

May 25, 2017

Direct Healthcare Professional Communication

IVEMEND®: be aware batch numbers M034017 and M035995 hold an old manufacturing site name and old leaflet version

Dear Health care professional,

As part of MSD's dedication and commitment to serving patients as well as their treating oncologists and pharmacists, we would like to bring to your attention that Fosaprepitant Dimeglumine (IVEMEND®) with batch numbers M034017 and M035995 holds an old manufacturing site name (DSM) and old leaflet version (September 2010).

The correct name for the new manufacturing site is 'Patheon Manufacturing Services LLC' and the correct leaflet should be the December 2013 Summary of product characteristics (SMPC). The December 2013 version contains several safety updates compared to the September 2010 version; that are all outlined in the below section.

An update to the section with the title "Interaction with other medicinal products and other forms of interaction" stated that caution is advised and additional monitoring may be appropriate in patients receiving medicinal products metabolized primarily or partly by CYP3A4.

Post-marketing events of neurotoxicity, a potential adverse reaction of Ifosfamide, have been reported after Aprepitant and Ifosfamide coadministration.

An update on the effect of Fosaprepitant Dimeglumine on "contraception in males and females" stated that the efficacy of hormonal contraceptives may be reduced during and for 28 days after administration of Fosaprepitant.

Alternative non-hormonal back-up methods of contraception should be used during treatment with Fosaprepitant and for 2 months following the last dose of Fosaprepitant.

Additionally, IVEMEND® may have minor influence on the ability to drive and use machines. Moreover, an update on the most common adverse reactions reported at a greater incidence in patients treated with the Aprepitant regimen than with standard therapy in patients receiving Highly Emetogenic Chemotherapy (HEC) included dyspepsia (2.6 % versus 2.0 %), and decreased appetite (2.0 % versus 0.5 %).

We sincerely apologize for this technical error and we remain at your disposal should you require any further support.