SUTENT® Capsules (sunitinib malate) - GIST, MRCC, PNET
COMBINED PRESCRIBING INFORMATION GB and NI

Please refer to the Summary of Product Characteristics (SmPC) before prescribing SUTENT 12.5 mg, 25 mg or 50 mg.

Presentation: Hard gelatin capsules containing sunitinib malate equivalent to 12.5 mg, 25 mg and 50 mg sunitinib. Indications: For the treatment of unresectable and/or metastatic malignant gastrointestinal stromal tumour (GIST) in adults after failure of imatinib treatment due to resistance or intolerance; advanced and/or metastatic renal cell carcinoma (MRCC) in adults; unresectable or metastatic, well differentiated pancreatic neuroendocrine tumours (pNET) with disease progression in adults. Dosage: Therapy should be initiated by a physician experienced in the administration of anticancer agents. The recommended dose for GIST and MRCC is 50 mg taken orally, once daily, with or without food, for 4 consecutive weeks, followed by a 2-week rest period, to comprise a complete cycle of 6 weeks (4/2 schedule). For pNET 37.5 mg taken orally once daily without a scheduled rest period. Dose modifications in 12.5 mg steps may be applied based on individual safety and tolerability. Dose interruption may be required based on individual safety and tolerability. Daily dose should not exceed 75 mg nor be decreased below 25 mg for GIST or MRCC, the maximum daily dose administered during the phase 3 pNET study was 50 mg. The safety and efficacy of Sutent in patients below 18 years of age have not been established and no recommendation on a posology can be made. Contra-indications: Hypersensitivity to the active substance or to any of the excipients. Special warnings and precautions for use: Co-administration of potent CYP3A4 inhibitors or inducers should be avoided if possible, or the dose of sunitinib altered, based on careful monitoring of tolerability. Depigmentation of the hair or skin and rash affecting the palms of hands and soles of feet, may occur during treatment. Pyoderma gangrenosum, generally reversible after drug discontinuation, has been reported. Severe cutaneous reactions have been reported, including cases of erythema multiforme (EM) and cases suggestive of Stevens-Johnson syndrome (SJS) and toxic epidermal necrolysis (TEN), some of which were fatal. If signs or symptoms of SJS, TEN, or EM are present, sunitinib should be discontinued. If SJS or TEN is confirmed, treatment must not be restarted. Haemorrhagic events, most common being epistaxis, and some of which were fatal, have been reported. Serious, sometimes fatal gastrointestinal complications have occurred in patients with intra-abdominal malignancies. Patients should be screened for hypertension and this should be controlled as appropriate. Temporary suspension is recommended in patients with severe hypertension that is not controlled with medical management. Decreased absolute neutrophil and platelet counts occurred during clinical trials and complete blood counts should be performed at the beginning of each treatment cycle. Cardiovascular events, including CHF, cardiomyopathy and myocardial ischemia and myocardial infarction, some of which were fatal, have been reported. Use with caution in patients who are at risk for, or have a history of such events. Closely monitor for clinical signs and symptoms of CHF and consider baseline and periodic evaluations of LVEF especially in patients with cardiac risk factors and/or history of coronary artery disease. If clinical manifestations of CHF present, discontinuation of sunitinib is recommended. The administration of sunitinib should be interrupted and/or dose reduced in patients without clinical evidence of CHF but who have a LVEF <50% and >20% below baseline. 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 intervals, or patients with relevant pre-existing cardiac disease, bradycardia, or electrolyte disturbances. Treatment-related venous thromboembolic events (VTE) have been reported. Arterial thromboembolic events (ATE), sometimes fatal, have been reported including cerebrovascular accident, transient ischaemic attack, and cerebral infarction. The use of vascular endothelial growth factor (VEGF) pathway inhibitors in patients with or without hypertension may promote the formation of aneurysms and/or artery dissections. Thrombotic Microangiopathy (TMA), including thrombotic thrombocytopenic purpura (TTP) and haemolytic uraemic syndrome (HUS), sometimes leading to renal failure or a fatal outcome, has been reported with sunitinib as monotherapy and in combination with bevacizumab. Sunitinib therapy should be discontinued in patients who develop TMA and prompt treatment is required. Baseline lab measurements and 3 monthly routine monitoring of thyroid function during treatment are required, including monitoring for signs and symptoms suggestive of thyroid dysfunction and patients treated as per standard medical practice. Cases of thyroiditis and hyperthyroidism, some followed by hypothyroidism have been uncommonly reported. Pancreatitis and serious pancreatic events, some with fatal outcome have been reported. Hepatotoxicity has been observed in patients treated with sunitinib. Monitor liver function tests at baseline during each cycle of treatment, and as clinically indicated. If symptoms of pancreatitis or hepatic failure are present, treatment with sunitinib should be discontinued and the patient provided with appropriate supportive care. Cases of renal impairment, renal failure and/or acute renal failure, in some cases with fatal outcome, have been reported. Baseline urinalysis is recommended. Patients should be monitored for the development or worsening of proteinuria. Sunitinib should be discontinued in patients with nephrotic syndrome. If fistula formation occurs, treatment with sunitinib should be interrupted. Cases of impaired wound healing have been reported during sunitinib therapy and the decision to resume sunitinib therapy following a major surgical intervention should be based upon clinical