

AXITINIB (Inlyta)

INDICATION (ICD10) C64

1. Treatment of advanced renal cell carcinoma, after first line treatment with a cytokine or a tyrosine kinase inhibitor.

REGIMEN

AXITINIB 5mg orally twice daily

If 5mg twice daily tolerated with no adverse reactions >Grade 2 (i.e. without severe adverse reactions for two consecutive weeks) dose may be increased to 7mg twice daily unless the patient's blood pressure is >150/90mmHg or the patient is receiving antihypertensive treatment. Subsequently, using the same criteria, if 7mg twice daily tolerated the dose may be increased to a maximum of 10mg twice daily.

CYCLE FREQUENCY AND NUMBER OF CYCLES

Daily for 28 days continuously until progression or toxicity

ADMINISTRATION

Available as 1mg, 3mg, 5mg and 7mg tablets

Swallow whole with or without food.

Grapefruit and grapefruit juice should be avoided while on Axitinib.

ANTI-EMETICS

Minimal risk all days

CONCURRENT MEDICATION REQUIRED

Axitinib	Loperamide cycle 1
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EXTRAVASATION AND TYPE OF LINE / FILTERS

Not applicable

INVESTIGATIONS

Blood results required before SACT administration

FBC, U&E and LFTs minimum monthly for first 3 months then alternate months

Neutrophils x $10^9/L$ ≥ 1.0

Platelets x $10^9/L$ ≥ 100

Thyroid function tests baseline, then every 3 months

Blood pressure weekly for cycle 1 then every cycle

MAIN TOXICITIES AND ADVERSE REACTIONS

Axitinib	Diarrhoea Hand-foot syndrome Haemorrhage – increased risk of bleeding Hypertension Hypothyroidism Proteinuria Wound healing delayed
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INTERACTIONS WHICH MAY REQUIRE DOSE MODIFICATIONS

(not exhaustive list check SPC/BNF/Stockleys)

Axitinib	Anticoagulants
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DOSE MODIFICATIONS

When dose reduction is necessary, the axitinib dose may be reduced to 3mg twice daily and further to 2mg twice daily.

Haematological

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Temporarily interrupt axitinib if any bleeding event requires medical intervention.

Non-haematological

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Hypertension	Blood pressure should be well-controlled prior to initiating axitinib. Patients should be monitored for hypertension and treated as needed with standard antihypertensive therapy. In the case of persistent hypertension, despite use of antihypertensive medicinal products, the axitinib dose should be reduced. For patients who develop severe hypertension, temporarily interrupt axitinib and restart at a lower dose once the patient is normotensive. If axitinib is interrupted, patients receiving antihypertensive medicinal products should be monitored for hypotension
Proteinuria	Moderate to severe proteinuria develops ($\geq 2+$ on dipstick, or $> 1\text{g}/24$ hours), reduce dose or temporarily interrupt axitinib. Axitinib should be discontinued if the patient develops nephrotic syndrome.

Hepatic impairment

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Child-Pugh scores are based on ascites, encephalopathy, INR, albumin, total bilirubin

Mild hepatic impairment (Child-Pugh A)	No dose adjustment
Moderate hepatic impairment (Child-Pugh B)	A dose decrease is recommended, the starting dose should be reduced from 5mg bd to 2mg bd
Severe hepatic impairment (Child-Pugh C).	Not recommended

Renal impairment

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No dose adjustment is required in renal impairment.

REFERENCES

1. Rini, B et al; Lancet 2011; 378: 1931-1939