NOVARTIS

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12/05/2025

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

Dear Healthcare Professional,

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

Summary

- **From 19th May , new batches of Kisqali will be supplied to the Irish market. These batches require that Kisqali should now be stored in a refrigerator (between 2°C to 8°C) for up to 10 months until dispensed to patients.**
- **Please inform patients that upon dispensing, Kisqali may be stored at up to 25°C for 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

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.

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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.

Call for reporting

Any suspected adverse events should be reported to HPRA Pharmacovigilance at www.hpra.ie. Adverse events can also be reported to Novartis preferably at www.novartis.com/report, by emailing drugsafety.dublin@novartis.com or by calling 01 2080 612.

Company contact point

Further information can be obtained by contacting Novartis Ireland Limited via email medinfo.dublin@novartis.com, phone 01 208 0612.

DocuSigned by:
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Yours sincerely,

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