Evamist (estradiol transdermal spray): Drug Safety Communication - Unintended Exposure of Children and Pets to Topical Estrogen

U.S. Food & Drug Administration

AUDIENCE: OB/GYN, Patient

ISSUE: FDA notified healthcare professionals and patients that it is reviewing reports of adverse effects from Evamist, an estrogen hormone used to reduce hot flashes during menopause. Children unintentionally exposed to the drug through skin contact with women may experience premature puberty. Female children may experience nipple swelling and breast development. Male children may experience breast enlargement.

BACKGROUND: Evamist is a topical product, sprayed on the skin on the inside of the forearm between the elbow and the wrist. FDA is currently reviewing reported adverse events and is working with the company to identify any factors that may contribute to unintended exposure. The Agency will update the public when this review is complete. FDA and the company are also evaluating ways to minimize the risk.

RECOMMENDATION: Patients should make sure that children are not exposed to Evamist and that children do not come into contact with any skin area where the drug was applied. Women who cannot avoid contact with children should wear a garment with long sleeves to cover the application site. Additional information for Healthcare Professionals, Information for Patients, and a Data Summary are provided in the Drug Safety Communication at the link below.

Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Online: www.fda.gov/MedWatch/report.htm [1]
- Phone: 1-800-332-1088
- Mail: return the postage-paid FDA form 3500, which may be downloaded from the MedWatch "Download Forms [2]" page, to address on the pre-addressed form
- Fax: 1-800-FDA-0178

[07/29/2010 - Drug Safety Communication [3] - FDA]
[07/29/2010 - Keep Kids, Pets Away From Skin Sprayed With Evamist [4] - FDA Consumer Updates]
[07/29/2010 - News Release [5] - FDA]
[07/2009 - Evamist Prescribing Information [6] - Ther-Rx Corporation]

SOURCE [7]

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http://www.mdtmag.com/news/2010/07/evamist-estradiol-transdermal-spray-drug-safety-communication-unintended-exposure-children-and-pets-topical-estrogen?qt-most_popular=0

Links:
[1] http://www.fda.gov/MedWatch/report.htm
[2] http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/default.htm
[3] http://www.fda.gov/Drugs/DrugSafety/PostmarketDrugSafetyInformationforPatientsandProviders/ucm220185.htm
[4] http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm220217.htm
[5] http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm220540.htm
[6] http://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?id=13274
[7] http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm220548.htm