# TIVOZANIB (Fotivda)

## INDICATION (ICD10) C64

*Check the most recent Blueteq eligibility criteria before prescribing. Blueteq registration required (www.england.nhs.uk/publication/national-cancer-drugs-fund-list/)*

**The treatment of advanced renal cell carcinoma where all the following criteria are met:**

2. Confirmed histological diagnosis of renal cell carcinoma with a clear cell component.
Note: papillary, chromophobe and Xp11 translocation sub types can be treated as per clear cell pathway
3. Either metastatic disease or inoperable locally advanced disease
4. Not previously received any vascular endothelial growth factor (VEGF)-targeted systemic therapy or mTOR pathway inhibitor-targeted treatment
5. ECOG performance status of either 0 or 1. A patient with a performance status of 2 is not eligible for tivozanib
6. If the patient has brain metastases, then these have been treated and are stable
7. Tivozanib is to be continued until loss of clinical benefit or unacceptable toxicity or patient choice to stop treatment
8. A formal medical review as to whether treatment with tivozanib should continue or not will be scheduled to occur at least by the end of the first 8 weeks of treatment
9. No treatment breaks of more than 6 weeks beyond the expected cycle length are allowed (to allow any toxicity of current therapy to settle or intercurrent comorbidities to improve)
10. No prior treatment either with pazopanib or sunitinib unless such prior treatment has had to be stopped solely as a consequence of dose-limiting toxicity and in the clear absence of disease progression. Patients treated with tivozanib may switch to pazopanib or sunitinib where treatment has had to be stopped early under the same circumstances.
11. Tivozanib is to be otherwise used as set out in its Summary of Product Characteristics

## REGIMEN

Days 1 to 21 TIVOZAINIB 1340mcg orally once daily

## CYCLE FREQUENCY AND NUMBER OF CYCLES

Every 28 days until disease progression

## ADMINISTRATION

Available as 890mcg and 1340mcg capsules
Swallowed whole with water with or without food

## ANTI-EMETICS

Minimal risk

## CONCURRENT MEDICATION REQUIRED

| | |
|---|---|
| Tivozanib | Moisturiser for hands and feet, to be applied regularly |

## EXTRAVASATION AND TYPE OF LINE / FILTERS

Not applicable

## INVESTIGATIONS

Blood results required before SACT administration
FBC, U&E and LFTs every cycle
Neutrophils x $10^9$/L ≥1.0
Platelets x $10^9$/L ≥75
Baseline weight and every cycle
Blood pressure every cycle
Thyroid function baseline then every 3 cycles

## MAIN TOXICITES AND ADVERSE REACTIONS

| | |
|---|---|
| Tivozanib | Gastrointestinal – serious gastrointestinal complications including gastrointestinal perforation have occurred rarely.<br>Hypertension – treatment induced hypertension, suspend treatment until controlled.<br>Hypothyroidism<br>Mucositis<br>Neutropenia<br>Palmar / plantar syndrome<br>QT prolongation<br>Skin discolouration and depigmentation of the hair and skin |

## INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS
**(not exhaustive list check SPC/BNF/Stockleys)**

| | |
|---|---|
| Tivozanib | Apalatumide, Carbamazepine, enzalutamide, Fosphenytoin, Mitotane, Phenobarbital, Phenytoin, Primidone, Rifampicin, ST John's wort |

## DOSE MODIFICATIONS

Undesirable effects may require temporary interruption and/or dose reduction, the dose was reduced for grade 3 events and interrupted for grade 4 events.
When dose reduction is necessary, the tivozanib dose can be reduced to 890microgram once daily with the normal treatment schedule of 21 days of dosing, followed by a 7-day rest period.

### Hepatic impairment

Tivozanib
Mild hepatic impairment no dose adjustment required.
Moderate hepatic impairment tivozanib dose reduce to 1340microgram capsule on alternate days as may increase risk of adverse reactions due to increased exposure with the full dose.
Mild and moderate hepatic impairment use with caution with close monitoring of tolerability.
Severe hepatic impairment not recommended.

### Renal impairment

Tivozanib
Mild or moderate renal impairment no dose adjustment is required.
Severe renal impairment caution is advised due to limited experience, and in patients undergoing dialysis as there is no experience of tivozanib.

## REFERENCES

1. Motzer, R et al; JCO 2013; 31 (30): 3791-3799