

Taxane toxicity criteria and severity descriptors for the listing of lapatinib on the PBS

ULN = upper limit of normal

Adverse event	Brief description of minimum grade	NIH common toxicity criteria grade
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Blood / Bone Marrow

Leukopaenia	Note: generally marrow suppression will be managed by supportive treatment, dose reduction / delay etc rather than cessation of therapy. Anaemia and thrombocytopaenia are also seen and may also require dose adjustment	
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Cardiovascular

Arrhythmia	Symptomatic and requiring treatment	3 (or higher)
Fluid retention	Severe, limiting function and requiring drug discontinuation	3 (or higher)
Thrombosis / embolism	Deep vein thrombosis requiring anti-coagulant therapy	3 (or higher)

Dermatological

Rash	Severe (eg generalised exfoliative or ulcerative rash requiring I.V. fluids)	4
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Gastrointestinal

Note: Anorexia, nausea, vomiting, and mucositis are common and usually manageable adverse reactions.

Abdominal pain	Severe pain – pain or analgesia severely interfering with activities of daily living	3 (or higher)
Anorexia	Requiring I.V. fluids	3 (or higher)
Diarrhoea	Increase of > 7 stools/day or requiring parenteral fluid support	3 (or higher)
Nausea	No significant intake, requiring I.V. fluids	3 (or higher)
Stomatitis / oesophagitis	Painful erythema, oedema or ulcers requiring I.V. rehydration	3 (or higher)
Vomiting	> 6 episodes in 24 hours over pre-treatment or need for I.V. fluids	3 (or higher)

Hepatic

Transaminases	ALT and/or AST > 2.5 x ULN (persistent)	2 (or higher)
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Musculoskeletal

Arthralgia / Myalgia	Severe pain – pain or analgesia severely interfering with activities of daily living	3 (or higher)
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Neurology / Senses

Note: neuropathy is common and usually managed by dose delay and / or dose reduction.

Ataxia (incoordination)	Interfering with activities of daily living	3 (or higher)
Decreased level of consciousness	Stupor, difficult to rouse, interfering with activities of daily living	3 (or higher)
Keratitis	Symptomatic and interfering with activities of daily living	3 (or higher)
Mood alteration	Severe mood alteration interfering with activities of daily living	3 (or higher)
Neuropathy - motor	Objective weakness interfering with activities of daily living	3 (or higher - persistent)
Neuropathy - sensory	Sensory loss or paresthesia interfering with activities of daily living	3 (or higher - persistent)
Vertigo	Interfering with activities of daily living	3 (or higher)

Other

Allergic reaction / hypersensitivity	Severe (eg bronchospasm / hypotension requiring treatment +/- angioedema or generalised urticaria)	3 (or higher)
Fatigue	Severe fatigue, or loss of ability to perform some activities	3 (or higher)
Febrile neutropaenia, infections etc	Life-threatening or disabling	4