



**PHARMACY AND POISONS BOARD
HONG KONG
香港藥劑業及毒藥管理局**

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20樓2002-05室
衛生署藥物辦公室

25th June 2025

To: Certificate holders of registered pharmaceutical products

Dear Sir/Madam,

New Warnings for Topical Testosterone

The Pharmacy and Poisons (Registration of Pharmaceutical Products and Substances) Committee (the Committee) under the Pharmacy and Poisons Board has considered the latest warnings regarding the risk of harm to children following accidental exposure of topical testosterone issued by the Medicines and Healthcare products Regulatory Agency of the United Kingdom, as well as the related safety labelling information as approved by the drug regulatory authorities of Australia, Canada, Singapore and the United States, and decided that the sales pack labels and / or package inserts of registered pharmaceutical products containing testosterone for topical use shall include the following new safety information (or equivalent^{Note 1}) as appropriate:

“Posology and method of administration

Method of administration

Patients should be informed that other persons (including children and adults) should not come in contact with the area of the body where testosterone gel has been applied).

- Wash hands thoroughly with soap and water after applying the gel.*
- Once the gel has dried, cover the application site with clean clothing (such as a T-shirt)*

^{Note 1} Related safety information with other wording in accordance with reputable references and/or approved package inserts from drug regulatory authorities of reference countries may also be accepted on a case-by-case basis.

- *After applying this medicine patients should wait at least 1 hour before showering or bathing.*

Skin to skin contact

Before close physical contact with another person (adult or child), wash the application site with soap and water once the recommended time period (at least 1 hour) has passed and cover the site again with clean clothing.

Special warnings and precautions for use

Skin to skin transfer

If no precautions are taken, testosterone gel can be transferred to other persons by close physical contact at any time after dosing, resulting in increased testosterone serum levels and possibly adverse effects (e.g. growth of facial and/or body hair, deepening of the voice, irregularities of the menstrual cycle in women and premature puberty and genital enlargement in children) in the event of repeated contact (inadvertent androgenization).

Additional caution should be taken when using this product and in close physical contact with children as secondary transmission of testosterone through clothing cannot be excluded. Consult a physician in case of signs and symptoms in another person that may have been exposed accidentally to testosterone gel. The physician should inform the patient carefully about the risk of testosterone transfer, for instance during contact with another person including children and about safety instructions. The treating physician should give extra attention to patients with a major risk of not being able to follow these instructions in Method of Administration. It is essential to adhere to the application technique when in physical contact with another person. Before close physical contact with another person (adult or child), wash the application site with soap and water once the recommended time period (at least 1 hour) has passed and cover the site again with clean clothing. In the event of a person coming into contact with this medicine, the person affected should immediately wash the affected area with soap and water.”

You are therefore required to ensure the sales pack labels and / or package inserts of the concerned products registered by your company contain the above safety information to comply with the new requirements. Please submit application for the change of the registered particular(s) to the Drug Office via the online Pharmaceutical Registration System 2.0 (PRS 2.0) at www.drugoffice.gov.hk/prs2-ext/client_authentication.jsp for approval within 2 months from the date of this letter. Failing to comply with the above requirements may result in de-registration of the products or registration not being renewed by the Committee upon certificate expiry.

For further enquiries on the registration matters of pharmaceutical products, please contact the Drug Office at 3974 4175.

Yours faithfully,

A handwritten signature in black ink, appearing to be 'Y. F. YEUNG', written in a cursive style.

(Y. F. YEUNG)
Secretary,
Pharmacy and Poisons (Registration of
Pharmaceutical Products and Substances)
Committee

c.c. 7-15/3, Product Files