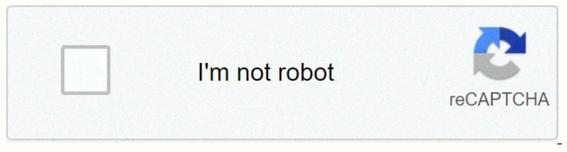

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Velcade package insert pdf

Adult Paediatric Forms of Dosing Lyophilized Reconstitution Powder Indicated for the treatment of patients with mantle cell lymphoma as a first line in patients receiving who have not been previously treated or those who have relapsed previously untreated MCL 1.3 mg/ m²/dose IV twice a week for 2 weeks (days 1, 4, 8, 11) followed by a rest period of 10 days (days 12 to 21) for six 3-week cycles; 8 cycles if the response is first observed in cycle 6 Give with rituximab 375 mg/m² IV, cyclophosphamide 750 mg/m² IV and doxorubicin 50 mg/m² IV on day 1, plus prednisone 100 mg/m² IV on days 1-5 Relapsed MCL 1,3 mg/m²/dose 4, 8, 11) followed by a 10-day rest period (days 12 to 21) Therapy, Continuing after 8 cycles: Give a standard multiple myeloma regimen Previously untreated multiple myeloma Apply in combination with prednisone and melphalan as part of the 6-wk treatment cycle for 9 cycles 1-1-1 1.3 mg/m² IV/SC on days 1, 4, 8, 11, 22, 25, 29 32 cycles 5-9 (once weekly) : 1.3 mg/m² IV/SC on days 1, 8, 22 and 29 Relapsed multiple myeloma 1.3 mg/m²/dose IV/SC twice weekly for 2 weeks 8, and 11), followed by a 10-day rest period (days 12-21) Therapy lasting more than 8 cycles: Standard schedule or maintenance schedule once a week for 4 weeks (days 1, 8, 15 and 22) followed by a 13-day rest period (Days 23 to 23 5) Re-treatment indicated for the re-treatment of adults with multiple myeloma who previously responded to bortezomib and responded at least 6 months after completion of previous bortezomib treatment treatment may be initiated at the last tolerated dose Administration twice a week for 2 weeks (day 1 , 4, 8, 11) followed by a 10-day rest period (days 12 to 21) Dosage Change Bortezomib, melphalan and prednisone toxicity During a cycle: If prolonged class 4 neutropenia or thrombocytopenia, or bleeding thrombocytopenia was observed in the previous cycle, consider reducing the dose of melphalan by 25% in the next platelet cycle ≤30 x 10^9/L or ANC ≤0.75 x 10^9^9/L for the day of bortezomib administration (other than day 1): Retains bortezomi 1. If several doses of bortezomib in successive cycles persist due to toxicity: Reduce bortezomib by 1 dose (e.g. 1.3 mg/m² to 1 mg/m² or from 1 mg/m² to 0.7 mg/m² ≥ Grade 3 non-haematological toxications: Keep bortezomib to symptoms to grade 1 or baseline; , can be recovered with 1 dose reduction (eg, from 1,3 mg/m² to 1 mg/m² or from 1 mg/m² to 0,7 mg/m²) Recurrent multiple myeloma and grade 3 non-haematological lymphoma or Grade 4 haematological toxicity (excluding neuropathy): Retention at the onset of the disease; symptoms resolved, bortezomib may be restored at a 25% reduced dose (e.g. 1.3 mg/m²/dose reduced to 1 mg/m²/dose; 1 mg/m²/dose reduced to 0.7 mg/m²/ Peripheral neuropathy Initiation of subcutaneous therapy may be considered in patients at pre-existing or high risk of neuropathy Patients with pre-existing severe neuropathy should be treated with bortezomib only after careful assessment of the benefit-risk balance grade 1 (asymptomatic; loss of deep tendon reflexes or paresthesia) without pain or loss of function: No action 1 with pain or Grade 2: Dose reduction to 1 mg / m² Grade 2 with pain or Grade 3: Drug retention to toxicity symptoms; may be resumed at 0.7 mg/m² qSek Grade 4: Discontinuation of bortezomib Hepatic impairment Moderate to severe (bilirubin >1.5 x ULN): Reduce to 0.7 mg/m² in the first cycle; consider increasing the dose to 1 mg/m² or further reducing the dose to 0.5 mg/m² in subsequent cycles based on tolerability orphans Designated Follicular non-Hodgkin's lymphoma Acute lymphoblastic leukemia Treatment of neurofibromatosis type 2 (NF2) Sponsors