

**Direct Healthcare Professional Communication**

20 November 2024

TOBREX® (Tobramycin): A Translation error on TOBREX Ophthalmic Ointment 0.3% folding boxes

**Dear Health Care Professionals,**

Novartis Saudi Ltd, in agreement with the Saudi Food and Drug Authority (SFDA) would like to inform you of the following:

**Summary**

- The purpose of this letter is to inform you of a translation error on TOBREX® (Tobramycin) Ophthalmic Ointment 0.3% folding boxes storage conditions.
- Please instruct patients to follow the correct product's storage conditions

**Further information on the quality concern**

On 8 September 2024, Novartis Saudi Ltd. received a complaint reporting an inconsistency between English and Arabic translation of the storage conditions on the packs of TOBREX® eye ointment 0.3%:

- The English text (correct): Do not store above 25°C, do not refrigerate or freeze
- The Arabic text (incorrect): يحفظ في درجة حرارة أقل من 25 م، لا تجمد العبوة تحفظ بالثلاجة
- The Arabic text should read: يحفظ في درجة حرارة أقل من 25 م، لا تجمد العبوة و لا تحفظ بالثلاجة
- The error might be misinterpreted as refrigeration is possible
- The error is only impacting the folding box: ointment tube and patient leaflet are not impacted

**Action to be taken by Health Care Professionals**

Please ensure patients are following the correct storage conditions for TOBREX® eye ointment 0.3% "Do not store above 25°C, do not refrigerate or freeze"

**Call for reporting**

Please report any suspected adverse reactions associated with the use of TOBREX® in accordance with the national requirements to:

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| <b>Novartis Saudi Ltd</b><br>Toll Free Number: 8001240078<br>Phone: +966112658100<br>Fax: +966112658107<br>Email: adverse.events@novartis.com<br>Or online: <a href="https://report.novartis.com">https://report.novartis.com</a> | <b>Saudi Food and Drug Authority National Pharmacovigilance Center</b><br>Unified Contact Center: 19999<br>Email: <a href="mailto:npc.drug@sfda.gov.sa">npc.drug@sfda.gov.sa</a><br>Or online: <a href="https://ade.sfda.gov.sa">https://ade.sfda.gov.sa</a> |
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We sincerely apologize for any inconvenience this may have caused and thank you for your continued support.

Sincerely,

Hajer Alsaleh  
Patient safety manager/ local QPPV for Novartis Saudi