judgment of recovery from surgery. Osteonecrosis of the jaw (ONJ) has been reported, the majority of cases occurred in patients who had received prior or concomitant treatment with IV bisphosphonates. Caution should therefore be exercised when sunitinib and IV bisphosphonates are used either simultaneously or sequentially. Prior to treatment with sunitinib either along with or subsequent to IV bisphosphonates, a dental examination and appropriate preventative dentistry should be considered. Invasive dental procedures are also an identified risk factor and should be avoided if possible. In case of angioedema due to hypersensitivity, treatment with sunitinib should be interrupted and medical care provided. Seizures with or without radiological evidence of brain metastases have been reported, including a few reports (<1%), some fatal, of seizures with radiological evidence of reversible posterior leukoencephalopathy syndrome (RPLS). Patients with seizures and signs/symptoms consistent with RPLS should be controlled with medical management, including control of hypertension as above and temporary suspension of sunitinib is recommended. Cases of Tumour Lysis Syndrome, some fatal, have been reported. Patients should be monitored closely and treated as indicated clinically and prophylactic hydration should be considered. Serious infections with or without neutropenia, including some with a fatal outcome, have been reported. Uncommon cases of necrotising fasciitis, including of the perineum, sometimes fatal, have been reported. Sunitinib therapy should be discontinued in patients who develop necrotising fasciitis, and appropriate treatment should be promptly initiated. During sunitinib treatment, decreases in blood glucose leading to loss of consciousness have been reported. In case of symptomatic hypoglycemia, sunitinib should be temporarily interrupted. Blood glucose levels in diabetic patients should be checked regularly in order to assess if anti-diabetic drug dosage needs to be adjusted to minimize the risk of hypoglycaemia. Other interactions: None. Fertility, pregnancy and lactation: Women of childbearing potential should be advised to use effective contraception and avoid becoming pregnant while receiving treatment with Sunitinib. Sunitinib should be used during pregnancy only if the potential benefit to the mother justifies the potential risk to the foetus and is not recommended during breast-feeding. Male and female fertility may be compromised during treatment with sunitinib. Driving and operating machinery: Patients should be advised that they may experience dizziness during treatment with sunitinib. Undesirable effects: The most important treatment-related serious adverse reactions associated with sunitinib, some fatal, are renal failure, heart failure, pulmonary embolism, gastrointestinal perforation, haemorrhages (e.g. respiratory tract, gastrointestinal, tumour, urinary tract, and brain haemorrhages) and colitis (colitis and colitis ischaemic). *Very common adverse events* are neutropenia, thrombocytopenia, anaemia, leukopaenia, hypothyroidism, decreased appetite, insomnia, dizziness, headache, taste disturbance, hypertension, dyspnoea, epistaxis, cough, stomatitis, abdominal pain, vomiting, diarrhoea, dyspepsia, nausea, constipation, skin discolouration, palmar-plantar erythrodysaesthesia syndrome, rash, hair colour changes, dry skin, pain in extremity, arthralgia, back pain, mucosal inflammation, fatigue, oedema, pyrexia. *Commonly* reported adverse events are viral infections, respiratory infections, abscess, fungal infections, urinary tract infection, skin infections, sepsis, lymphopaenia, dehydration, hypoglycaemia, depression, neuropathy peripheral, paraesthesia, hypoaesthesia, hyperaesthesia, periorbital oedema, eyelid oedema, lacrimation increased, myocardial ischemia, ejection fraction decreased, deep vein thrombosis, hot flush, flushing, pulmonary embolism, pleural effusion, haemoptysis, dyspnoea exertional, oropharyngeal pain, nasal congestion, nasal dryness, gastro-oesophageal reflux disease, dysphagia, gastrointestinal haemorrhage, oesophagitis, abdominal distension, abdominal discomfort, rectal haemorrhage, gingival bleeding, mouth ulceration, proctalgia, cheilitis, haemorrhoids, glossodynia, oral pain, dry mouth, flatulence, oral discomfort, eructation, skin exfoliation, skin reaction, eczema, blister, erythema, alopecia, acne, pruritus, skin hyperpigmentation, skin lesion, hyperkeratosis, dermatitis, nail disorder, myalgia, musculoskeletal pain, muscle spasms, muscular weakness, renal failure, renal failure acute, chromaturia, proteinuria, chest pain, pain, influenza like illness, chills, weight decreased, white blood cell count decreased, lipase increased, platelet count decreased, haemoglobin decreased, amylase increased, aspartate aminotransferase increased, alanine aminotransferase increased, blood creatinine increased, blood pressure increased, blood uric acid increased. *Refer to SmPC for information on other adverse effects.* Legal Category: POM. Basic NHS cost and Marketing Authorisation (MA) numbers for GB and NI: Pack of 28, 12.5 mg capsules [PLGB 00057/1640 and EU/1/06/347/004] £784.70, Pack of 28, 25 mg capsules [PLGB 00057/1641 and EU/1/06/347/005] £1,569.40, Pack of 28, 50 mg capsules [PLGB 00057/1643 and EU/1/06/347/006] £3,138.80. MA Holder (GB): Pfizer Limited, Ramsgate Road, Sandwich, Kent CT13 9NJ, UK. MA Holder (NI): Pfizer Europe MA EEIG, Boulevard de la Plaine 17, 1050 Bruxelles, Belgium. Further Information is available on request from: Medical Information at Pfizer Limited, Walton Oaks, Dorking Road, Tadworth, Surrey, KT20 7NS, UK. Tel +44 (0) 1304 616161

Adverse events should be reported. Reporting forms and information can be found at www.mhra.gov.uk/yellowcard or search for MHRA Yellow Card in the Google Play or Apple App Store.
Adverse events should also be reported to Pfizer Medical Information on 01304616161

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