

- pain · haemolytic anaemia · hallucination · hyperthyroidism · increased leucocytes · injury · irritable bowel syndrome · joint disorders · lymphadenopathy · memory loss · movement disorders · mucous membrane disorder · myopathy · neurotoxicity · palpitations · pancreatitis · pancytopenia · pericardial disorders · pericarditis · posterior reversible encephalopathy syndrome (PRES) (discontinue) · proteinuria · psychiatric disorders · psychotic disorder · pulmonary hypertension · pulmonary oedema · reflexes abnormal · respiratory disorders · rhinorrhoea · seizure · sensation of pressure · severe cutaneous adverse reactions (SCARs) · sexual dysfunction · shock · SIADH · skin mass · skin ulcers · speech disorder · sweat changes · temperature sensation altered · thirst change · tremor · tumour lysis syndrome · urinary disorders · urinary tract disorder · vascular disorders · vasculitis · vasodilation
- ▶ **Rare or very rare** Acidosis · acute coronary syndrome · alcohol intolerance · amyloidosis · apnoea · ascites · atrioventricular block · bladder irritation · blood disorders · bone disorder · bone fracture · brain oedema · breast disorder · cardiac valve disorder · cholelithiasis · CNS haemorrhage · cognitive disorder · coma · coronary artery insufficiency · delirium · drooling · ear disorder · erythromelalgia · fistula · gout · healing impaired · hypothyroidism · inflammation · lymphoedema · macrophage activation · mass · meningitis · metabolic disorder · multi organ failure · nail disorder · neoplasm malignant · neoplasms · nervous system disorder · paralysis · paresis · pelvic pain · perforation · photosensitivity reaction · platelet abnormalities · procedural complications · prostatitis · radiation injury · seborrhoea · sudden death · suicidal ideation · testicular disorders · throat complaints · ulcer · vaginal ulceration · venous insufficiency · vitamin deficiencies
 - ▶ **Frequency not known** Herpes zoster reactivation · JC virus infection · progressive multifocal leukoencephalopathy (PML)
 - **CONCEPTION AND CONTRACEPTION** Manufacturer advises effective contraception during and for 3 months after treatment in men or women.
 - **PREGNANCY** Toxicity in *animal studies*. See also *Pregnancy and reproductive function* in Cytotoxic drugs p. 938.
 - **BREAST FEEDING** Discontinue breast-feeding.
 - **HEPATIC IMPAIRMENT** Manufacturer advises caution in moderate to severe impairment—monitor for toxicity. **Dose adjustments** Manufacturer advises reduce dose in moderate to severe impairment—consult product literature.
 - **RENAL IMPAIRMENT** No information available for creatinine clearance less than 20 mL/minute/1.73 m².
 - **MONITORING REQUIREMENTS**
 - ▶ Monitor blood-glucose concentration in patients on oral antidiabetics.
 - ▶ Monitor for symptoms of progressive multifocal leukoencephalopathy (presenting as new or worsening neurological signs or symptoms)—discontinue treatment if diagnosed.
 - ▶ Chest x-ray recommended before treatment to monitor for pulmonary disease—discontinue if interstitial lung disease develops.
 - **NATIONAL FUNDING/ACCESS DECISIONS**
 - NICE decisions**
 - ▶ **Bortezomib for previously untreated mantle cell lymphoma (December 2015)** NICE TA370
Bortezomib is recommended as an option for the treatment of previously untreated mantle cell lymphoma in adults for whom haematopoietic stem cell transplantation is unsuitable.
www.nice.org.uk/guidance/ta370

- ▶ **Bortezomib for induction therapy in multiple myeloma before high-dose chemotherapy and autologous stem cell transplantation (April 2014)** NICE TA311

Bortezomib is recommended as an option within its marketing authorisation, in combination with dexamethasone, or with dexamethasone and thalidomide, for the induction treatment of adults with previously untreated multiple myeloma, who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

www.nice.org.uk/guidance/ta311

- ▶ **Bortezomib and thalidomide for the first-line treatment of multiple myeloma (July 2011)** NICE TA228
Bortezomib in combination with an alkylating drug and a corticosteroid is recommended as an option for the first-line treatment of multiple myeloma if:
 - high-dose chemotherapy with stem cell transplantation is considered inappropriate **and**
 - the person is unable to tolerate or has contraindications to thalidomide.

www.nice.org.uk/guidance/ta228

- ▶ **Bortezomib monotherapy for relapsed multiple myeloma (October 2007)** NICE TA129
Bortezomib monotherapy is an option for the treatment of progressive multiple myeloma in patients who are at first relapse having received one prior therapy and who have undergone, or are unsuitable for, bone-marrow transplantation, under the following circumstances:
 - the response to bortezomib is measured using serum M protein after a maximum of four cycles of treatment, and treatment is continued only in patients who have a reduction in serum M protein of 50% or more (where serum M protein is not measurable, an appropriate alternative biochemical measure of response should be used) **and**
 - the manufacturer rebates the full cost of bortezomib if there is an inadequate response (as defined above) after four cycles of treatment.

www.nice.org.uk/TA129

Scottish Medicines Consortium (SMC) decisions

The *Scottish Medicines Consortium*, has advised (January 2014) that bortezomib (Velcade[®]) is accepted for restricted use within NHS Scotland in combination with dexamethasone and thalidomide for the induction treatment of adults with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematopoietic stem cell transplantation.

- **MEDICINAL FORMS** There can be variation in the licensing of different medicines containing the same drug. Forms available from special-order manufacturers include: solution for injection

Solution for injection

▶ Bortezomib (Non-proprietary)

Bortezomib 2.5 mg per 1 ml Bortezomib 3.5mg/1.4ml solution for injection vials | 1 vial [PoM] £495.55 (Hospital only)

Powder for solution for injection

▶ Bortezomib (Non-proprietary)

Bortezomib 1 mg Bortezomib 1mg powder for solution for injection vials | 1 vial [PoM] £217.82 (Hospital only)

Bortezomib 2.5 mg Bortezomib 2.5mg powder for solution for injection vials | 1 vial [PoM] £544.56 (Hospital only)

Bortezomib 3.5 mg Bortezomib 3.5mg powder for solution for injection vials | 1 vial [PoM] £762.38 (Hospital only)

▶ Velcade (Janssen-Cilag Ltd)

Bortezomib 3.5 mg Velcade 3.5mg powder for solution for injection vials | 1 vial [PoM] £762.38 (Hospital only)