# Sunitiban®

## Sunitinib (as malate)

Sobhan Oncology

**Capsule (12.5mg&25mg&50mg)**

**Read all of this leaflet carefully before you start taking this medicine.**

- Keep this leaflet. You may need to read it again.
- If you have further question, ask your doctor or your pharmacist.
- This medicine has been prescribed for you. Do not pass it on to others. It may harm them, even if their symptoms are the same as yours.

**In this leaflet:**



**1- What Sunitiban® is and what it is used for**

Sunitinib, the active ingredient of Sunitiban® exhibits antitumor and antiangiogenic properties by inhibiting multiple receptor tyrosine kinase; including platelet-derived growth factor (PDGFR-alpha and PDGFR-beta) , vascular endothelial growth factors (VEGFR1, VEGFR2,and VEGFR3), FMS-like tyrosine kinase-3 (FLT3) ,colony-antimulating factor type 1 receptor (CSF-IR) ,and glial cell-line derived neurotrophic factor receptor (RET). Sunitiban® is used to treat:

***Gastrointestinal stromal tumor:***

treatment of gastrointestinal stromal tumor (GIST) after disease progression on or intolerance to imatinib.

***Pancreatic neuroendocrine tumors,advanced :***

treatment of progressive,well-differentiated pancreatic neuroendocrine tumors in patients with unresectable locally advanced or metastatic disease.

***Renal cell carcinoma,advanced:***

treatment of advanced renal cell carcinoma.

**2- Before you take Sunitiban®**

***Do not take Sunitiban®:***

If you are allergic (hypersensitive) to the active ingredient and any other ingredient in Sunitiban® product.

If you are pregnant or think that you might be pregnant.

If you are breast feeding.

**Take special care with Sunitiban®:**

***Hepatotoxicity:***

Hepatotoxicity, which may be severe and/or result in fatal liver failure, has been observed in clinical trials and in post marketing surveillance. Signs of liver failure include jaundice, elevated transaminases, and/or hyperbilirubinemia, in conjunction with encephalopathy, coagulopathy, and/or renal failure. Monitor liver function tests at baseline, with each treatment cycle and if clinically indicated. Do not reinitiate in patients with severe changes in liver function tests or other signs/symptoms of liver failure. Sunitinib has not been studied in patients with ALT or AST greater than 2.5 times upper limit of normal (ULN)(or greater than 5 times ULN if due to liver metastases)

***Left ventricular dysfunction/ heart failure:***

May cause a decrease in left ventricular ejection fraction (LVEF).

***QT interval prolongation:***

QT prolongation and torsades de pointes have been observed (dose dependent); use caution in patients with a history of QT prolongation or patients with preexisting cardiac disease, bradycardia or electrolyte imbalance.

***Hypertension:***

May cause hypertension; monitor and control with anti-hypertension if needed.

***Bleeding:***

Hemorrhage events have been reported including rectal, gingival, upper GI, wound bleeding, urinary tract, genital, brain, tumor-related, and hemoptysis/pulmonary hemorrhage.

***Osteonecrosis of the jaw:***

Osteonecrosis of the jaw (ONJ) has been observed with sunitinib. Concurrent bisphosphonate use or dental disease may increase the risk for ONJ.

***Tumor lysis syndrome:***

Tumor lysis syndrome, including fatalities, has been reported, predominantly in patients with renal cell cancer or GIST.

***GI complications:***

Serious and fatal GI complications, including GI perforation, have occurred. Pancreatitis has been observed in renal cell cancer patients; discontinue Sunitiban® if symptoms are present.

***Thyroid disorders:***

Thyroid dysfunction may occurred; the risk for hypothyroidism appears to increase with therapy duration. Hyperthyroidism, sometimes followed by hypothyroidism, has also been reported.

***Hypoglycemia:***

Symptomatic hypoglycemia has been associated with Sunitiban®, may result in loss of consciousness or require hospitalization.

Wound healing complications:

Impaired wound healing has been reported with Sunitiban®.

***Dermatologic toxicity:***

Severe cutaneous reaction, including erythema multiforme, Sevens-Johnson syndrome, and TEN have been reported during treatment with Sunitiban®, if these symptoms are present, discontinue Sunitiban®.

***Renal function impairment:***

An increased incidence of fatigue, thyroid dysfunction and treatment-induced hypertension was reported in patients with renal insufficiency.

