SUNitinib 50mg Therapy – 42 days

INDICATIONS FOR USE:

INDICATION	ICD10	Regimen Code	HSE approved reimbursement status*
Treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance.	C26, C49	00325a	CDS
Treatment of advanced/metastatic renal cell carcinoma (mRCC) in adults.	C64	00325b	CDS

* This applies to post 2012 indications

TREATMENT:

The starting dose of the drugs detailed below may be adjusted downward by the prescribing clinician, using their independent medical judgement, to consider each patients individual clinical circumstances.

The recommended dose of SUNitinib is 50mg taken orally, once daily for 4 weeks followed by a 2 week rest period to comprise a complete cycle of 6 weeks (42 days).

Treatment is administered continuously until disease progression or unacceptable toxicity occurs.

Day	Drug	Dose	Route
1-28	SUNitinib	50mg daily	PO once daily with or without food. Swallow whole with a glass of water.
29-42	REST PERIOD		
If a dose is missed, the patient should not be given an additional dose. The patient should take the usual prescribed dose on the following day. SUNitinib is commonly available in 12.5mg/25mg/37.5 mg and 50mg hard capsules			

ELIGIBILITY:

- Indications as above
- ECOG 0-2

EXCLUSIONS:

- Hypersensitivity to SUNitinib, or any of the excipients
- Uncontrolled hypertension
- Pregnancy
- Breastfeeding

CAUTIONS:

- SUNitinib should be used with caution in patients with a known history of QT interval prolongation, patients who are taking antiarrhythmics or medicinal products that can prolong QT interval, or patients with relevant pre-existing cardiac disease, bradycardia, or electrolyte disturbances

- Concomitant administration of SUNitinib with potent CYP3A4 inhibitors should be limited because of the possible increase in SUNitinib plasma concentrations
- History of cardiac disease. Consider the risk/ benefit of treatment

PRESCRIPTIVE AUTHORITY:

The treatment plan must be initiated by a Consultant Medical Oncologist.

TESTS:

Baseline tests:

- FBC, renal and liver profile
- Cardiac assessment as clinically indicated
- Thyroid Function tests
- Blood pressure
- MUGA scan or echocardiogram if clinically indicated or history of cardiac problems

Regular tests:

- FBC, renal and liver profile prior to each cycle
- Thyroid function tests every 12 weeks
- Assess blood pressure at each attendance or appointment
- MUGA scan or echocardiogram as clinically indicated

Disease monitoring:

Disease monitoring should be in line with the patient's treatment plan and any other test/s as directed by the supervising Consultant.

DOSE MODIFICATIONS:

- Any dose modification should be discussed with a Consultant
- Dose interruptions may be required based on individual safety and tolerability
- For GIST and MRCC, dose modifications in 12.5 mg steps may be applied based on individual safety and tolerability
    - Dose level -1 : 37.5mg
    - Dose level -2 : 25mg
- Daily dose should not be decreased below 25 mg.
- A dose increase to a maximum of 87.5 mg (GIST and RCC) should be considered if SUNitinib must be co-administered with a CYP3A4 inducer. If dose is increased, the patient should be monitored carefully for toxicity
- Co-administration of SUNitinib with potent CYP3A4 inhibitors, should be avoided. If this is not possible, the dose of SUNitinib may need to be reduced to a minimum of 37.5mg daily for GIST and mRCCbased on careful monitoring of tolerability

Haematological:

Table 1: Dose modification of SUNitinib in haematological toxicity

ANC ($x10^9$/L)		Platelets ($x10^9$/L)	Dose
≥ 1	and	≥ 75	100%
<1	or	< 75	Delay

Renal and hepatic impairment:

Table 2: Dose modification of SUNitinib in renal and hepatic impairment

Renal Impairment		Hepatic Impairment	
No dose adjustment is needed		Child-Pugh A/B:	No dose adjustment is needed
Haemodialysis:	No initial dose adjustment is needed, increase dose based on SUNitinib and active metabolite trough concentration levels.	Child-Pugh C:	Consider 75% of the original dose, increase if tolerated
Recommendations as per Giraud et al 2023			

