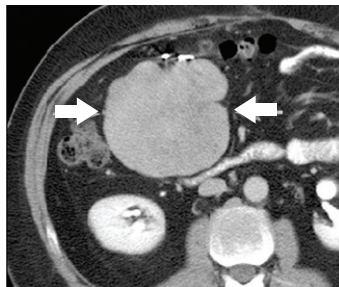


# RECOGNIZE TUMOR RESPONSE TO GLIVEC THERAPY IN THE TREATMENT OF KIT+ GIST

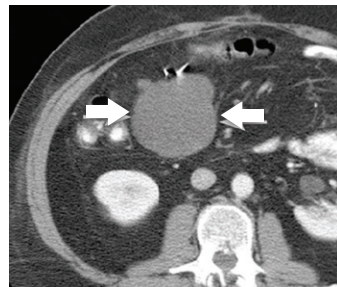


## RADIOLOGIC ASSESSMENT OF KIT+ GIST RESPONSE TO GLIVEC

### RESPONSE: Tumor size decrease<sup>1</sup>



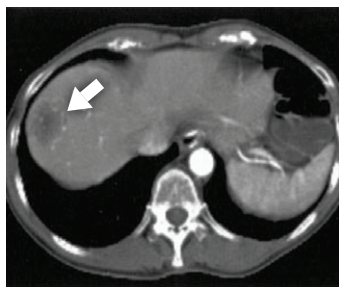
Recurrent GIST (arrows) in small-bowel mesentery



2 months post-treatment shows significant decrease in tumor size

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### STABLE DISEASE: Tumor size remains the same or there is a slight increase in size with a decrease in density<sup>2,3</sup>



Hepatic metastasis (arrow) from GIST



1 month post-treatment shows no significant change in tumor size

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### PROGRESSION: Tumor size increase and/or development of additional masses<sup>2</sup>



Recurrent intratumoral nodule (arrow) in GIST in the duodenum



22 months post-treatment shows increased size of nodule

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- Each pair of images is from a single patient and may not be typical or representative of all patients receiving treatment
- In GIST, stable disease represents a clinical response to treatment<sup>4</sup>

**References:** 1. Choi H, Charnsangavej C, de Castro Faria S, et al. CT evaluation of the response of gastrointestinal stromal tumors after imatinib mesylate treatment: a quantitative analysis correlated with FDG PET findings. *ARJ Am J Roentgenol*. 2004;183(6):1619-1628. 2. Demetri GD, von Mehren M, Antonescu CR, et al. NCCN Task Force report: update on the management of patients with gastrointestinal stromal tumors. *J Natl Compr Canc Netw*. 2010;8(suppl 2):S1-S41. 3. Antoch G, Kanja J, Bauer S, et al. Comparison of PET, CT, and dual-modality PET/CT imaging for monitoring of imatinib (STI571) therapy in patients with gastrointestinal stromal tumors. *J Nucl Med*. 2004;45(3):357-365. 4. Le Cesne A, Van Glabbeke M, Verweij J, et al. Absence of progression as assessed by response evaluation criteria in solid tumors predicts survival in advanced GI stromal tumors treated with imatinib mesylate: the intergroup EORTC-ISG-AGITG phase III trial. *J Clin Oncol*. 2009;27(24):3969-3974.

Please see Important Safety Information on reverse side and the full Summary of Product Characteristics on [www.glivec.com](http://www.glivec.com).

 **glivec**<sup>®</sup>  
imatinib

# IMPORTANT SAFETY INFORMATION



## Indication

GLIVEC® (imatinib) is indicated for the treatment of adult patients with KIT (CD117)-positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST) and for the adjuvant treatment of adult patients who are at significant risk of relapse following resection of KIT (CD117)-positive GIST. Patients who have a low or very low risk of recurrence should not receive adjuvant treatment.

**Contraindications:** Hypersensitivity to imatinib or to any of the excipients.

## Special warnings and precautions

**Precautions/Warnings:** GLIVEC should be taken with food and a large glass of water to minimize the risk of gastrointestinal disturbances. Severe fluid retention has occurred. It is recommended that patients be weighed regularly and undergo regular monitoring of complete blood counts and liver function tests. Patients with hepatic dysfunction should be monitored carefully. Caution should be exercised in patients with history of cardiac disease. Carefully monitor patients with cardiac impairment or risk factors for cardiac failure. Caution should be exercised in patients with severe renal disease. Monitor TSH levels in thyroidectomy patients undergoing levothyroxine replacement. GLIVEC should not be used during pregnancy unless clearly necessary. GLIVEC should not be used by breast-feeding mothers.

**Interactions:** Caution should be exercised with CYP3A4 inhibitors (eg, ketoconazole, itraconazole, erythromycin, clarithromycin), which may increase plasma concentrations of imatinib. Caution should be exercised with CYP3A4 inducers (eg, dexamethasone, rifampicin, phenytoin, carbamazepine, phenobarbital, St. John's Wort), which may decrease plasma concentrations of imatinib. Caution should be exercised with substrates of CYP3A4 (eg, triazolo-benzodiazepines, dihydropyridine calcium channel blockers, simvastatin, cyclosporin, pimozone), CYP2C9 (eg, warfarin) or CYP2D6 (eg, metoprolol). Caution should be exercised with concomitant use of paracetamol/acetaminophen.

### Adverse reactions:

**Very common (>1/10):** Neutropenia, thrombocytopenia, anemia, headache, nausea, diarrhea, vomiting, dyspepsia, abdominal pain, periorbital edema, dermatitis, eczema, rash, muscle spasm and cramps, musculoskeletal pain including myalgia, arthralgia, bone pain, fluid retention and edema, fatigue, weight increase.

**Common (>1/100, ≤1/10):** Pancytopenia, febrile neutropenia, anorexia, insomnia, dizziness, paresthesia, taste disturbance, hypoesthesia, eyelid edema, lacrimation increase, conjunctival hemorrhage, conjunctivitis, dry eye, blurred vision, flushing, hemorrhage, dyspnea, epistaxis, cough, flatulence, abdominal distension, gastroesophageal reflux, constipation, dry mouth, gastritis, increased hepatic enzymes, GI bleeding, pruritus, facial edema, dry skin, erythema, alopecia, night sweats, photosensitivity reaction, joint swelling, weakness, pyrexia, anasarca, chills, rigors, weight decrease.

**Rare (≥1/10,000 to <1/1,000):** Fungal infection, haemolytic anemia, hyperkalaemia, hypomagnesaemia, confusional state, increased intracranial pressure, convulsions, optic neuritis, cataract, glaucoma, papilloedema, arrhythmia, atrial fibrillation, cardiac arrest, myocardial infarction, angina pectoris, pericardial effusion, pleuritic pain, pulmonary fibrosis, pulmonary hypertension, pulmonary haemorrhage, colitis, ileus, inflammatory bowel disease, hepatic failure, hepatic necrosis, acute febrile neutrophilic dermatosis (Sweet's syndrome), nail discolouration, angioneurotic oedema, rash vesicular, erythema multiforme, leucocytoclastic vasculitis, Stevens-Johnson syndrome, acute generalised exanthematous pustulosis (AGEP), muscular weakness, arthritis, rhabdomyolysis/myopathy, haemorrhagic corpus luteum/haemorrhagic ovarian cyst, blood amylase increase.

**Note:** Before prescribing, please read full Summary of Product Characteristics.