

Uncommon:	Anaemia, febrile neutropenia	Lymphopenia, petechiae
<b>Endocrine disorders</b>		
Uncommon:	Cushingoid	Cushingoid
<b>Metabolism and nutrition disorders</b>		
Very Common:	Anorexia	Anorexia
Common:	Hyperglycaemia, weight decreased	Weight decreased
Uncommon:	Hypokalemia, alkaline phosphatase increased, weight increased	Hyperglycaemia, weight increased
<b>Psychiatric disorders</b>		
Common:	Anxiety, emotional lability, insomnia	Anxiety, depression, emotional lability, insomnia
Uncommon:	Agitation, apathy, behaviour disorder, depression, hallucination	Hallucination, amnesia
<b>Nervous system disorders</b>		
Very Common:	Headache	Headache, convulsions
Common:	Dizziness, aphasia, balance impaired, concentration impaired, confusion, consciousness decreased, convulsions, memory impairment, neuropathy, paresthesia, somnolence, speech disorder, tremor	Dizziness, aphasia, balance impaired, concentration impaired, confusion, dysphasia, hemiparesis, memory impairment, neurological disorder (NOS), neuropathy, peripheral neuropathy, paresthesia, somnolence, speech disorder, tremor
Uncommon:	Ataxia, cognition impaired, dysphasia, extrapyramidal disorder, gait abnormal, hemiparesis, hyperesthesia, hypoesthesia, neurological disorder (NOS), peripheral neuropathy, status epilepticus	Ataxia, coordination abnormal, gait abnormal, hemiplegia, hyperesthesia, sensory disturbance

<b>Eye disorders</b> Common:  Uncommon:	Vision blurred  Eye pain, hemianopia, vision disorder, visual acuity reduced, visual field defect	Vision blurred, diplopia, visual field defect  Eye pain, eyes dry, visual acuity reduced
<b>Ear and labyrinth disorders</b> Common:  Uncommon:	Hearing impairment  Earache, hyperacusis, tinnitus, otitis media	Hearing impairment, tinnitus  Deafness, earache, vertigo
<b>Cardiac disorders</b> Uncommon:	Palpitation	
<b>Vascular disorders</b> Common:  Uncommon:	Oedema, oedema leg, haemorrhage  Hypertension, cerebral haemorrhage	Oedema leg, haemorrhage, deep venous thrombosis  Oedema, oedema peripheral, embolism pulmonary
<b>Respiratory, thoracic and mediastinal disorders</b> Common:  Uncommon:	Coughing, dyspnoea  Pneumonia, upper respiratory infection, nasal congestion	Coughing, dyspnoea  Pneumonia, sinusitis, upper respiratory infection, bronchitis
<b>Gastrointestinal disorders</b> Very Common:  Common:	Constipation, nausea, vomiting  Abdominal pain, diarrhoea, dyspepsia, dysphagia, stomatitis	Constipation, nausea, vomiting  Diarrhoea, dyspepsia, dysphagia, mouth dry, stomatitis

Uncommon:		Abdominal distension, fecal incontinence, gastrointestinal disorder (NOS), gastroenteritis, haemorrhoids
<b>Skin and subcutaneous tissue disorders</b>		
Very Common:	Alopecia, rash	Alopecia, rash
Common:	Dermatitis, dry skin, erythema, pruritus	Dry skin, pruritus
Uncommon:	Photosensitivity reaction, pigmentation abnormal, skin exfoliation	Erythema, pigmentation abnormal, sweating increased
<b>Musculoskeletal and connective tissue disorders</b>		
Common:	Arthralgia, muscle weakness	Arthralgia, musculoskeletal pain, myalgia, muscle weakness
Uncommon:	Back pain, musculoskeletal pain, myalgia, myopathy	Back pain, myopathy
<b>Renal and urinary disorders</b>		
Common:	Micturition frequency, urinary incontinence	Urinary incontinence
Uncommon		Dysuria
<b>Reproductive system and breast disorders</b>		
Uncommon:	Impotence	Amenorrhea, breast pain, menorrhagia, vaginal haemorrhage, vaginitis
<b>General disorders and administration site conditions</b>		
Very Common:	Fatigue	Fatigue
Common:	Fever, pain, allergic reaction, radiation	Fever, pain, allergic reaction, radiation

Uncommon:	injury, face oedema, taste perversion  Flushing, hot flushes, asthenia condition aggravated, rigors tongue discolouration, parosmia, thirst	injury, taste perversion  Asthenia, condition aggravated, pain, rigors, tooth disorder, face oedema, taste perversion
<b>Investigations</b>		
Common:	ALT increased	ALT increased
Uncommon:	Gamma GT increased, hepatic enzymes increased, AST increased	

\*A patient who was randomised to the RT arm only, received Temodal + RT.

Laboratory results: Myelosuppression (neutropenia and thrombocytopenia), which is known dose-limiting toxicity for most cytotoxic agents, including Temodal, was observed. When laboratory abnormalities and adverse events were combined across concomitant and monotherapy treatment phases, Grade 3 or Grade 4 neutrophil abnormalities including neutropenic events were observed in 8 % of the patients. Grade 3 or Grade 4 thrombocyte abnormalities, including thrombocytopenic events were observed in 14 % of the patients who received Temodal.

### **Recurrent or progressive malignant glioma**

In clinical trials, the most frequently occurring treatment-related undesirable effects were gastrointestinal disturbances, specifically nausea (43 %) and vomiting (36 %). These effects were usually Grade 1 or 2 (0 – 5 episodes of vomiting in 24 hours) and were either self-limiting or readily controlled with standard anti-emetic therapy. The incidence of severe nausea and vomiting was 4 %.

**Table 5** includes undesirable effects reported during clinical trials for recurrent or progressive malignant glioma and following the marketing of Temodal.