such as fatigue, weakness and loss of energy that may affect your ability to drive.

Don't drive or use machines unless you're feeling well.

How do I take VOTRIENT?

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

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 it 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.

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. Don't stop unless your doctor advises you to.

What do I do if I take too much? (Overdose)

Immediately telephone your doctor or Poisons Information Centre (In Australia call 131126. In New Zealand call 0800 POISON or 0800 764 766) for advice if you think you or anyone else may have taken too much VOTRIENT, even if there are no signs of discomfort or poisoning. If you are not sure what to do, contact your doctor or pharmacist.

While you are taking VOTRIENT

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

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 so.

What are the side effects?

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.

Very common side effects

These may affect more than 1 in 10 people:

- diarrhoea
- feeling or being sick (nausea or vomiting)
- loss of appetite
- stomach pain or discomfort
- high blood pressure
- headache
- loss of strength and energy, weakness
- changes in hair colour

Very common side effect that may show up in your blood tests:

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

Common side effects

These may affect up to 1 in 10 people:

- 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)
- chest pain
- under-active thyroid gland
- abnormal liver function
- indigestion
- nose bleed
- hoarseness
- 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

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

- a decrease in the number of cells involved in blood clotting (thrombocytopenia)
- low white blood cell count (neutropenia)
- protein in urine
- increase in lipase (an enzyme from the pancreas)

Uncommon side effects

These may affect up to 1 in 100 people:

- stroke
- severe bleeding in digestive tract (stomach and intestine), lung and brain
- a dangerous rapid fluttering of the heart (Torsade de Pointes)
- hole (perforation) in digestive tract
- abnormal connection between parts of the digestive tract (fistula)
- heart becomes less effective at pumping blood (cardiac dysfunction)
- heart attack
- a sudden and severe rise in blood pressure which may be life-threatening
- liver failure

Other side effects

Other side effects have occurred, at an uncommon rate:

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

Tell your doctor immediately if you notice any of the following:

- Wheezing, swelling of the lips/mouth, difficulty in breathing, hayfever, lumpy rash (hives) or fainting. These could be a symptom of an allergic reaction.

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.

How do I store VOTRIENT?

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

Do not store above 30°C.

Do not leave in a car, on a window sill or in a bathroom.

Do not use VOTRIENT after the expiry date which is stated on the bottle.

Keep VOTRIENT in its bottle until it's time to take it.

Disposal

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

Product description

What VOTRIENT looks like

The 200 mg tablets of VOTRIENT are modified capsule-shaped, grey or pink, film-coated with 'GS JT' debossed on one side and are available in:

Bottles of 30 tablets and 90 tablets.

The 400 mg tablets are modified capsule-shaped, yellow or white, film-coated with 'GS UHL' debossed on one side and are available in:

Bottles of 30 tablets and 60 tablets.

Ingredients

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

VOTRIENT also contains Microcrystalline Cellulose, Povidone, Sodium Starch Glycolate, Magnesium Stearate, Hypromellose, Titanium Dioxide, Macrogol/PEG400, Polysorbate 80, and Iron Oxide Red E172 (200 mg tablets only).

Sponsor

VOTRIENT is supplied in Australia by:

GlaxoSmithKline Australia Pty Ltd
Level 4, 436 Johnston St,
Abbotsford, Victoria, 3067
Australia.

VOTRIENT is supplied in New Zealand by:

GlaxoSmithKline NZ Limited
Private Bag 106600
Downtown
Auckland 1143
New Zealand

Where to go for further information:

Pharmaceutical companies are not in a position to give people an individual diagnosis or medical advice. Your doctor or pharmacist is the best person to give you advice on the treatment of your condition. You may also be able to find general information about your disease and its treatment from patient information groups and product specific organisations.

This leaflet was prepared on 6 March 2012.

The information provided applies only to: VOTRIENT.

VOTRIENT® is a registered trade mark of the GlaxoSmithKline group of companies.

VOTRIENT®:
200mg -AUST R 161282

VOTRIENT®:
400mg - AUST R 161281

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