

03 Aug , 2026

Dear Healthcare professional,

Velcade (Bortezomib)- Updated Genotoxicity Contraception Guidance in the PIL for Velcade"

Janssen Egypt in agreement with General Administration for Pharmaceutical Vigilance of the Central Administration for Pharmaceutical Care at the Egyptian Drug Authority would like to inform you of the following safety update under the pregnancy and breast-feeding section about genotoxicity contraception in the updated PIL of Velcade (Bortezomib) as below.

Summary

- **Female Patients:** Women of childbearing potential must use effective contraception during treatment and for **8 months** following the completion of therapy. Patients are advised to consult their doctor if they wish to consider egg freezing before starting treatment.
- **Male Patients:** Men should not father a child while receiving Velcade and must use effective contraception during treatment and for **up to 5 months** after treatment has ceased. Patients are advised to consult their doctor if they wish to consider sperm conservation before starting treatment.

Background & Further Information on the safety concerns and recommendations

Velcade is a cancer medicine that is generally used in combination with other medicines to treat multiple myeloma, a blood cancer, in:

- adults whose disease is getting worse after at least one other treatment and who have already had blood stem-cell transplantation or cannot have it. In these patients, Velcade is used either on its own or with pegylated liposomal doxorubicin or dexamethasone;
- previously untreated adults who cannot have high-dose chemotherapy with blood stem-cell transplantation. In these patients, Velcade is used in combination with melphalan and prednisone;
- previously untreated adults who are going to receive high-dose chemotherapy followed by a blood stem-cell transplantation. In these patients, Velcade is used in combination with dexamethasone, or with dexamethasone plus thalidomide.

Velcade is also used to treat mantle cell lymphoma, another blood cancer. It is used in adults who have not received any treatment for their cancer and who cannot have blood stem-cell transplantation. In these patients Velcade is used with rituximab, cyclophosphamide, doxorubicin and prednisone.

- It was recommended to follow the below durations of contraception in male and female patients as follows:
- The recommended duration of contraception in male patients should be until the end of relevant systemic exposure to the genotoxic compound including potential genotoxic metabolites (i.e five half-lives after the last dose) plus 90 days. The same would be true for a pure aneugenic compound
- The recommended duration of contraception in female subjects participating in clinical trials should be until the end of relevant systemic exposure incl potential genotoxic metabolites (i.e five half-lives after the last dose plus 6 months. In the more theoretical case of treatment with a pure aneugenic pharmaceutical recommended duration of contraception should be until the end of relevant systemic exposure (i.e five half-lives after the last dose) plus 1 month.

References

Velcade (Bortezomib) EUPI May 2024

https://ema.europa.eu/en/documents/product-information/velcade-epar-product-information_en.pdf

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