

## HEALTINIB

**For the use of a Registered Medical Practitioner or Hospital or a Laboratory only.**

Abbreviated Prescribing information for HEALTINIB (Sunitinib Malate Capsules)

[Please refer the complete prescribing information available at [www.torrentpharma.com](http://www.torrentpharma.com)]

### PHARMACOLOGICAL PROPERTIES:

**Mechanism of action:**

**DOSAGE AND ADMINISTRATION:** One tablet once daily or as directed by physician.

**CONTRAINDICATION:** Hypersensitivity to the active substance or to any of the excipients.

**WARNINGS & PRECAUTIONS:** Co-administration with potent CYP3A4 inducers should be avoided because it may decrease sunitinib plasma concentration. Co-administration with potent CYP3A4 inhibitors should be avoided because it may increase the plasma concentration of sunitinib, Skin and tissue disorders, Haemorrhage and tumour bleeding, Gastrointestinal disorders, Hypertension, Haematological disorders, Cardiac disorders, QT interval prolongation, Venous thromboembolic events, Arterial thromboembolic events, Aneurysms and artery dissections, Thrombotic microangiopathy (TMA), Thyroid dysfunction, Pancreatitis, Hepatotoxicity, Renal function, Fistula, Impaired wound healing, Osteonecrosis of the jaw (ONJ), Hypersensitivity/angioedema, Seizures, Tumour lysis syndrome (TLS), Infections, Hypoglycaemia.

**DRUG INTERACTION:** Medicinal products that may increase sunitinib plasma concentrations: Effect of CYP3A4 inhibitors: Administration of sunitinib with potent CYP3A4 inhibitors (e.g., ritonavir, itraconazole, erythromycin, clarithromycin, grapefruit juice) may increase sunitinib concentrations. Combination with CYP3A4 inhibitors should therefore be avoided. Medicinal products that may decrease sunitinib plasma concentrations: Effect of CYP3A4 inducers: Administration of sunitinib with potent CYP3A4 inducers (e.g., dexamethasone, phenytoin, carbamazepine, rifampicin, phenobarbital or herbal preparations containing St. John's Wort/*Hypericum perforatum*) may decrease sunitinib concentrations.

**ADVERSE REACTIONS:** Viral infections, Respiratory infections, Abscess, Fungal infections, Urinary tract infection, Skin infections, Sepsis, Necrotising fasciitis, Bacterial Infections, Neutropenia, Thrombocytopenia, Anaemia, Leukopenia, Lymphopenia, Pancytopenia, Thrombotic micro angiopathy, Hypersensitivity, Angioedema, Hypothyroidism, Hyper-thyroidism, Thyroiditis, Decreased appetite, Dehydration, Hypoglycaemia, Tumour lysis syndrome, Insomnia, Depression, Dizziness, Headache, Taste disturbance, Neuropathy peripheral, Paraesthesia, Hypoaesthesia, Hyperaesthesia, Cerebral haemorrhage, Cerebrovascular accident, Transient ischaemic attack, Posterior reversible encephalopathy syndrome, Periorbital oedema, Eyelid oedema, Lacrimation increased, Myocardial ischemia, Ejection fraction decreased, Cardiac failure congestive, Myocardial infarction, Cardiac failure, Cardiomyopathy, Pericardial effusion, Electrocardiogram, QT prolonged, Left ventricular failure, Torsade de pointes, Hypertension, Deep vein thrombosis, Hot flush, Flushing, Tumour haemorrhage, Aneurysms and artery dissections, Dyspnoea, Epistaxis, Cough, Pulmonary embolism, Pleural effusion, Haemoptysis, Dyspnoea, exertional Oropharyngeal pain, Nasal congestion, Nasal dryness, Pulmonary haemorrhage, Respiratory failure, Stomatitis, Abdominal pain, Vomiting, Diarrhoea, Dyspepsia, Nausea, Constipation, 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, Gastro-intestinal perforation, Pancreatitis, Anal fistula, Colitis, Hepatic failure, Cholecystitis, Hepatic function abnormal, Hepatitis, Skin discolouration, Palmar-plantar erythrodysesthesia syndrome, Rash, Hair colour changes, Dry skin, Skin exfoliation, Skin reaction, Eczema, Blister, Erythema, Alopecia, Acne, Pruritus, Skin hyperpigmentation, Skin lesion, Hyperkeratosis, Dermatitis, Nail disorder, Erythema multiform, Stevens- Johnson syndrome, Pyoderma gangrenosum, Toxic epidermal necrolysis, Pain in extremity, Arthralgia, Back pain, Musculoskeletal pain, Muscle spasms, Myalgia, Muscular weakness, Osteonecrosis of the jaw Fistula, Rhabdomyolysis, Myopathy, Renal failure, Renal failure acute, Chromaturia, Proteinuria, Haemorrhage urinary tract, Nephrotic syndrome, Mucosal inflammation, Fatigue, Oedema, Pyrexia, Chest pain, Pain Influenza like illness, Chills, Impaired healing, Weight decreased, White blood cell count decreased, Lipase increased, Platelet count decreased, Haemoglobin decreased, Amylase increased, Aspartate aminotransferase increased, Alanine aminotransferase increased, Blood creatine increased, Blood pressure increased, Blood uric acid increased, Blood creatinine phosphokinase increased, Blood thyroid stimulating hormone increased.

**Marketed by:**



**IN/HEALTINIB 12.5/25/50 mg/APR-21/01/ABPI**

(Additional information is available on request)