

SFDA

Safety Communication

[19/02/2023]

Accidental Exposure to Topical Testosterone Causes Harm in Children

The Saudi Food and Drug authority (SFDA) would like to notify healthcare professionals that the repeated accidental exposure of children to topical testosterone elevates their blood testosterone levels.

Topical testosterone products are approved to treat men with hypogonadism. These topical gels or creams are used to replace natural testosterone in men who do not have sufficient levels of natural testosterone that is responsible for maintaining sexual characteristics. This may lead to side effects including genital enlargement and premature puberty, such as development of pubic hair. Healthcare professionals should advise patient about the consequences of accidental transfer of topical testosterone to other people including children, and counsel patients on methods to reduce accidental exposure.

Internationally, reports of repeated accidental exposure of children to topical testosterone leading to increased growth and genital enlargement were identified after their close contact with an adult who uses topical testosterone; an elevation in blood testosterone levels was confirmed in some of the reports. Patients should observe any signs of accidental exposure, and seek medical advice if accidental exposure is suspected.

Advice for healthcare professionals:

- Advise patients about the consequences of accidental transfer of topical testosterone to other people including children
- Explain to the patients that accidental exposure may lead to increased blood testosterone levels
- Inform the patients about the possible side effects if accidental exposure occurs in children (genital enlargement and premature puberty) or women (facial/body hair growth, deepening of voice, changes in menstrual cycle)

- Instruct the patients to wash their hands with soap and water after application, cover the application area with clean clothing once the gel is dried, and washing the area with soap and water before physical contact with another person
- Counsel the patients to be vigilant for signs of accidental exposure, and to seek medical attention should they occur.

• **Please see the Summary of Product Characteristics (SPC) for further information.**

Generics Name	Trade Name	Dosage form	MAH
Testosterone	Androgel® 1% Gel	Gel	Abbott Products GmbH
Testosterone	Testavan®	Gel	Ferring GmbH

Call for reporting:

The SFDA urges both healthcare professionals and patients to report ADRs related to use of any medication to the SFDA using the following contact information:

The National Pharmacovigilance Centre (NPC):

Fax: +966-11-205-7662

SFDA Call Center: 19999

E-mail: npc.drug@sFDA.gov.sa

Website: <https://ade.sFDA.gov.sa>

aRMM:

