



MEDICINES NOTIFICATION

CLASS 4 MEDICINES DEFECT INFORMATION

Caution in Use Pharmacy/Wholesaler Level

Date: 31 August 2023

EL (23)A/33

Our Ref: MDR 013-08/23

Dear Healthcare Professional,

Kyowa Kirin Limited

Tostran (Testosterone, 2% gel)

PL 16508/0025

SNOMED Code: 777722004

Batch No	Expiry Date	Pack Size	First Distributed
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.



Medicines & Healthcare products Regulatory Agency

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.

Tel: +44 (0)1896 664 000.

For stock control enquiries please contact 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. NHS regional teams are asked to forward this to community pharmacists and dispensing general practitioners for information.

Yours faithfully

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