Management of adverse events:

Table 3: Dose Modification of SUNitinib for Adverse Events

Adverse reactions	Recommended dose modification
Grade 1-2 reactions	100%
Grade 3-4 reaction	Delay until Grade 1 Dose reduce by 1 dose level

SUPPORTIVE CARE:

EMETOGENIC POTENTIAL

- As outlined in NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting Available on the NCCP website

SUNitinib: Minimal - Low (**Refer to local policy)**

For information:
Within NCIS regimens, antiemetics have been standardised by the Medical Oncologists and Haemato-oncologists and information is available in the following documents:

- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Medical Oncology) - Available on the NCCP website
- NCCP Supportive Care Antiemetic Medicines for **Inclusion in NCIS** (Haemato-oncology) - Available on the NCCP website

PREMEDICATIONS: None required

OTHER SUPPORTIVE CARE:
Anti-diarrhoeal treatment may be required

ADVERSE EFFECTS:

- Please refer to the relevant Summary of Product Characteristics (SmPC) for details.

REGIMEN SPECIFIC COMPLICATIONS

- **Haemorrhage and tumour bleeding:** Haemorrhagic events, some of which were fatal, reported through post-marketing experience have included gastro-intestinal, respiratory, urinary tract and brain haemorrhages. Patients receiving concomitant treatment with anticoagulants) may be periodically monitored by complete blood counts (platelets), coagulation factors (PT/INR) and physical examination.

DRUG INTERACTIONS:

- Current SmPC and drug interaction databases should be consulted for more information.

REFERENCES:

1. Demetri, GD., van Oosterom, AT, et al. Efficacy and safety of SUNitinib in patients with advanced gastrointestinal stromal tumour after failure of imatinib: a randomised controlled trial. Lancet 2006;. 368(9544): 1329-1338.
2. Choueiri TK et al. Efficacy of SUNitinib and sorafenib in metastatic papillary and chromophobe renal cell carcinoma. J Clin Oncol 2008; 26:127
3. Motzer R, et al: Phase III randomized trial of SUNitinib malate (SU11248) versus interferon-alfa (IFN-a) as first-line systemic therapy for patients with metastatic renal cell carcinoma. NEJM 356;2: 115-124, 2007
4. Giraud E L, Lijster B D, et al. Dose recommendations for anticancer drugs in patients with renal or hepatic impairment: an update. Available at: https://www.thelancet.com/journals/lanonc/article/PIIS1470-2045(23)00216-4/fulltext
5. NCCP Classification Document for Systemic Anti-Cancer Therapy (SACT) Induced Nausea and Vomiting. V6 2025. Available at: https://www.hse.ie/eng/services/list/5/cancer/profinfo/chemoprotocols/nccp-classification-document-for-systemic-anti-cancer-therapy-sact-induced-nausea-and-vomiting.pdf
6. SUNitinib (SUTENT®) Summary of Product Characteristics. Accessed May 2025. Available at: https://www.ema.europa.eu/en/documents/product-information/sutent-epar-product-information_en.pdf

Version	Date	Amendment	Approved By
1			Prof Maccon Keane
2	30/05/2018	Updated with new NCCP regimen template and drug interations	Prof Maccon Keane

3	23/10/2019	Updated adverse effects/regimen specific events regarding aortic aneurysms and dissections as per SmPC update	Prof Maccon Keane
4	13/05/2020	Update of emetogenic potential	Prof Maccon Keane
5	14/07/2025	Regimen reviewed. Title amendment. Updated ICD-10 code. Updated exclusions section. Addition of cautions section. Updated testing section. Updated dose modifications in renal and hepatic impairment table to align with Giraud et al 2023. Regimen updated in line with NCCP standardisation.	Prof Maccon Keane

Comments and feedback welcome at oncologydrugs@cancercontrol.ie.