EMA/427397/2017
EMEA/H/C/004131

**EPAR summary for the public**

# Fotivda

tivozanib

This is a summary of the European public assessment report (EPAR) for Fotivda. It explains how the Agency assessed the medicine to recommend its authorisation in the EU and its conditions of use. It is not intended to provide practical advice on how to use Fotivda.

For practical information about using Fotivda, patients should read the package leaflet or contact their doctor or pharmacist.

## What is Fotivda and what is it used for?

Fotivda is a medicine for treating adults with advanced renal cell carcinoma (a kidney cancer).

Fotivda may be used in previously untreated patients or in those whose disease has got worse despite treatment with another medicine working in a different way.

It contains the active substance tivozanib.

## How is Fotivda used?

Fotivda is available as capsules (890 and 1,340 micrograms). The usual dose is one 1,340-microgram capsule once a day for three weeks, followed by a week when the patient does not take any capsules. The patients should continue repeating this 4-week course for as long as the disease does not get worse or until side effects become unacceptable. If the patient has troublesome side effects, the doctor may decide to switch to the lower-strength 890-microgram capsules or interrupt treatment.

Fotivda can only be obtained with a prescription, and treatment should be supervised by a doctor with experience of treating cancers. For further information, see the package leaflet.

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## How does Fotivda work?

The active substance in Fotivda, tivozanib, works by blocking the activity of proteins known as VEGF, which stimulate the formation of new blood vessels. By blocking this protein, tivozanib stops the formation of new blood vessels that the tumour needs, thereby cutting off its blood supply and reducing the growth of the cancer.

## What benefits of Fotivda have been shown in studies?

A main study of 517 patients with advanced renal cell carcinoma that had either come back or spread to other parts of the body has shown that Fotivda can help stop the disease from getting worse. In this study, patients taking Fotivda lived for longer without their disease worsening (12 months) than those given another approved medicine sorafenib (9 months).

## What are the risks associated with Fotivda?

The most important serious side effect with Fotivda is high blood pressure. The most common side effects are high blood pressure (which occurs in almost half of patients) and voice changes, tiredness and diarrhoea (which occur in about a quarter of patients). For the full list of all side effects, see the package leaflet.

Patients must not take St John's wort (a herbal remedy for depression) during treatment with Fotivda. For the full list of restrictions, see the package leaflet.

## Why is Fotivda approved?

A main study showed that Fotivda increased the time it took for the disease to get worse by almost 3 months when compared with another approved medicine sorafenib. The most common side effects with Fotivda are considered manageable, although they may affect the patient's quality of life. On the whole, its side effects are in line with what is expected of a medicine of its class (VEGF inhibitors).

The European Medicines Agency therefore concluded that the benefits of Fotivda outweighed its risk and recommended that it be granted authorisation in the EU.

## What measures are being taken to ensure the safe and effective use of Fotivda?

Recommendations and precautions to be followed by healthcare professionals and patients for the safe and effective use of Fotivda have been included in the summary of product characteristics and the package leaflet.

## Other information about Fotivda

The European Commission granted a marketing authorisation valid throughout the European Union for Fotivda on 24 August 2017.

The full EPAR for Fotivda can be found on the Agency's website: ema.europa.eu/Find medicine/Human medicines/European public assessment reports. For more information about treatment with Fotivda, read the package leaflet (also part of the EPAR) or contact your doctor or pharmacist.

This summary was last updated in 08-2017.