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## EPAR summary for the public

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# Votrient

## pazopanib

This document is a summary of the European Public Assessment Report (EPAR) for **Votrient**. It explains how the Committee for Medicinal Products for Human Use (CHMP) assessed the medicine to reach its opinion in favour of granting a marketing authorisation and its recommendations on the conditions of use for **Votrient**.

### What is **Votrient**?

**Votrient** is a medicine that contains the active substance pazopanib. It is available as tablets (200 mg; 400 mg).

### What is **Votrient** used for?

**Votrient** is used to treat adults with the following types of cancer:

- advanced renal cell carcinoma, a type of kidney cancer. It is used in patients who have not received any previous treatment or in patients who have already been treated for their advanced disease with anticancer medicines called 'cytokines'. 'Advanced' means that the cancer has started to spread;
- certain forms of soft-tissue sarcoma, a type of cancer that develops from the soft, supporting tissues of the body. It is used in patients who have been previously treated with chemotherapy (medicines to treat cancer) because their cancer had spread, or in patients whose cancer has progressed within 12 months after receiving adjuvant or neoadjuvant therapy (treatment received after or before their main treatment).

The medicine can only be obtained with a prescription.



## **How is Votrient used?**

Treatment with Votrient should only be started by a doctor who has experience in giving anticancer medicines. The recommended dose is 800 mg once a day, but this may need to be reduced if the patient has side effects. Votrient should be taken with water but without food, at least one hour before or two hours after a meal.

In patients with moderate liver problems the dose should be reduced to 200 mg once a day. Votrient is not recommended in patients with severe liver problems.

## **How does Votrient work?**

The active substance in Votrient, pazopanib, is a protein kinase inhibitor. This means that it blocks some specific enzymes known as protein kinases. These enzymes can be found in some receptors on the surface of cells that are involved in the growth and spread of cancer cells, such as 'VEGFR', 'PDGFR' and 'KIT'. By blocking these enzymes, Votrient can reduce the growth and spread of the cancer.

## **How has Votrient been studied?**

Votrient has been compared with placebo (a dummy treatment) in one main study involving 435 patients with advanced renal cell carcinoma, some of whom had previously been treated with cytokines. Votrient has also been compared with placebo in a main study involving 369 patients with soft-tissue sarcoma whose disease had progressed during or following previous chemotherapy.

In all of the studies, the main measure of effectiveness was progression-free survival (how long the patients lived without their disease getting worse).

## **What benefit has Votrient shown during the studies?**

Votrient was more effective than placebo at treating advanced renal cell carcinoma. On average, the patients who took Votrient lived for 9.2 months without their disease getting worse, compared with 4.2 months for the patients who took placebo.

Votrient was also more effective than placebo at treating soft-tissue sarcoma. On average, the patients who took Votrient lived for 20 weeks without their disease getting worse, compared with seven weeks for the patients who took placebo.

## **What is the risk associated with Votrient?**

The most common side effects with Votrient (seen in more than 1 patient in 10) include reduced appetite, dysgeusia (taste disturbances), hypertension (high blood pressure), diarrhoea, nausea (feeling sick), vomiting, pain, hair colour change, fatigue (tiredness), skin hypopigmentation (discolouration of the skin), exfoliative (flaky) rash, headache, stomatitis (inflammation of the lining of the mouth), decreased weight and increased blood levels of certain liver enzymes. For the full list of all side effects reported with Votrient, see the package leaflet.

Votrient must not be used in people who are hypersensitive (allergic) to pazopanib or any of the other ingredients.

## **Why has Votrient been approved?**

The CHMP considered that Votrient has been shown to be an effective medicine for patients with advanced renal cell carcinoma and soft-tissue sarcoma, with a clinically relevant improvement in progression-free survival. The safety profile of Votrient is considered acceptable and generally manageable. Therefore, the Committee decided that Votrient's benefits are greater than its risks and recommended that it be given marketing authorisation.

Votrient was originally given 'conditional approval' because there was more evidence to come about the medicine, in particular in the treatment of renal cell carcinoma. As the company has supplied the additional information necessary, the authorisation has been switched from conditional to full approval.

## **Other information about Votrient:**

The European Commission granted a conditional marketing authorisation valid throughout the European Union for Votrient on 14 June 2010. This was switched to a full marketing authorisation on 1 July 2013.

The full EPAR for Votrient can be found on the Agency's website: [ema.europa.eu/Find\\_medicine/Human\\_medicines/European\\_public\\_assessment\\_reports](http://ema.europa.eu/Find_medicine/Human_medicines/European_public_assessment_reports). For more information about treatment with Votrient, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 07-2013.