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HPRA DRUG SAFETY
NEWSLETTER
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Estradiol transdermal spray and gel: Reminder of precautions to avoid unintentional secondary transfer to others, especially children

Following recent national reports of unintentional secondary exposure, the HPRA advises healthcare professionals to ensure patients using estradiol transdermal spray or gel are aware of the potential harm to children from unintended exposure and that patients understand the precautions to prevent accidental transfer.

National reports recently received by the HPRA predominantly concern Lenzetto 1.53 mg/spray (Transdermal Spray, Solution) and involve patients using the product for hormone replacement therapy who have close or regular contact with younger children.

Key Messages

- **Method of administration:** patients dispensed or prescribed an estradiol transdermal spray or gel should be counselled on the correct administration method and the importance of precautionary measures to ensure others, especially children, do not come in contact with the area of the body where the product was applied to avoid accidental transfer.
- **Accidental transfer:** patients should be counselled on the steps to take in case of suspected accidental transfer, including the need to wash the skin with soap and water as soon as possible. In case of symptoms in children, patients should be advised to follow up with a healthcare professional.

There are a number of estradiol transdermal sprays and gels available in Ireland as part of hormone replacement therapy (see below for links to product information). Accidental transfer to others, especially children, is a recognised potential risk. Product information describes reports from post-marketing experience of accidental transfer to children, which have involved breast budding and breast masses in prepubertal females, precocious puberty, gynaecomastia and breast masses in prepubertal males. In most cases, the condition resolved with removal of estradiol exposure.

During initial and periodic clinical evaluations, and when dispensing, healthcare professionals are advised to counsel patients on the correct administration method, including measures to avoid accidental transfer, as described in product information. This is especially relevant if there is contact with children, and patients should be informed of the potential consequences should transfer occur.

Key measures for patients to avoid accidental transfer to others include:

- washing hands with soap and water following application;
- avoiding contact between the application site and another person's skin, particularly that of children; and
- covering the application site with clothing.

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Healthcare professionals should counsel patients on the steps to take in case of suspected accidental transfer, including:

- Should contact with the part of the body where estradiol was applied be suspected, the child's skin should be washed with soap and water as soon as possible.
- A physician should be consulted in case of signs and symptoms (breast development or other sexual changes) suggestive of unintentional estradiol exposure in a child.

Healthcare professionals should also consider the possibility of accidental exposure to estradiol where a child presents with unexpected breast development or other unexpected sexual or pubertal changes. In case of suspected accidental transfer, the patient using the estradiol product should be further counselled to assess administration method and implementation of preventative measures, as part of the overall clinical evaluation.

Product information

Product-specific Summary of Product Characteristics (SmPC) and package leaflets (PL) are accessible through www.hpra.ie. Advise patients to follow the specified application instructions and precautions for the product they are using

- Lenzetto 1.53 mg/spray, Transdermal Spray, Solution: SmPC and PL
- Oestrogel Pump-Pack 750 micrograms/actuation Gel: SmPC and PL
- Divigel 0.1% w/w Gel, 1 mg/dose: SmPC and PL

National reports received in relation to accidental exposure, as noted above, continue to be evaluated by the HPRA.

Reporting suspected adverse reactions

Healthcare professionals are encouraged to report suspected adverse reactions, including those associated with suspected accidental exposure or transfer of a medicine to another person, to the HPRA via the available options at http://www.hpra.ie/report, including an online reporting form, or by email to medsafety@hpra.ie.

Reports are evaluated as part of pharmacovigilance procedures, and regulatory action taken, as appropriate, should new risks or aspects of known risks be identified.

Any updated advice will be reflected in product information and communicated, as appropriate.

A privacy notice relating to the processing of personal data collected by the HPRA in relation to adverse reaction reports is available at www.hpra.ie

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