If undelivered please return to Post-Licensing Directorate, Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN 3000, Malta

5th August 2025

Kisqali (ribociclib): change to storage conditions and shelf-life

Novartis Europharm Ltd. in agreement with the European Medicines Agency and the Malta Medicines Authority would like to inform you of the following:

Summary

- **Kisqali should now be stored in a refrigerator (between 2°C to 8°C) for up to 10 months until dispensed to patients.**
- **Inform patients that upon dispensing, Kisqali may be stored at up to 25°Cfor up to 2 months in the original blister packs.**
- **The shelf life of Kisqali is now limited to 12 months in total.**
- **The product information, labelling and package leaflet have been amended to reflect the new storage conditions and shelf life.**

Background on the safety concern

Kisqali is indicated for the treatment of women with hormone receptor (HR)-positive, human epidermal growth factor receptor 2 (HER2)-negative locally advanced or metastatic breast cancer in combination with an aromatase inhibitor or fulvestrant as initial endocrine-based therapy, or in women who have received prior endocrine therapy.

In pre- or perimenopausal women, the endocrine therapy should be combined with a luteinising hormone-releasing hormone (LHRH) agonist.

The following additional indication has recently been authorised in the EU:

Kisqali, in combination with an aromatase inhibitor, is indicated for the adjuvant treatment of patients with HR-positive, HER2-negative early breast cancer at high risk of recurrence (see SmPC section 5.1 for selection criteria).

In pre- or perimenopausal women, or in men, the aromatase inhibitor should be combined with a LHRH agonist.

The storage conditions and shelf-life have been updated to ensure the quality of the product throughout its shelf-life in the new indication, however these are to be applied to the product irrespective of indication. Current stock should be stored as per instructions in the applicable product information. Novartis will implement a detailed plan for managing existing stock and ensuring the transition to the revised product.

The product information (summary of product characteristics and package leaflet) has been updated to reflect the new storage conditions. Please refer to SmPC:

https://www.ema.europa.eu/en/documents/product-information/kisqali-epar-product-information_en.pdf

Call for reporting

Healthcare providers and patients are encouraged to report Suspected Adverse Drug Reactions (side effects) or medication errors by using the Malta Medicines Authority ADR reporting form available online at http://medicinesauthority.gov.mt/adrportal and sent to Pharmacovigilance Section at Post-Licensing Directorate, Malta Medicines Authority, Sir Temi Żammit Buildings, Malta Life Sciences Park, San Ġwann SĠN or sent by email to: postlicensing.medicinesauthority@gov.mt

Healthcare Professionals may also report any adverse events associated with the use of Kisqali 200 mg film coated tablets to: Novartis Pharma Services Inc., Representative Office, Malta or by phone on +356 21222872, online on https://www.novartis.com/report or by e-mail at drug_safety.malta@novartis.com.

Company contacts point

Company	Product Name	Email	Contact
Novartis Pharma Services Inc., Representative Office, Malta	Kisqali 200 mg film coated tablets	novartis.malta@novartis.com	+356 21222872

Disclaimer

This Direct Healthcare Professional Communication has been submitted to you on behalf of Novartis Pharma Services Inc., Representative Office, Malta

The MMA receives the relevant contact details from both the Medical Council and the Pharmacy Council. Should you wish to amend your details including address, you are asked to contact the Medical Council or Pharmacy Council directly, as may apply.