

MHRA Drug Safety Update

January 2023



Topical testosterone (Testogel): risk of harm to children following accidental exposure

Reports of accidental exposure of topical testosterone to children

The MHRA received a report of a child who was repeatedly accidentally exposed to the topical testosterone product that their parent was using, resulting in increased growth and genital enlargement. It was confirmed through clinical investigations that the child had increased testosterone in their blood and that the topical testosterone product was the source of the testosterone. There are also literature reports and non-UK reports of premature puberty and genital enlargement in children who were repeatedly accidentally exposed to a topical testosterone product via transfer from an adult with whom they were in close contact.

The risk was reviewed by the Paediatric Medicines Expert Advisory Group of the Commission on Human Medicines, which recommended that a specific paediatric warning be added to the product information for topical testosterone products. The MHRA has requested that the manufacturers of topical testosterone products update the Summary of Product Characteristics and the Patient Information Leaflet. These updates will provide warnings about accidental exposure to children and set out the precautions concerning washing the application site before physical contact with another person (adult or child). A specific warning will be included about the risk of accidental testosterone transfer to children.

Advice for healthcare professionals:

- when prescribing topical testosterone, inform patients of the potential consequences if it is accidentally transferred to other people
- inform patients that accidental transfer can lead to increased blood testosterone levels in the other person
- advise patients of the possible effects should accidental exposure occur in adult women (facial and/or body hair growth, deepening of voice, changes in menstrual cycle) or children (genital enlargement and premature puberty, including development of pubic hair)
- counsel patients on methods to reduce the risks of accidental exposure, including washing their hands with soap and water after application, covering the application site with clean clothing (such as a t-shirt) once the gel has dried, and washing the application area with soap and water before physical contact with another person
- encourage patients to be vigilant about implementing measures to minimise risk, to be alert for signs of accidental exposure, and to seek medical advice if accidental exposure is suspected
- report suspected adverse drug reactions associated with topical testosterone on a [Yellow Card](#)

Advice for healthcare professionals to provide to patients:

- topical testosterone products are used for testosterone replacement. When using these products on your skin, you must take care that the testosterone product is not accidentally transferred onto the skin of someone else
- if the testosterone in the product is accidentally transferred to someone else through physical contact, it can lead to increased blood testosterone levels in the other person. It can cause facial and body hair growth, deepening of voice and changes in the menstrual cycle of women, or accelerated height, genital enlargement, and early puberty (including development of pubic hair) in children
- the following precautions can reduce the risk of accidentally transferring testosterone from the patient's skin to another person:
 - after applying the product, wash your hands with soap and water
 - once the product has dried, cover the application site with clean clothing (such as a t-shirt)
 - before physical contact with another person (adult or child), wash the application site with soap and water after the recommended time period following application has passed