



Xulane[®] (ethinyl estradiol/norelgestromin) – First-time generic

- On March 1, 2021, [Amneal launched](#) Zafemy[™], an [AB-rated](#) generic version of Mylan's [Xulane \(ethinyl estradiol/norelgestromin\)](#) transdermal system.
 - OrthoEvra[®] was the original brand and reference listed product (RLD). However, OrthoEvra was discontinued in 2014 and at that time Xulane became the RLD.
 - Zafemy has been granted 180-days of exclusivity under the Competitive Generic Therapy pathway.
- Xulane is approved for the prevention of pregnancy in women with a body mass index (BMI) < 30 kg/m² for whom a combined hormonal contraceptive is appropriate.
- Xulane carries a boxed warning for cigarette smoking and serious cardiovascular events and contraindicated in women with a BMI ≥ 30 kg/m².
- According to IQVIA[™], U.S. sales for Xulane were approximately \$332 million for the 12 months ended December 2020.



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