***Pregnancy:***

Advise women of childbearing potential to avoid pregnancy if receiving Sunitiban® (Category D).

***Lactation:***

It is known if Sunitiban® is excreted in human milk. Due to the potential for serious adverse reactions in the breast-feeding infant, the decision to discontinue breast-feeding or Sunitiban® should take into account the benefits of treatment to the mother.

**Drug interactions:**

***Afatinib***: P-glycoprotein/ABCB1 inhibitors (such as Sunitiban®) may increase the serum concentration of Afatinib.

***Antifungal agents***: May decrease the metabolism of Sunitiban®.

***Aprepitant***: May increase the serum concentration of Sunitiban®.

***BCG***: Sunitiban® may diminish the therapeutic effect of BCG. Avoid combination.

***Bevacizumab***: Sunitiban® may enhance the adverse/toxic effect of Bevacizumab.

***Bosentan***: May decrease the serum concentration of Sunitiban®.

***Bosutinib***: Sunitiban® may increase the serum concentration of Bosutinib.

***Colchicine***: Sunitiban® may increase the serum concentration of Colchicine.

***CYP3A4 inducers***: May decrease the serum concentration of Sunitiban®.

***CYP3A4 inhibitors***: May decrease the metabolism of Sunitiban®.

***Dabigatran Etexilate***: Sunitiban® may increase serum concentrations of active metabolite(s) of Dabigatran Etexilate.

***Dabrafenib***: May decrease the serum concentration of Sunitiban®.

***Dasatinib***: May increase the serum concentration of Sunitiban®.

***Deferasirox***: May decrease the serum concentration of Sunitiban®.

***Denosumab***: May enhance the adverse/toxic effect of Sunitiban®.

***Dexamethasone***: May decrease the serum concentration of Sunitiban®.

***Doxorubicin***: Sunitiban® may increase the serum concentration of Doxorubicin.

***Edoxaban***: Sunitiban® may increase the serum concentration of Edoxaban.

***Everolimus***: Sunitiban® may increase the serum concentration of Everolimus.

***Fosaprepitant***: May increase the serum concentration of Sunitiban®.

***Ivabradine***: May enhance the QTc-prolonging effect of Sunitiban®.

***Ledipasvir***: Sunitiban® may increase the serum concentration of Ledispavir.

***Leflunomide***: Sunitiban® may enhance the adverse/toxic effect of ***Leflunomide***.

***Mifepristone***: May enhance the QTc-prolonging effect of Sunitiban®.

***Mitotane***:May decrease the serum concentration of concentration of Sunitiban®.

***Natalizumab***: Sunitiban® may enhance the adverse/toxic effect of Natalizumab.

***Pazopanib***: Sunitiban® may increase the serum concentration of Pazopanib.

***Pimecrolimus***: May enhance the adverse/toxic effect of Sunitiban®.

***Rivaroxaban***: Sunitiban® may increase the serum concentration of Rivaroxaban.

***Tacrolimus***: May enhance the adverse/toxic effect of Sunitiban®.

***Topotecan***: Sunitiban® may increase the serum concentration of Topotecan. Vaccines (inactivated): Sunitiban® may diminish the therapeutic effect of vaccines.

***Vaccines (live)***: Sunitiban® may enhance the adverse/toxic effect of vaccines.

***Vincristine (liposomal)***: Sunitiban® may increase the serum concentration of Vincristine (liposomal).

***Grapefruit***: may increase the levels/effects of Sunitiban®.

**3- How to take Sunitiban®**

Patient receiving Sunitiban® should be under the supervision of a physician experienced in cancer chemotherapy. Your doctor will decide about the dose, which will depend upon your height and body weight.

**Usual adult dose:**

***Gastrointestinal stromal tumor and advanced renal cell carcinoma:***

50 mg once daily on a schedule of 4 weeks on treatment followed by 2 weeks off.

***Pancreatic neuroendocrine tumor:***

37.5 mg once daily continuously without a schedule off-treatment period.