Drugs, Inc; 40 Landsdown Street; Cambridge, MA 02139 3 BioXcel Corporation; 780 Main East, ST, TT 2; Branford, CT 06405 Safety and Efficacy not found No Interactions Found Interactions FoundContraindicatedContraindicatedContaining - Use AlternativeKnowledents - MonitorClose-Col interactions Sort by: Weights (61-65%) Nausea (61-65%) Diarrhea (51-55%) Anorexia (41-45%) Constipation (41-45%) Thrombocytopenia (41-45%) Peripheral neuropathy (IV: 16-41%; 24% Pyrexia (36-40%) Vomiting (36-40%) Anemia (31-35%) Arthralgia (26-30%) Headache (26-30%) Insomnia (26-30%) Pain in the extremities (26-30%) Dizziness (21-25%) Dyspnoea (21-25%) Edema (21-25%) Neutropenia (21-25%) Paresthesia (21-25%) Rash (21-25%) Cough (15-20%) Dehydration (15-20%) URI (15-20%) Demanding, Grade 4 toxicity (10-15%) Frequency Not defined Hypotension Anxiety Pain Pruritus Abdominal pain Abdominal pain Back pain Back pain Bone pain Myalgia Muscle spasms Shingles Pneumonia Blurred vision Poster cardiovascular: Atrioventricular block full, cardiac tamponade GI: Ischemic colitis, hepatitis, acute pancreatitis CNS: Encephalopathy, disotonomy, progressive multifocal leukoencephalopathy (PML), acute diffuse intractable lung disease, PRES (formerly RPLS), herpes meningoencephalitis Hematologic: Dyseminated intravascular coagulation Pulmonary: Acute diffuse infiltrative pulmonary disease Co: Toxic epidermal necrolysis, acute febrile neutrophilic dermatosis (Sweet syndrome) Sensory: Optic neuropathy, deafness bilateral blindness, and eye herpes Hypersensitivity to any component or boron or mannitol; intrathecal administration Warning Cases, sometimes fatal, of thrombotic microangiopathy (eg, thrombotic thrombocytopenic purpura/hemolytic uremic syndrome [TTP/HUS]), have been reported in the post-marketing setting Be wary of hepatic impairment (decrease in the initial dose); monitor liver enzymes during treatment High tumor load (risk of tumor lysis syndrome); patients with high tumour load Syndrome reversible encephalopathy, REVERSIBLE ENCEPHALOPATHY SYNDROME, PRES (before RPLS); the safety of re-initiation of therapy in patients who previously had a history of thrombocytopenia and neutropenia, which follow a cyclic pattern with nadir, appearing after the last dose of each cycle and usually subside before the start of the next cycle; observed regularly CBCs during treatment Hypotension (orthostatic, orthostatic, and hypotension NOS) observed during treatment; treatment of orthostatic/orthostatic/orthostatic hypotension may include correction of antihypertensive medications, hydration and administration of mineralocorticoids and/or sympathomimetics Nausea, diarrhea, constipation and vomiting may require the use of antiemetic and antidiarchic drugs or fluid substitution Women should avoid becoming pregnant during treatment; pregnant women from potential embryo-foetal impairment (see Pregnancy) Associated with thrombocytopenia and neutropenia, which follows a cyclic pattern with a nadir occurring after the last dose of each cycle and usually recovers before the start of the next cycle Acute development or exacerbation of clogged acute respiratory distress (ARDS) and acute diffuse infiltrative lung disease of unknown etiology, such as pneumonitis, interstitial pneumonia, pulmonary infiltration have occurred Peripheral neuropathy Treatment causes peripheral neuropathy (mostly sensory); cases of severe sensory and motor peripheral neuropathy numbness have been reported, pain or burning of the legs or hands) and/or signs of peripheral neuropathy during treatment Consider starting SC treatment in patients with a prior or high risk of peripheral neuropathy New or worsening peripheral neuropathy may require a reduced dose or change in the dosing schedule (see Dose adjustment) Based on the