

## DRUG ALERT

### CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use

Distribute to Pharmacy / Wholesaler Level

Dear Healthcare Professional

**Kyowa Kirin Limited**

**Tostran (Testosterone, 2% gel)**

**PL 16508/0025**

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**SNOMED Code:** 777722004

<b>Batch No</b>	<b>Expiry Date</b>	<b>Pack Size</b>	<b>First Distributed</b>
2649810	11/2024	60g	September-2023
2649850	12/2024	60g	September-2023
2649860	12/2024	60g	September-2023
2649820	12/2024	60g	September-2023
2661080	02/2025	60g	September-2023
2661090	02/2025	60g	September-2023
2650030	01/2025	60g	September-2023

Active Pharmaceutical Ingredient: Testosterone

### **Brief description of the problem**

Kyowa Kirin Limited has notified MHRA that the priming instructions in the current PIL for Tostran 2% gel require updating.

Following a manufacturing change to the Tostran 2% gel dosage pump/dispenser system, the manufacturer has observed that the priming instruction requires changing. Data from the end of shelf life in-use testing has shown that the number of actuations required to prime the device to achieve correct dosing increases over time. This means that more pumps to prime the device being using it for the first time are now required. If these instructions are not followed then a less accurate first dose may be delivered. The Patient Information Leaflet and Summary Product Information will be updated to include these the new priming instructions, subject to approval by MHRA.

### **Advice for healthcare professionals**

Healthcare professionals are advised to inform patients that there was a change to the pump/dispenser device supplied with this medicine and the priming instructions prior to use in the current PIL are not accurate.

Advise patients that priming should performed before first use as follows:

1. *With the canister in the upright position, slowly and fully depress and release the actuator until gel is dispensed.*
2. *Slowly depress and release the actuator a further 6 times.*
3. *Discard the gel from the 6 depressions safely in household waste (outside of reach of children or pets).*
4. *Deliver the dose as instructed by a healthcare professional and follow the instructions to prevent accidental transfer to others.*

*It is only necessary to prime the pump before the first dose.* There have been no changes to the content of the canister or the quality of the gel. The device continues to deliver a total of 120 active dose pumps, each dispensing 0.5g of gel (equivalent to 10 mg of testosterone). The storage conditions specified on the pack remain correct.

The change to the priming instruction is considered a low risk to patient safety. To avoid shortages of this medicine, Kyowa Kirin Limited intend to distribute these batches whilst the new PIL is being assessed.

## Advice for patients

Patients are advised that there are new instructions for patients using Tostran (Testosterone, 2% gel). For the batches impacted, and all future manufacture, more pumps are required to prime the device before using it for the first time. If these instructions are not followed then a less accurate first dose may be delivered.

Patients should continue to take medicines from these batches as prescribed by your healthcare professional but use the following instructions to prime the pump before using this product for the first time:

1. *With the canister in the upright position, slowly and fully depress and release the actuator until gel is dispensed.*
2. *Depress and release the actuator a further 6 times.*
3. *Discard the gel from the 6 depressions in household waste (outside the reach of children or pets).*
4. *Deliver the dose as instructed by a healthcare professional and follow the instructions to prevent accidental transfer to others.*

*Note, it is only necessary to prime the pump before the first dose.* Following priming, the device will deliver a total of 120 active dose pumps.

Patients who experience adverse reactions or have any questions about the medication, should seek medical attention. Any suspected adverse reactions should also be reported via the [MHRA Yellow Card scheme](#).

## Further Information

For medical information enquiries please contact at [medinfo@kyowakirin.com](mailto:medinfo@kyowakirin.com).

Tel: +44 (0)1896 664 000.

For stock control enquiries please contact [customerqueries-uk@kyowakirin.com](mailto:customerqueries-uk@kyowakirin.com).

Tel: +44 (0) 7712 001288.

Recipients of this Medicines Notification should bring it to the attention of relevant contacts by copy of this notice.

RQIA should bring this information to the attention of private hospitals/clinics registered with them and any other relevant care facilities.

**MPS 3091**  
**MMS 2147**



The Business Services Organisation is asked to bring this information to the attention of Community Pharmacists and General Medical Practitioners directly

Recipients of this Drug Alert should bring it to the attention of relevant contacts by copy of this letter.

**TO ALL CHEMISTS, DOCTORS ON THE LISTS**

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**31<sup>st</sup> August 2023**

Pharmaceutical website: <http://www.hscbusiness.hscni.net>