**4- Possible side effects**

Every medicine has some side effects or risks associated with its use. Although most people take medicines without experiencing any side effects, some may be affected. In these cases, please consult your physician or pharmacist. Many side effects of antineoplastic therapy are unavoidable and represent the medication's pharmacologic action. Some of these are actually used as parameters to aid in individual dosage titration. The following side/adverse effects have been selected on the basis of their occurrence probability:

***Common side effects:***

Cardiac failure; Chest pain; Decreased left ventricular ejection fraction; Hypertension; Peripheral edema; Chills; Depression; Dizziness; fatigue; Glossalgia; Headache; Insomnia; Mouth pain; Alopecia; Erythema; Hair discoloration; Palmar-plantar erythrodysesthesia; Pruritus; Skin discoloration; Skin rash; Xeroderma; Hypercalcemia; Hyperglycemia; Hyperkalemia; Hypernatremia; Hyperuricemia; Hypoalbuminemia; Hypocalcemia; Hypoglycemia; Hypokalemia; Hypomagnesemia; Hyponatremia; Hypophosphatemia; Hypothyroidism; Weight loss; Abdominal pain; Anorexia; Constipation; diarrhea; Dysgeusia; Dyspepsia; Flatulence; GERD; Hemorrhoids; Increased serum amylase; Increased serum lipase; Mucositis; Nausea; Vomiting; Xerostomia; Anemia; Hemorrhage; Leukopenia; Lymphocytopenia; Neutropenia; Thrombocytopenia; Hyperbilirubinemia; Increased serum alkaline phosphatase, Increased serum ALT; Increased serum AST; Fever; Arthralgia; Back pain; Increased creatine phosphokinase; Limb pain; Myalgia; Weakness; Increased serum creatinine; Cough; Epistaxis; Nasopharyngitis; Upper respiratory tract infection.

***Less common side effects:***

Deep vein thrombosis; Pulmonary embolism; Venous thrombosis; Pancreatitis; Flu-like syndrome.

***Rare side effects:***

Arterial thrombosis; Arterial flutter; Cardiomyopathy; Cerebral infarction; Cerebrovascular accident; Coronary artery dissection; Hypotension; Myocardial infarction; Preeclampsia; Prolonged QT interval on ECG; Septic shock; torsades depointes; Transient ischemia attacks; ventricular arrhythmia; Cerebral hemorrhage; Coma; reversible posterior leukoencephalopathy syndrome; seizure; Erythema multiforme; pyoderma gangrenosum; Skin infection; Stevens-Johnson syndrome; toxic epidermal necrolysis; Adrenocortical insufficiency; Hyperthyroidism; Hypothyroidism; Thyroiditis; Cholecystitis; Esophagitis; Gastrointestinal perforation; Nephrotic syndrome; Proteinuria; Urinary tract infection; Febrile neutropenia; Hemolytic anemia; Hemorrhage; Macrocytosis; Neutropenic infection; Pulmonary hemorrhage; Thrombotic thrombocytopenic purpura; Tumor lysis syndrome; Hepatic failure; Hepatotoxicity; Angioedema; Hypersensitivity; Increased susceptibility to infection; Sepsis; Fistula; Tissue necrosis; Wound healing impairment; Fulminant necrotizing fasciitis; Myopathy; Osteonecrosis; Rhabdomyolysis; Acute renal failure; Glomerulonephritis; Renal insufficiency, Epistaxis; Pneumonitis.

**5- Storing Sunitiban®**

Keep out of the reach and sight of children.

Store in the original package in order to protect from light.

Store Sunitiban® below 30° C.

Do not use Sunitiban® after the expiry date which is stated on the carton after "Exp.".

Medicines should not be disposed of via wastewater or household waste. Ask your pharmacist how to dispose of medicines no longer required. These measures will help to protect the environment.

**6- Further information**

**What Sunitiban® contains**

**Active substance:**

1 capsule contains 12.5mg or 25mg or 50 mg Sunitinib (as malate)

**Other ingredient:**

Mannitol; Crosscarmellose sodium; Povidone; Magnesium stearate; Gelatin capsule.

**Contains of the pack:**

Each bottle contains 30 capsules.

SUBC-0000-LF-00


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| شرکت سبحان انکولوژی | |
|---|---|
| *Leaflet* | ***Sunitinib (Sunitiban®)*** |
| *Color* | PANTONE 294U PANTONE 185C |
| *Size* | 220 mm x 320 mm Tolerance: ±1mm |
| *File name* | SUBC-0000-LF-00 |
| *Date* | 10.04.1399 |