mechanism of action and findings in animals, therapy may cause a fetal wound when administered to a pregnant woman; there are no studies in pregnant women to inform about the risks associated with medicines; therapy causes embryo-foetal lethality in rabbits at doses lower than the clinical dose; advise pregnant women at potential risk to the fetus Check pregnancy status of female reproductive potential before starting treatment Advise patients with reproductive potential to use effective contraception during treatment and for at least 2 months after treatment Lactation There are no evidence of the presence of bortezomib or metabolites in breast milk, the effects of the drug on breast milk or breast milk Many drugs are excreted in breast milk and the potential for serious side effects in breast infants from therapy is unknown I advise nursing mothers not to breast-feeding during treatment and for 2 months after treatmentGrativity categories A: Usually acceptable. Controlled studies in pregnant women have shown no evidence of risk of fetal development. B: It can be acceptable. There is no risk, but human studies have shown no evidence of animals or animal studies involving studies and showed no risk. C: Use with caution if the benefits outweigh the risks. Animal studies have shown that neither animal nor human studies have been conducted. D: Use in emergencies that endanger life when no safer drug is available. Positive evidence of germ risk. X: Do not use during pregnancy. The risks that are associated are greater than the potential benefits. There are safer alternatives. NA: No information available. Reversible inhibitor of chymoprypsin-like activity in the proteasezoma 26-S, which in turn causes cessation of the cell cycle and apoptosis absorption plenary in plasma plasma level: 509 ng/ml protein limit distribution: 83% Vd: 498-1884 L/m² Metabolism hepatic P450 enzyme CYP3A4 (large); also CYP1A2, 2C9, 2C19, 2D6 (minor) Inhibition of enzymes: CYP2C19 Elimination half-life: 9-15 hours (single dose IV); 40-193 (repeated dosing of 1 mg/m²); 76- 108 hours (multiple dosing of 1.3 mg/m²) Reconstitute the vial with 0.9% NaCl IV administration: Add 3.5 ml in a 1 mg/ml SC final concentration vial application: 2.5 mg/ml: Add 1.4 ml to a 2.5 mg/ml final concentration vial If local injection reactions occur, occur after subcutaneous administration, a less concentrated solution (1 mg / ml) can be administered subcutaneously or SUBCUTANEOUSly Application No for intrathecal (IT) use; inadvertentLY IT has led to death and is contraindicated Individual consecutive doses of at least 72 hours Is given IV as a bolus for 3-5 seconds or as an SC injection Give SC injection into the thigh or abdomen; alternate the injection site with each dose monitor hydration Use cytotoxic procedures for preparation, administration and disposal Storage Protection from unused vials: Store the vial at controlled room temperature (25° C [77°F]) Reconstituted vials Does not contain antimicrobial preservative; Administered within 8 hours of the preparation Do not store the solution in a syringe for >3 h. FormularyPatient DiscountsAdding plans allows to compare formula condition with other drugs in the same class. To see formula information, first create a list of plans. Your list will be saved and can be edited at any time. Adding plans allows you to:View formulas and limitations for each plan. Manage and review all your plans together – even plans in different countries.Compare a formula with other drugs in the same class. Access the plan list on any device – mobile device or desktop. Medscape prescription drug monographs are based on FDA-approved labeling information, unless otherwise noted, combined with additional data obtained from primary medical literature. Literature.