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(IN REPLY PLEASE QUOTE THIS FILE REF.)

26 Jan 2023

Dear Healthcare Professionals,

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

Your attention is drawn to the United Kingdom Medicines and Healthcare products Regulatory Agency's (MHRA) announcement that premature puberty and genital enlargement have been reported in children who were in close physical contact with an adult using topical testosterone and who were repeatedly accidentally exposed to this medicine.

Topical testosterone products are gels or creams applied directly to the skin. They are authorised to replace testosterone in men who do not produce sufficient natural testosterone; a condition known as hypogonadism. These products are also used outside of the licence for a range of conditions, including for peri/post-menopausal symptoms in women. If this product is repeatedly accidentally transferred to another person through physical contact, it can increase their blood testosterone levels. This may result in possible side effects (for example, growth of facial and/or body hair, deepening of the voice, irregular menstrual cycles in women, and premature puberty and genital enlargement in 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-United Kingdom 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. MHRA has requested that the manufacturers of topical

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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 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.

Please refer to the following website in MHRA for details:

<https://www.gov.uk/drug-safety-update/topical-testosterone-testogel-risk-of-harm-to-children-following-accidental-exposure>

In Hong Kong, there are 3 registered pharmaceutical products which are topical testosterone. All products are prescription-only medicines. So far, the Department of Health (DH) has received one case of adverse drug reaction related to topical testosterone, but this case was not related to premature puberty or genital enlargement in children due to accidental exposure to the drug. In light of the above MHRA's announcement, the matter will be discussed by the Registration Committee of the Pharmacy and Poisons Board.

Please note that this letter serves as a means for the DH to communicate important new safety information about registered pharmaceutical products with healthcare professionals in Hong Kong and is not intended to serve as guidelines or to replace professional clinical judgement. Healthcare professionals are advised to balance the risk of possible adverse effects against the benefit of treatment.

Please report any adverse events caused by drugs to the Adverse Drug Reaction Unit of the DH (tel. no.: 2319 2920, fax: 2319 6319 or email: adr@dh.gov.hk). For details, please refer to the website at Drug

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Office under "ADR Reporting": <http://www.drugoffice.gov.hk/adr.html>. You may wish to visit the Drug Office's website for subscription and browsing of "Drug News" which is a monthly digest of drug safety news and information issued by Drug Office.

Yours faithfully,



PP (Terence MAN)
for Assistant Director (Drug)