



Cosmegen® (dactinomycin) – First-time generic

- On December 7, 2017, Prasco launched an authorized generic version of Recordati Rare Diseases' [Cosmegen \(dactinomycin\)](#) injection.
 - Luitpold received FDA approval of an [AP-rated](#) generic version of Cosmegen on August 13, 2013.
 - Mylan received FDA approval of an [AP-rated](#) generic version of Cosmegen on November 9, 2017.
 - Launch plans for both of these generics are pending.
- Cosmegen, either as a single agent or in combination therapy, is indicated for the treatment of Wilms' tumor; childhood rhabdomyosarcoma; Ewing's sarcoma; metastatic, nonseminomatous testicular cancer; and gestational trophoblastic neoplasia. It is also indicated as a component of regional perfusion, for the palliative and/or adjunctive treatment of locally recurrent or locoregional solid malignancies.
- Cosmegen carries a boxed warning stating that it should be administered only under the supervision of a physician who is experienced in the use of cancer chemotherapeutic agents, and it is highly toxic.



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